Creation Date : 31/01/2023

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
TÜV NORD CERT GmbH Am TÜV 1 45307 Essen Germany	0044	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0318 Other active non-implantable devices	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			without medicinal products derived from human blood or human plasma
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			

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		MDS 1005 Devices in sterile condition			including: aseptic processing; ethylene oxide gas sterilisation (EOG); low temperature steam and formaldehyde sterilisation; moist heat sterilisation; radiation sterilisation (gamma, x-ray, electron beam); sterilisation with hydrogen peroxide; additional: Sterilisationsverfahren mit Plasma
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather,			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			
National Standards Authority of Ireland (NSAI) 1 Swift Square, Northwood, Santry Dublin 9 Ireland	0050	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1207 Non-active non-implantable diagnostic devices	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		disinfecting, cleaning and rinsing	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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		non-implantable devices	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- A. Active devices			
		- - 1. Active implantable devices - MDA 0101 Active implantable devices for stimulation/inhibition/monitoring	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including EtO, Moist Heat, Aseptic, Chemical, Irradiation

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDS 1006 Reusable surgical instruments			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			
IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A. Via Quintiliano, 43 20138 - MILANO Italy	0051	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 1. Active implantable devices - MDA 0101 Active implantable devices for stimulation/inhibition/monitoring	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitrofertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1102 Non-active osteo- and orthopaedic implants	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III devices
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III devices
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III devices
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III devices
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III devices
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III devices
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III devices
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III devices
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III devices
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Excluding formaldehyde sterilization.
		MDS 1006 Reusable surgical instruments			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			
TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 MÜNCHEN Germany	0123	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product conformity verification		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	For breast implants only Annex IX applicable
		- - 2. Non-active non-implantable devices	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product conformity verification		
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		assisted reproductive technologies (ART)	technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- A. Active devices			
		- - 1. Active implantable devices - MDA 0101 Active implantable devices for stimulation/inhibition/monitoring	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(B)	
		- - 1. Active implantable devices - MDA 0102 Active implantable devices delivering drugs or other substances	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 1. Active implantable devices - MDA 0103 Active implantable devices supporting or replacing organ functions	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 1. Active implantable devices - MDA 0104 Active implantable devices utilising radiation and other active implantable devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		of substances and haemapheresis	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		or organs including in vitrofertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1002 Devices manufactured utilising tissues or cells of human origin, or their derivatives			
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including aseptic processing,

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					ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), sterilisation with hydrogen peroxide, sterilisation with liquid chemical sterilising agents, thermic sterilisation with dry heat
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1013 Class III custom-made implantable devices			
		MDS 1014 Devices incorporating as an integral part an			

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		in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			Only for medical devices that are forseen by the manufacturer to

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					undergo reprcessing
DEKRA Certification GmbH Handwerkstraße 15 70565 STUTTGART Germany	0124	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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		monitoring of vital physiological parameters	technical documentation Conformity assessment based on product quality assurance		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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			Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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			based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitrofertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	excluding IVF and ART; limited to devices for cryopreservation
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0318 Other active non-implantable devices	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	excluding breast implants whose purpose is the enlargement or replacement of the volume of the breast
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	excluding devices for ingestion
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1002 Devices manufactured utilising tissues or cells of human origin, or their derivatives			restricted to devices manufactured utilising human serum albumin (HSA)
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			including aseptic processing; ethylene oxide gas sterilisation (EOG); low temperature steam and formaldehyde sterilisation; moist heat sterilisation; radiation sterilisation (gamma, x-ray, electron beam); sterilisation with hydrogen peroxide; sterilisation with liquid chemical sterilising agens;
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			only products within the designation according to MDA/MDN-codes excluding products according to section 3 of annex XVI
		MDS 1013 Class III custom-made implantable devices			only products within the designation according to MDA/MDN-codes
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			only products within the designation according to MDA/MDN-codes
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			excluding reprocessing of single-use devices
TÜV Rheinland LGA Products GmbH Tillystraße 2 90431 Nürnberg Germany	0197	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 1. Active implantable devices - MDA 0101 Active implantable devices for stimulation/inhibition/monitoring	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	limited to stimulation devices excluding brain stimulators and pacemakers

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Active non-implantable devices for imaging,	Conformity assessment based on type-examination	Annex X Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	excluding brain stimulation devices

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			technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	excluding hyperbaric chamber

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			technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitrofertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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			based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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			based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	excluding heart valves introduced into the body by open heart surgeries
		-	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	excluding joint implants

