Notification of a Body in the framework of a technical harmonization directive

From:

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To:

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Other Member States

Reference:

Legislation: Regulation (EU) 2017/745 on medical devices

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Body:

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Products	Procedures	Articles /Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-A. Active devices** **-2. Active non-implantable devices for imaging, monitoring and/or diagnosis** **-MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-A. Active devices** **-2. Active non-implantable devices for imaging, monitoring and/or diagnosis** **-MDA 0204 Other active non-implantable devices 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)	
-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 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)	
-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 0306 Active non-implantable devices for extra-corporal circulation, administration or removal of substances and haemapheresis**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding extracorporal circulation and haemapheresis devices
-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 0307 Active non-implantable respiratory devices**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding hyperbaric chambers

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-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 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)	
-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 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)	
-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 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)	
-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 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)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-B. Non-active devices** **-1. Non-active implants and long term surgically invasive devices** **-MDN 1101 Non-active cardiovascular, vascular and neurovascular implants**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding vascular stents and artificial heart valves

Products	Procedures	Articles /Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-B. Non-active devices** **-1. Non-active implants and long term surgically invasive devices** **-MDN 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)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-B. Non-active devices** **-1. Non-active implants and long term surgically invasive devices** **-MDN 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)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-B. Non-active devices** **-1. Non-active implants and long term surgically invasive devices** **-MDN 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 intrauterine contraceptive implants, breast implants, eyelid implants, lung implants and bariatric surgery devices
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-B. Non-active devices** **-2. Non-active non-implantable devices** **-MDN 1201 Non-active non-implantable devices for anaesthesia, emergency and intensive care**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-B. Non-active devices** **-2. Non-active non-implantable devices** **-MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

Products	Procedures	Articles /Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active 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)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

Products	Procedures	Articles /Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-B. Non-active devices** **-2. Non-active non-implantable devices** **-MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-B. Non-active devices** **-2. Non-active non-implantable devices** **-MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	

Horizontal technical competences	Limitations
MDS 1001 Devices incorporating medicinal substances:	
MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1):	
MDS 1005 Devices in sterile condition:	-aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam)
MDS 1006 Reusable surgical instruments:	
MDS 1007 Devices incorporating or consisting of nanomaterial:	
MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body:	
MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices:	
MDS 1010 Devices with a measuring function:	
MDS 1011 Devices in systems or procedure packs:	

Horizontal technical competences	Limitations
MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745:	
MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device:	
MDT 2001 Devices manufactured using metal processing:	
MDT 2002 Devices manufactured using plastic processing:	
MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics):	
MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper):	
MDT 2005 Devices manufactured using biotechnology:	
MDT 2006 Devices manufactured using chemical processing:	
MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals:	
MDT 2008 Devices manufactured in clean rooms and associated controlled environments:	
MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin:	Limited to devices manufactured using processing materials of microbial origin
MDT 2010 Devices manufactured using electronic components including communication devices:	
MDT 2011 Devices which require packaging, including labelling:	
MDT 2012 Devices which require installation, refurbishment:	Limited to devices which require installation
MDT 2013 Devices which have undergone reprocessing:	Limited to reusable instruments and surgical instruments