

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

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Reference:

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

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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 0201 Active non-implantable imaging devices utilising ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices
-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 product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical 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 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -A. Active devices -3. Active non-implantable therapeutic devices and general active non-implantable devices -MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical 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 0305 Active non-implantable devices for stimulation or inhibition	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices

Products	Procedures	Articles /Annexes	Conditions
-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 product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical 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 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical 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 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices Excluded active non implantable devices for nose and throat
-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 product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical 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 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Excluded Class III Medical Devices

Products	Procedures	Articles /Annexes	Conditions
-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 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex IX(I) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices
-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)	Excluded Class III Medical Devices excepted those classified in Class III only composed of substances or a combination of substances that are absorbed by or locally dispersed in the human body and/or utilising tissues of animal origin, including Commission Regulation (UE) n. 722/2012.
-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 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)	
-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)	
-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)	Excluded Class III Medical Devices

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 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices
-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 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)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Excluded Class III Medical Devices
-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 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)	
-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 type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices

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 1209 Non-active non-implantable dental materials	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1210 Non-active non-implantable devices used for contraception or prevention of the transmission of sexually transmitted diseases	Conformity assessment based on type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices excepted those classified in Class III only as incorporating medicinal substances according to Directive 2001/83/EC and/or composed of substances or a combination of substances that are absorbed by or locally dispersed in the human body.
-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 type-examination Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Excluded Class III Medical Devices
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -2. Non-active non-implantable devices -MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Exclusion of in vitro fertilisation (IVF) and assisted reproductive technologies (ART)

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 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)	
-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)	Excluded Class III Medical Devices

Horizontal technical competences	Limitations
MDS 1001 Devices incorporating medicinal substances:	Excluded derived from human blood or human plasma
MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their derivatives:	
MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1):	
MDS 1005 Devices in sterile condition:	Including: aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation (gamma-ray, x-ray, electron beam, beta-ray.).
MDS 1006 Reusable surgical instruments:	
MDS 1007 Devices incorporating or consisting of nanomaterial:	
MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body:	
MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices:	
MDS 1010 Devices with a measuring function:	
MDS 1011 Devices in systems or procedure packs:	
MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745:	

Horizontal technical competences		Limitations
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:	