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		- 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		anaesthesia, emergency and intensive care	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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			technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			including aseptic processing ethylene oxide gas sterilisation (EOG) low temperature steam and formaldehyde sterilisation moist heat sterilisation radiation sterilisation (gamma, x-ray, electron beam) sterilisation with hydrogen peroxide sterilisation with liquid chemical sterilising agens thermic sterilisation with dry heat

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1013 Class III custom-made implantable devices			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather,			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			excluding “under processing of materials of human origin”
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			
DQS Medizinprodukte GmbH August-Schanz-Straße 21 60433 FRANKFURT AM MAIN Germany	0297	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 1. Active implantable devices - MDA 0101 Active implantable devices for stimulation/inhibition/monitoring	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	restricted to active implantable devices for cardiovascular/vascular stimulation / inhibition / monitoring

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	restricted to external hearing aids
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	restricted to active non-implantable devices for patient positioning and transport
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		implants	technical documentation		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			including aseptic processing; ethylene oxide gas sterilisation (EOG); low temperature steam and formaldehyde sterilisation; moist heat sterilisation; radiation sterilisation (gamma, x-ray, electron beam); sterilisation with hydrogen peroxide; thermic sterilisation with dry heat

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDS 1006 Reusable surgical instruments			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			restricted to products corresponding Regulation (EU) 2017/745 in Annex XVI section 1. and section 2.
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			restricted to devices manufactured using processing of materials of animal or microbial origin
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
CENTRO NACIONAL DE CERTIFICACION DE PRODUCTOS SANITARIOS Campezo 1. Edificio 7. 28022 MADRID Spain	0318	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Limited to x-ray medical devices, gamma cameras and positron emission tomography
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Limited to medical devices for magnetotherapy and microwaves
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Limited to diagnostic medical devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitrofertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Limited to stents, sutures for cardiovascular surgery, and implantable drug delivery systems
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Neurological, neurosurgical and breast implants are excluded
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	Annex X limited to medical devices for puncture, injection and/or extraction of fluids
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	Annex X limited to contact lens care products

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			Excluding medical devices utilising tissues or cells of animal origin under Regulation (UE) No. 722/2012
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			Excluding human and animal material of Regulation (UE) No. 722/2012
		MDT 2010 Devices manufactured using electronic			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			
DEKRA Certification B.V. Meander 1051 / P.O. Box 5185 6825 MJ ARNHEM / 6802 ED ARNHEM Netherlands	0344	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 1. Active implantable devices - MDA 0101 Active implantable devices for stimulation/inhibition/monitoring	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 1. Active implantable devices - MDA 0102 Active implantable devices delivering	Conformity assessment based on type-examination Conformity assessment	Annex X Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		drugs or other substances	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(A) Annex XI(B)	
		- - 1. Active implantable devices - MDA 0103 Active implantable devices supporting or replacing organ functions	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 1. Active implantable devices - MDA 0104 Active implantable devices utilising	Conformity assessment based on type-examination Conformity assessment	Annex X Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		radiation and other active implantable devices	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(A) Annex XI(B)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis	Conformity assessment based on type-examination Conformity assessment	Annex X Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(A) Annex XI(B)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis	Conformity assessment based on type-examination Conformity assessment	Annex X Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on type-examination Conformity assessment	Annex X Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0302 Active non-implantable devices utilising non-ionizing radiation	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on type-examination Conformity assessment	Annex X Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on type-examination Conformity assessment	Annex X Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on type-examination Conformity assessment	Annex X Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0308 Active non-implantable devices for wound and skin care	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on type-examination Conformity assessment	Annex X Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0310 Active non-implantable devices for ear, nose and throat	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on type-examination Conformity assessment	Annex X Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0312 Other active non-implantable surgical devices	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on type-examination Conformity assessment	Annex X Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0315 Software	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on type-examination Conformity assessment	Annex X Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- B. Non-active devices			
		-	Conformity assessment based on type-examination	Annex X Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 1. Non-active implants and long term surgically	Conformity assessment based on type-examination	Annex X Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices	Conformity assessment based on type-examination	Annex X Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices	Conformity assessment based on type-examination	Annex X Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices	Conformity assessment based on type-examination	Annex X Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices	Conformity assessment based on type-examination	Annex X Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices	Conformity assessment based on type-examination	Annex X Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices	Conformity assessment based on type-examination	Annex X Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1002 Devices manufactured utilising tissues or			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		cells of human origin, or their derivatives			
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			including aseptic processing, ethylene oxide gas sterilization (EOG), low temperature steam and formaldehyde sterilization, moist heat sterilization, radiation sterilization (gamma, x-ray, electron beam), sterilisation with hydrogen peroxide, sterilization with liquid chemical sterilizing agents, thermic sterilization with dry heat
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1013 Class III custom-made implantable devices			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			
		MDT 2010 Devices manufactured using electronic			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			
ISTITUTO SUPERIORE DI SANITA' Viale Regina Elena, 299 00161 - ROMA Italy	0373	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on product conformity verification	Annex X Annex XI(B)	Limited to therapeutic cyclotrons and linear accelerators
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear,	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		nose and throat	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		and neurovascular implants	technical documentation Conformity assessment based on product quality assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam, moist heat sterilisation, radiation

