Creation Date : 10/04/2021

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
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			
		- A. Active devices			
		- - 1. 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)	
		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
		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			

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Name and address of the notified 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 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			

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 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)	
		- - 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	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		
		- - 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	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		
		- - 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 0301 Active non-implantable devices utilising 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) 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		
		- - 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	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		
		- - 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	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		
		- - 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	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		
		- - 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	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		
		- - 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	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		
		- - 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	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		
		- - 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	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 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	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		
		- - 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 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 class III devices
		-	Conformity assessment	Annex IX(I)	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
		- 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and 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 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
		- - 2. Non-active non-implantable devices	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	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 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	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 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 class III 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)	Excluding class III devices
		- - 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable	Conformity assessment based on a quality management system	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
		ophthalmologic devices	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality 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)	Excluding class III devices
		- - 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	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 assessment of technical documentation 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)	Excluding class III 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)	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	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding class III 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
			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)	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 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			
		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 labelling			
		MDT 2012 Devices which require installation, refurbishment			
		MDT 2013 Devices which have undergone reprocessing			
TÜV SÜD Product Service GmbH Zertifizierstellen Ridlerstraße 65	0123	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
80339 MÜNCHEN Germany					
		- 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 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 a quality management system	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
		invasive devices - MDN 1103 Non-active dental implants and dental materials	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 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 - 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 a quality management system 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 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 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 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. 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)	
		-	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 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	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 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	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 1213 Non-active non-implantable devices composed of substances to be introduced into the 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	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 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)	

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Name and address of the notified 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. 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 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)	

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Name and address of the notified 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. 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 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)	

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Name and address of the notified 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		
		- - 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 technical documentation Conformity assessment based on product quality assurance	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 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 technical documentation Conformity assessment based on product quality assurance	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 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 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)	

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Name and address of the notified 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		
		- - 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	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 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 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)	

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Name and address of the notified 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		
		- - 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	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

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			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 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)	

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Name and address of the notified 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		
		- - 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	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 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 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 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
		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 Conformity assessment based on product conformity verification	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)	
		- - 3. Active non-implantable therapeutic devices and	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
		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 Conformity assessment based on product conformity verification	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, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), sterilisation with

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					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 in vitro diagnostic device			
		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 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 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			

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		- 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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		- 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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		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)	excluding IVF and ART; limited to devices for cryopreservation
		- - 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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			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)	
		- - 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)	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 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)	

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Name and address of the notified 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)	

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Name and address of the notified 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)	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 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			restricted to devices manufactured utilising human serum albumin

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					(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 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			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			
		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			

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

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Name and address of the notified 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		
		- - 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 assurance Conformity assessment based on product	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 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 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)	

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Name and address of the notified 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		
		- - 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 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)	

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Name and address of the notified 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		
		- - 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 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	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
		thereof	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 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	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)	
		- 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
		- - 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	Annex IX(I) Annex IX(II) Annex XI(A)	excluding joint implants

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			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 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 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 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 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	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)	

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Name and address of the notified 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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Name and address of the notified 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			
		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			
		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			
		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			

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Name and address of the notified 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 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
		- - 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)	

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Name and address of the notified 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	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	Conformity assessment based on a quality management system Conformity assessment	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
		ionizing radiation	based on assessment of technical documentation		
		- - 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 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	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 0309 Active non-implantable ophthalmologic 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 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)	
		- - 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)	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 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 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 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 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)	

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Name and address of the notified 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	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 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)	

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Name and address of the notified 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 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)	
		-	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 1206 Non-active non-implantable ophthalmologic 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)	
		- - 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	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 1209 Non-active non-implantable 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 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)	
		- - 2. Non-active non-implantable devices - MDN 1214 General 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
		devices used in health care and other non-active non-implantable devices	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality 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 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 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			

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Name and address of the notified 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			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			
		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

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					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			
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	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)	

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
		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			
GMED 1, rue Gaston Boissier 75015 PARIS France	0459	I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE			
		- A. Active devices			
		- - 1. Active implantable 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)	

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Name and address of the notified 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	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 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		
		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 : ethylene oxide gas sterilisation (EOG), radiation sterilisation (gamma, x-ray, electron beam), moist heat sterilization, dry heat, aseptic processing, low temperature steam, formaldehyde 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			

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Name and address of the notified 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			Only applicable as of the date of application of the relevant common specifications referred to in Article 1(2) of the MDR.
		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			

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Name and address of the notified 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			
MEDCERT ZERTIFIZIERUNGS- UND PRÜFUNGSGESELLSCHAFT FÜR DIE MEDIZIN 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	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	Conformity assessment based on a quality management system 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 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 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 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 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 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			
		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			
		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			

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Name and address of the notified 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 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)	
		- - 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	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 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 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	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 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 based on product quality	Annex IX(I) Annex IX(II) Annex XI(A)	Except external pacemakers and heart defibrillators

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Name and address of the notified 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)	Except 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)	

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Name and address of the notified 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)	excluding in vitro ferti¬lisation (IVF) and assisted reproductive technologies (ART)
		- - 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)	
		- - 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)	
		- - 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)	

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Name and address of the notified 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)	
		- - 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 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 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			excluding reprocessing of single-use devices
Eurofins Expert Services 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 - MDA 0202 Active non-implantable imaging 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)	
		- - 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 product quality	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

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Name and address of the notified 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 of vital physiological parameters	assurance		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.
		- - 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

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Name and address of the notified 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 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 controlling, monitoring or directly influencing the performance of active implantable devices are excluded.
		- - 3. Active non-implantable therapeutic devices and	Conformity assessment based on a quality	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
		general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	management system 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 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.
		- - 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.