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					sterilisation (gamma-ray, electron beam), dry heat.
		MDS 1006 Reusable surgical instruments			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1013 Class III custom-made implantable devices			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather,			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
ICIM S.P.A. Piazza Don Enrico Mapelli, 75 20099 - Sesto San Giovanni (MI) Italy	0425	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- B. Non-active devices			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		instruments	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		human body via a body orifice or the dermal route	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including: - aseptic processing - ethylene oxide gas sterilisation (EOG) - moist heat sterilisation - radiation sterilisation (gamma-ray, x-ray, electron beam)
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDT 2001 Devices manufactured using metal processing			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
ITALCERT SRL Viale Sarca, 336 20126 - MILANO Italy	0426	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		for monitoring and/or diagnosis	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1102 Non-active osteo- and orthopaedic implants	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded devices for In Vitro Fertilisation (IVF) and Assisted Reproductive Technologies (ART)

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			Excluded human blood or plasma derivatives
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			Excluded medical devices utilising tissues of animal origin under Commission Reulation (UE) No. 722/2012.
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including: - aseptic processing - ethylene oxide gas sterilisation (EOG) - moist heat sterilisation - radiation sterilisation (gamma-ray, x-ray, electron beam) - hydrogen peroxide sterilisation
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1013 Class III custom-made implantable devices			Limited to non-active osteo- and orthopaedic implants, non-active dental implants and dental materials, non-active soft tissue and other implants
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
GMED SAS 1, rue Gaston Boissier 75015 PARIS France	0459	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- B. Non-active devices			
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on type-examination Conformity assessment based on a quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex X	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex X	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		-	Conformity assessment	Annex X	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		-	Conformity assessment	Annex X	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		-	Conformity assessment	Annex X	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		-	Conformity assessment	Annex X	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		-	Conformity assessment	Annex X	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		-	Conformity assessment	Annex X	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		-	Conformity assessment	Annex X	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 1. Active implantable devices - MDA 0104 Active implantable devices utilising radiation and other active implantable devices	based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Active implantable devices - MDA 0101 Active implantable devices for stimulation/inhibition/monitoring	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Active implantable devices - MDA 0102 Active implantable devices delivering drugs or other substances	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 1. Active implantable devices - MDA 0103 Active implantable devices supporting or replacing organ functions	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			The covered sterilization processes are : - aseptic processing - ethylene oxide gas sterilisation (EOG), - low temperature steam, formaldehyde sterilization, - moist heat sterilization, - radiation

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					sterilisation (gamma, x-ray, electron beam), - hydrogen peroxyde, - liquid chemical sterilising agents, - dry heat.
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1013 Class III custom-made implantable devices			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			
KIWA CERMET ITALIA S.P.A. Via Cadriano, 23 40057 - Cadriano di Granarolo (BO) Italy	0476	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- B. Non-active devices			
		- - 2. Non-active non-implantable devices	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		wound and skin care	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded in vitro fertilisation (IVF) and assisted reproductive technologies (ART)

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		assisted reproductive technologies (ART)	technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- A. Active devices			
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded magnetic resonance
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding hyperbaric chamber for oxygen therapy

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Limited to ear equipment
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	Excluded in vitro fertilisation (IVF) and assisted reproductive

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitrofertilisation (IVF) and assisted reproductive technologies (ART)	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	technologies (ART)
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			Excluding plasma and blood derivatives
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			The following processes are covered: aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					heat sterilisation, dry heat sterilization, radiation sterilisation (gamma-ray, x-ray, electron beam)
		MDS 1006 Reusable surgical instruments			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1013 Class III custom-made implantable devices			Limited to devices within the scope of designation related to MDN codes
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			Limited to processing of materials of animal and microbial origin
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			Limited to devices which require installation
		MDT 2013 Devices which have undergone reprocessing			Limited to reusable devices which have to undergone reprocessing
Eurofins Product Testing Italy S.r.l. Via Courgnè, 21 10156 - TORINO (TO) Italy	0477	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis	Conformity assessment based on a quality management system	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		hyperthermia/hypothermia	based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on product quality	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices Excluded active non implantable devices for nose and throat
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Excluded Class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices excepted those classified in Class III only composed of substances or a combination of substances that are absorbed by or locally dispersed in the human body and/or utilising tissues of animal origin, including Commission Regulation (UE) n. 722/2012.
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance Conformity assessment based on product conformity verification		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on product quality	Annex IX(I) Annex XI(A)	Excluded Class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			conformity verification		
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices excepted those classified in Class III only as incorporating medicinal substances according to Directive 2001/83/EC and/or composed of substances or a combination of substances that are absorbed by or locally dispersed in the human body.

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			conformity verification		
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Exclusion of in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the	Conformity assessment based on type-examination Conformity assessment based on a quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		human body via a body orifice or the dermal route	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(B)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		MDS 1001 Devices incorporating medicinal substances			Excluded derived from human blood or human plasma
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including: aseptic processing,

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma-ray, x-ray, electron beam, beta-ray,).
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather,			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
DNV MEDCERT GmbH Pilatuspool 2 20355 HAMBURG Germany	0482	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 1. Active implantable devices - MDA 0101 Active implantable devices for stimulation/inhibition/monitoring	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		-	Conformity assessment	Annex IX(I)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 1. Active implantable devices - MDA 0103 Active implantable devices supporting or replacing organ functions	based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(II)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		extra-corporal circulation, administration or removal of substances and haemapheresis	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(II)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			including: aseptic processing; ethylene oxide gas sterilisation (EOG); low temperature steam and formaldehyde sterilisation; moist heat sterilisation; radiation sterilisation (gamma, x-ray, electron beam); sterilisation with hydrogen peroxide; sterilisation with liquid chemical sterilising agens; thermic sterilisation with dry heat
		MDS 1006 Reusable surgical instruments			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1013 Class III custom-made implantable devices			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			
MDC MEDICAL DEVICE CERTIFICATION GMBH Kriegerstrasse 6 70191 STUTTGART Germany	0483	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	Except external pacemakers and heart defibrillators

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Except hyperbaric chambers
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	excluding in vitro ferti¬lisation (IVF) and assisted reproductive technologies (ART)

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		or organs including in vitrofertilisation (IVF) and assisted reproductive technologies (ART)	technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), sterilisation with hydrogen peroxide, thermic sterilisation with dry heat
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1013 Class III custom-made implantable devices			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			excluding reprocessing of single-use devices
SLG PRÜF UND ZERTIFIZIERUNGS GMBH Burgstädter Strasse 20 09232 Hartmannsdorf Germany	0494	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	restricted to X-ray diagnostics, scintigraphy

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance Conformity assessment based on product conformity verification		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	excluding devices for external whole-body hyperthermia therapy and hyperthermic perfusion

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	excluding devices for emergency medicine and anesthesia

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	restricted to products for minimally invasive surgery
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	excluding prostheses

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	restricted to central gas supply according to EN ISO 7396
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			restricted to products included in the scope
		MDS 1011 Devices in systems or procedure packs			restricted to products included in the scope
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			without Regulation (EU) 2017/745 Appendix XVI paragraph 1.; 2.; 3.; 4. restricted to products included in the scope
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			excluding sterile packaging
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			restricted to products that need to be reprocessed for use, excluding single-use devices
Eurofins Electric & Electronics Finland Oy PL 47 Kivimiehentie 4 FI-02150 Espoo. Finland	0537	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	based on product quality assurance		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices that directly contact central nervous system or central circulatory system, active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (e.g. closed loop systems or automated external defibrillators), and devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are excluded.
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices that directly contact central nervous system or central circulatory system, active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (e.g. closed loop systems or automated external defibrillators), and devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are excluded.

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices that directly contact central nervous system or central circulatory system, active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (e.g. closed loop systems or automated external defibrillators), and devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are excluded.
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Heater-cooler units (blood warmers) are excluded.
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices that directly contact central nervous system or central circulatory system, therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (e.g. closed loop systems or automated external defibrillators), and devices that are intended for

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					controlling, monitoring or directly influencing the performance of active implantable devices are excluded.
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are excluded.
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices that directly contact central nervous system or central circulatory system are excluded.