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Name and address of the notified 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 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 - MDA 0318 Other 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)	
		- B. Non-active devices			
		- - 1. Non-active implants and long term surgically	Conformity assessment based on a quality management system	Annex IX(I) Annex XI(A)	Other devices except sutures, staples, screws, wedges, plates, wires, pins, clips and connectors

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Name and address of the notified 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 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on product quality assurance		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)	
		- - 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.
		-	Conformity assessment	Annex IX(I)	

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		- 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	based on a quality management system 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 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 based on product quality assurance	Annex IX(I) 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 product quality	Annex IX(I) Annex XI(A)	Devices (or their products of metabolism) that are systemically absorbed by the human body 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
			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 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
		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			

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		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 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

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					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			
SGS FIMKO OY Takomotie 8 00380 HELSINKI Finland	0598	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 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
		- - 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
		- - 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

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Name and address of the notified 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 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
		- - 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

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Name and address of the notified 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)	Up to class IIb, excluding blood warmers
		- 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

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		- - 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
		- - 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

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		- 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
		- 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

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Name and address of the notified 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)	Up to class IIb, limited to hospital beds, physiotherapy equipment, rehabilitation, patient positioning and transport 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 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	Conformity assessment based on type-examination	Annex X Annex IX(I)	Up to class IIb, limited to autoclaves

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Name and address of the notified 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 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 Conformity assessment based on product conformity verification	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)	Up to class IIb
		- B. Non-active devices			
		-	Conformity assessment	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
		- 2. Non-active non-implantable devices - 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	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)	Up to class IIb
		- - 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	Conformity assessment based on a quality	Annex IX(I) Annex IX(II)	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
		- MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	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 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)	Up to class IIb
		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)

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Name and address of the notified 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			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 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			

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Name and address of the notified 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			
DARE!! Services 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	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
		monitoring of vital physiological parameters	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 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 0305 Active non-implantable devices for stimulation or inhibition	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 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	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluding inhalation anaesthesia devices, lung ventilators and heart-lung machines

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Name and address of the notified 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 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)	

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Name and address of the notified 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)	

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Name and address of the notified 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 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	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
		positioning and transport	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	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	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 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)	
		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,

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					procedure packs are excluded
		MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745			Only for active devices.
		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			
3EC International a.s. 3EC International a.s. Hranicna 18 Bratislava 82105 SLOVAKIA Bratislava 82105 Slovakia	2265	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	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 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	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 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 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)	

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Name and address of the notified 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 a quality management system 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 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 0307 Active non-implantable respiratory 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 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	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 0310 Active non-implantable devices for ear, nose and throat	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 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	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 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	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
		thereof	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)	
		- 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 neurovascular implants

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Name and address of the notified 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 1101 Non-active cardiovascular, vascular and neurovascular 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 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	Annex IX(I) Annex IX(II) Annex XI(A)	excluding breast implants

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Name and address of the notified 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 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	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 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	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 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	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 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)	

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Name and address of the notified 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 a quality management system 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			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

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					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) 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)			

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Name and address of the notified 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			
		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			
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	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
			Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance		
		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 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			

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Name and address of the notified 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			
		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			

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
		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 3 1363 Høvik Norway	2460	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	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 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 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)	

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Name and address of the notified 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 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 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)	
		-	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 0305 Active non-implantable devices for stimulation or inhibition	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 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	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 0308 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)	
		- - 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	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 0314 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
		processing and preservation of human cells, tissues or organs including in vitrofertilisation (IVF) and assisted reproductive technologies (ART)	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)	
		- - 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	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 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)	Cardiac valves excluded
		- - 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) 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
		implants	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 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 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	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 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	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 a quality management system 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)	

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Name and address of the notified 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	Conformity assessment based on a quality management system 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)	
		-	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			
		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), plasma sterilisation, chemical sterilisation and dry heat 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			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,			

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Name and address of the notified 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			
		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	Annex IX(I) Annex IX(II) Annex XI(A)	EXCLUDING GAMMA RAY 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 product quality assurance		
		- - 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 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)	
		-	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 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 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	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 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 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	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 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)	

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		
		- - 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 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 - 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)	

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. 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 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	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 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	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 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			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

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Name and address of the notified bodies	ID	Responsible for the following products /Horizontal technical competence	Responsible for the following procedures or modules	Annexes or articles of the directives	Conditions
					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			
		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			

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Name and address of the notified 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 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			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	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. 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 assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
		- - 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	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 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	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 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	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 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 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 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	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 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	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 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	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 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	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 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			
		- - 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)	

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Name and address of the notified 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 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 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	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)	
		- - 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	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Annex X and XI(B) limited to gloves

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Name and address of the notified 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		
		- - 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	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)	
		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

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Name and address of the notified 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, 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 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			

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Name and address of the notified 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 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			
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			

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Name and address of the notified 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 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 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	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	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 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	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 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 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	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		
		- 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 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)	
		-	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 1104 Non-active soft tissue and other implants	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)	
		- - 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	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
		catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on assessment of technical documentation Conformity assessment 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 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)	Excluding gels and solutions.
		- - 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	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 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.
		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			

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Name and address of the notified 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 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, 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			