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Active prostheses and exoskeletons are excluded.
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Software intended to provide information, which is used to take decisions having an impact that may cause death or an irreversible deterioration of a person's state of health, and therapeutic devices with an integrated or incorporated diagnostic function, which significantly determines the patient management by the device e.g. closed loop systems or automated external defibrillators, are excluded.
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices for sterilization are excluded.
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0318 Other active non-implantable devices	Conformity assessment based on product quality assurance		
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Other devices except sutures, staples, screws, wedges, plates, wires, pins, clips and connectors are excluded.
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices for dialysis are excluded.
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Contact lenses and intraocular lenses are excluded.
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices (or their products of metabolism) that are systemically absorbed by the human body are excluded.
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			Devices other than those intended to come into contact with intact skin only are excluded.
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			- Processes covered: aseptic processing, ethylene oxide gas sterilisation (EOG),moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam) - Processes excluded: low temperature steam and formaldehyde sterilisation

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			Devices presenting a high or medium potential for internal exposure are excluded.
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			Devices intended for controlling, monitoring or directly influencing the performance of the active implantable are excluded.
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		processing			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			Devices manufactured using materials of human origin and devices other than intended to come into contact with intact skin only are excluded.
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			
CERTIQUALITY S.r.l. Via G. Giardino, 4 20123 - MILANO Italy	0546	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC Excluding all devices depending on a source of electrical energy

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC Excluding all devices depending on a source of electrical energy
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC Excluding all devices depending on a source of electrical energy
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- B. Non-active devices			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		-	Conformity assessment	Annex IX(I)	Excluded Class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		- - 2. Non-active non-implantable devices	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	Excluded Class III Medical Devices Except those classified in Class III

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1207 Non-active non-implantable diagnostic devices	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		disinfecting, cleaning and rinsing	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Exluding devices for in vitro fertilisation (IFV) and assisted reproductive technologies (ART)
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		non-implantable devices	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		MDS 1001 Devices incorporating medicinal substances			Excluding plasma and blood derivatives
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including: - aseptic processing - ethylene oxide gas sterilisation (EOG) - low temperature steam - moist heat sterilisation - radiation sterilisation (gamma-ray, x-ray, electron beam)
		MDS 1006 Reusable surgical instruments			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDT 2001 Devices manufactured using metal			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			Limited to reusable devices which have to undergone reprocessing
SGS FIMKO OY Takomotie 8 00380 HELSINKI Finland	0598	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Up to class IIb
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Up to class IIb, excluding ultrasound devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Up to class IIb
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Up to class IIb, excluding audiometers

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Up to class IIb
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Up to class IIb, excluding blood warmers

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Up to class IIb, limited to extracorporeal shockwave therapy of limbs and joints and shockwave HIFU
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Up to class IIb

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Up to class IIb, excluding hyperbaric chambers
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Up to class IIb, excluding surgical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Up to class IIb
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Up to class IIb, limited to hospital beds, physiotherapy equipment, rehabilitation, patient positioning and transport devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Up to class IIb, limited to autoclaves
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on type-examination	Annex X Annex IX(I)	Up to class IIb

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(II) Annex XI(A) Annex XI(B)	
		- B. Non-active devices			
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Up to class IIb
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	Up to class IIb

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Up to class IIb
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Up to class IIb
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	Up to class IIb

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Aseptic Processing, Ethylene Oxide gas sterilization, Low temperature steam and formaldehyde sterilization, Low temperature H2O2 sterilization, Moist heat sterilization, Radiation sterilization (gamma, x-ray, electron beam)
		MDS 1007 Devices incorporating or consisting of nanomaterial			Up to class IIb
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
Berlin Cert Prüf- und Zertifizierstelle für Medizinprodukte GmbH Dovestraße 6 10587 Berlin Germany	0633	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices	Conformity assessment based on type-examination Conformity assessment based on a quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		utilising non-ionizing radiation	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(B)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices	Conformity assessment based on type-examination Conformity assessment based on a quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		for monitoring and/or diagnosis	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for	Conformity assessment based on type-examination Conformity assessment based on a quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		stimulation or inhibition	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Without active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body if this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application (Rule 12 Annex VIII Regulation (EU) 2017/745)
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory	Conformity assessment based on type-examination Conformity assessment based on a quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		devices	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear,	Conformity assessment based on type-examination Conformity assessment based on a quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		nose and throat	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical	Conformity assessment based on type-examination Conformity assessment based on a quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		devices	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on type-examination Conformity assessment based on a quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for	Conformity assessment based on type-examination Conformity assessment based on a quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		cleaning, disinfection and sterilisation	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- B. Non-active devices			
		- - 2. Non-active non-implantable devices	Conformity assessment based on type-examination Conformity assessment	Annex X Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable	Conformity assessment based on type-examination Conformity assessment	Annex X Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		instruments	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(A) Annex XI(B)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		the Council (1)			
		MDS 1006 Reusable surgical instruments			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
INSTITUT PRO TESTOVÁNI A CERTIFIKACI, a. s. (INSTITUTE FOR TESTING AND	1023	I. CODES REFLECTING THE DESIGN AND			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
CERTIFICATION) merged with ex-NB 1390 trida Tomase Bati 299 Louky, 76302 ZLIN Czech Republic		INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding IUD, breast implants and non-absorbable dermal fillers based on methylmethacrylate nad silicones
		- 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1208 Non-active non-implantable instruments	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		disinfecting, cleaning and rinsing	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		the Council (1)			
		MDS 1005 Devices in sterile condition			Aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			Excluding products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts. Excluding equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			including only devices manufactured using processing of materials of microbial origin
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
ENTE CERTIFICAZIONE MACCHINE SRL Via Ca' Bella, 243/A - loc. Castello di Serravalle 40053 Valsamoggia (BO)	1282	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
Italy					
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices Limited to video endoscopes
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices Limited to infusion pump
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices Ecluding hyperbaric chambers
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices
		-	Conformity assessment	Annex IX(I)	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices Limited to devices for patient positioning and transport
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices Limited to moist heat sterilizers
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices
		- B. Non-active devices			
		-	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		wound and skin care	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III medical devices
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Limited to aseptic processing,

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation
		MDS 1006 Reusable surgical instruments			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			Limited to reusable devices which have to undergone reprocessing
SLOVENIAN INSTITUTE OF QUALITY AND METROLOGY - SIQ Mašera - Spasi#eva ulica 10 1000 LJUBLJANA Slovenia	1304	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance Conformity assessment based on product conformity verification		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Annex X and XI(B) for lasers only. Other annexes with no limitations.

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Annex X and XI(B) for lasers only. Other annexes with no limitations.

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- B. Non-active devices			
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Nonabsorbable sutures only
		- - 2. Non-active non-implantable devices	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	Devices for dialysis excluded

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		orthopaedic and rehabilitation devices	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Aseptic processing, filtration, steam, EtO, irradiation included
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			Biologically active coatings/materials excluded
		MDS 1009 Devices incorporating software/utilising			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1013 Class III custom-made implantable devices			Orthopaedic implantable devices only
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2010 Devices manufactured using electronic components including communication devices			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			
BUREAU VERITAS ITALIA S.P.A. Viale Monza, 347 20126 - MILANO (MI) Italy	1370	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
			Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding hyperbaric chamber
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses,	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		devices for rehabilitation and devices for patient positioning and transport	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1103 Non-active dental implants and dental materials	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including: - aseptic processing - ethylene oxide gas sterilisation (EOG) - low temperature steam - moist heat sterilisation - radiation sterilisation (gamma-ray, x-ray, electron beam)
		MDS 1006 Reusable surgical instruments			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			Limited to reusable devices which have to undergone reprocessing
POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A. ul. Pu#awska 469 02-844 Warszawa Poland	1434	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		devices	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitrofertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding active non-implantable devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1003 Devices manufactured utilising tissues or			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), sterilisation with liquid chemical sterilising agents
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDS 1013 Class III custom-made implantable devices			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			Excluding materials of human origin
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
SGS Belgium NV Noorderlaan 87 BE-2030 Antwerpen Belgium	1639	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding surgically invasive devices for transient/short term use utilising ionizing radiation
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding surgically invasive devices for transient/short term use utilising ionizing radiation
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitrofertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0315 Software	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0318 Other active non-implantable devices	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding heart valves
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	- Excluding breast implants - Excluding implants and long term invasive devices utilising ionizing radiation
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		substances, including devices for dialysis	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding non-active devices for ingestion
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including: - aseptic processing - ethylene oxide gas sterilization - moist heat sterilization - radiation sterilization (gamma, x-ray & electron beam) - gas plasma sterilization
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1013 Class III custom-made implantable devices			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			Excluding devices manufactured using processing of materials of human origin
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		labelling			
		MDT 2012 Devices which require installation, refurbishment			Excluding reprocessed single use devices
Kiwa Dare B.V. Vijzelmolenlaan 7 NL-3447 GX Woerden Netherlands	1912	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Limited to devices for administration and removal of substances
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluding inhalation anaesthesia devices, lung ventilators and heart-lung machines

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		-	Conformity assessment	Annex X	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Limited to ethylene oxide gas sterilisation and radiation sterilisation
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			Only for active devices
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			Only devices in systems, procedure packs are excluded
		MDS 1012 Products without an intended medical			Only for active devices.

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
TUV Rheinland Italia SRL Via Mattei, 3 20010 - Pogliano Milanese (MI) Italy	1936	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded, only for annex X and XI B: Transcutaneous partial pressure monitoring equipment, Electroencephalographs, Blood pressure indirect, automatic and periodic measuring equipment, Direct blood pressure monitoring equipment, Multiparametric patient monitors, Medical device for registration and analysis of data from single and multiple channel electrocardiograps, Screening thermographic device for verification of human fever, Electromechanic blood pressure measuring device, Clinical thermometers
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices Excluded, only for Annex X and XI B: Medical diagnostric Nuclear magnetic risonance device, Device for ultrasonic diagnosis and monitoring, Audiometers.

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices Excluded, only for Annex X and XI B: Short wave therapy device, Ultrasonic therapy device, Microwave therapy device, Infant phototherapy equipment.
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded, only for Annex X and XI B: Neuromuscular stimulators.
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices Excluded, only for Annex X and XI B : Hemodialysis, Hemodiafiltration and haemofiltration device, Infusion pumps and control device, Peritoneal dialysis device.

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices Excluding hyperbaric chamber Excluded, only for Annex X and XI B: Pulmunary ventilators, Systems for anesthesia, Iperbaric chambers, Device for the respiratory therapy of apnea during sliping, Spirometers.
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices Excluded, only for Annex X and XI B: Lifting equipment used to transfer disable patients.
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices Excluded in vitro fertilisation (IVF) and assisted reproductive technologies (ART)

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		or organs including in vitrofertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		-	Conformity assessment	Annex IX(I)	Excluded Class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded neurovascular implant
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	Excluded Class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded dialysis devices in class III
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		wound and skin care	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Excluded in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including: - aseptic processing - ethylene oxide gas sterilisation (EOG) - low temperature steam - moist heat sterilisation - radiation sterilisation (gamma-ray, x-ray, electron beam)
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU)			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		2017/745			
		MDS 1013 Class III custom-made implantable devices			Limited to devices within the scope of designation related to the codes
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			Limited to reusable devices which have to undergone reprocessing
3EC International a.s. 3EC International a.s. Hranicna 18 Bratislava 82105 SLOVAKIA	2265	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
Bratislava 82105 Slovakia					
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitrofertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	excluding neurovascular implants
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		materials	technical documentation Conformity assessment based on product quality assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	excluding breast implants
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			excluding Reg. 722/2012
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			except active implantable MDs
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU)			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		2017/745			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2013 Devices which have undergone reprocessing			
TUV NORD Polska Sp. z o.o ul. Mickiewicza 29 40-085 Katowice Poland	2274	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding MRI
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding products used in ophthalmology

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		for monitoring and/or diagnosis	technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	Including only infusion pumps, devices for dialysis, anaesthesia machines and devices for administration or removal of substances

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding hyperbaric chambers
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding active prostheses
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding bone graft substitute for orthopaedic indications, knee, shoulder and hip joint replacement, hyaluronic acid implant for intra-articular use, bone cement
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Including only urological tapes, surgical meshes ligament and tendon prostheses made of multifilament polyester fibers
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding sutures

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	Excluding devices for in vitro

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	fertilisation (IVF) and assisted reproductive technologies (ART)
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Including only ultrasound gels, medication cups
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1005 Devices in sterile condition			Including: aseptic processing,

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation, filtration
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			Limited to devices emitting electromagnetic radiation for use on the human body according to Annex XVI p. 5
		MDS 1013 Class III custom-made implantable devices			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			Excluding processing of glass

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			Excluding processing of leather
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			Excluding processing of animal materials
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			Limited to electronic devices and medical gas installations
CE Certiso Orvos- és Kórháztechnikai Ellen#rz# és Tanúsító Kft. Erd# u.101. Budakeszi Hungary	2409	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- A. Active devices			
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0311 Active non-implantable dental devices	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			excluding medicinal substances derived from human blood or human plasma
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG) low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray , electron beam), sterilisation with liquid chemical sterilising agents, sterilisation with hydrogen peroxide, sterilisation with dry heat
		MDS 1006 Reusable surgical instruments			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1014 Devices incorporating as an integral part an			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			excluding human origin
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
DNV Product Assurance AS Veritasveien 1 1363 Høvik Norway	2460	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		devices	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitrofertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Cardiac valves excluded
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1002 Devices manufactured utilising tissues or cells of human origin, or their derivatives			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), plasma sterilisation, chemical sterilisation and dry heat sterilisation
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			All products without a medical purpose except: Devices intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of fixation of body parts.
		MDS 1013 Class III custom-made implantable devices			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			
UDEM Adriatic d.o.o. Radni#ka cesta 54/R3 Zagreb Croatia	2696	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	EXCLUDING GAMMA RAY DEVICES
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		wound and skin care	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	EXCLUDING HEART VALVES

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	EXCLUDING BREAST IMPLANTS

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			EXCLUDING HUMAN BLOOD DERIVATIVES
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1013 Class III custom-made implantable devices			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			EXCLUDING REFURBISHMENT
		MDT 2013 Devices which have undergone reprocessing			
BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands	2797	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 1. Active implantable devices - MDA 0101 Active implantable devices for stimulation/inhibition/monitoring	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Active implantable devices - MDA 0102 Active implantable devices delivering drugs or other substances	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 1. Active implantable devices - MDA 0103 Active implantable devices supporting or replacing organ functions	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Active implantable devices - MDA 0104 Active implantable devices utilising radiation and other active implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		general active non-implantable devices - MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 Active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0314 Active non-implantable devices for processing and preservation of human cells, tissues or organs including in vitrofertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		-	Conformity assessment	Annex IX(I)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- B. Non-active devices			
		-	Conformity assessment	Annex IX(I)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1204 Non-active non-implantable devices for wound and skin care	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		devices	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the	Conformity assessment based on type-examination Conformity assessment based on a quality	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	Annex X and XI(B) Limited to male condoms

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		transmission of sexually transmitted diseases	management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(B)	
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Annex X and XI(B) limited to gloves
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		MDS 1001 Devices incorporating medicinal substances			
		MDS 1002 Devices manufactured utilising tissues or cells of human origin, or their derivatives			
		MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives			
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), sterilisation with hydrogen peroxide, sterilization with liquid chemical sterilizing agents, thermic sterilization with dry heat
		MDS 1006 Reusable surgical instruments			
		MDS 1007 Devices incorporating or consisting of nanomaterial			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			
		MDS 1013 Class III custom-made implantable devices			
		MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			
Intertek Medical Notified Body AB Torshamnsgatan 43, Box 1103 SE-164 22 Kista Sweden	2862	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0301 Active non-implantable devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0306 Active non-implantable devices for	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		extra-corporal circulation, administration or removal of substances and haemapheresis	based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			assurance		
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1101 Non-active cardiovascular, vascular and neurovascular implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
		- - 1. Non-active implants and long term surgically invasive devices	Conformity assessment based on a quality management system	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		- MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care	Conformity assessment based on a quality management system Conformity assessment	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			based on assessment of technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			technical documentation Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II) Annex XI(A)	

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
			Conformity assessment based on product quality assurance		
		- - 2. Non-active non-implantable devices - MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	Code scope limited to male condoms.
		- - 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		MDS 1001 Devices incorporating medicinal substances			Restricted to Article 117 devices.

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)			
		MDS 1005 Devices in sterile condition			Including ethylene oxide gas sterilisation (EtO, EOG, moist heat sterilisation, aseptic processing, radiation sterilisation (gamma, x-ray, electron beam)
		MDS 1006 Reusable surgical instruments			
		MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body			
		MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices			
		MDS 1010 Devices with a measuring function			
		MDS 1011 Devices in systems or procedure packs			
		MDT 2001 Devices manufactured using metal processing			
		MDT 2002 Devices manufactured using plastic processing			
		MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)			
		MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather,			

LIST OF BODIES NOTIFIED UNDER DIRECTIVE : Regulation (EU) 2017/745 on medical devices

Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		paper)			
		MDT 2005 Devices manufactured using biotechnology			
		MDT 2006 Devices manufactured using chemical processing			
		MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals			
		MDT 2008 Devices manufactured in clean rooms and associated controlled environments			
		MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin			
		MDT 2010 Devices manufactured using electronic components including communication devices			
		MDT 2011 Devices which require packaging, including labelling			
		MDT 2012 Devices which require installation, refurbishment			