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

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To : **European Commission**
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200 Rue de la Loi,
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Other Member States

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

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Body : **NB 0537**

Tasks performed by the Body :

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Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	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	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 monitoring of vital physiological parameters	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices that directly contact central nervous system or central circulatory system, active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (e.g. closed loop systems or automated external defibrillators), and devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are excluded.
- 2. Active non-implantable devices for imaging, monitoring and/or diagnosis - MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices that directly contact central nervous system or central circulatory system, active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (e.g. closed loop systems or automated external defibrillators), and devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are excluded.
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0302 Active non-implantable devices utilising non-ionizing radiation	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices that directly contact central nervous system or central circulatory system, active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device (e.g. closed loop systems or automated external defibrillators), and devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are excluded.
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Heater-cooler units (blood warmers) are excluded.

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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 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 general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are excluded.
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental devices	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical devices	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices that directly contact central nervous system or central circulatory system are excluded.
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Active prostheses and exoskeletons are excluded.
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0315 Software	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Software intended to provide information, which is used to take decisions having an impact that may cause death or an irreversible deterioration of a person's state of health, and therapeutic devices with an integrated or incorporated diagnostic function, which significantly determines the patient management by the device e.g. closed loop systems or automated external defibrillators, are excluded.
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	Devices for sterilization are excluded.
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - 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 invasive devices - MDN 1102 Non-active osteo- and orthopaedic	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 are

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implants	Conformity assessment based on product quality assurance		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.
- 2. Non-active non-implantable devices - MDN 1207 Non-active non-implantable diagnostic devices	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	
- 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	
- 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	
- 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing	Conformity assessment based on a quality management system Conformity assessment 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 assurance	Annex IX(I) Annex XI(A)	Devices (or their products of metabolism) that are systemically absorbed by the human body are excluded.
- 2. Non-active non-implantable devices - MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices	Conformity assessment based on a quality management system Conformity assessment based on product quality assurance	Annex IX(I) Annex XI(A)	

Horizontal technical competence	Conditions
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

Horizontal technical competence	Conditions
	potential for internal exposure are excluded.
MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body	
MDS 1009 Devices incorporating software/utilising software/controlled by software, including devices intended for controlling, monitoring or directly influencing the performance of active or active implantable devices	Devices intended for controlling, monitoring or directly influencing the performance of the active implantable are excluded.
MDS 1010 Devices with a measuring function	
MDS 1011 Devices in systems or procedure packs	
MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device	
MDT 2001 Devices manufactured using metal processing	
MDT 2002 Devices manufactured using plastic processing	
MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)	
MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	
MDT 2005 Devices manufactured using biotechnology	
MDT 2006 Devices manufactured using chemical processing	
MDT 2008 Devices manufactured in clean rooms and associated controlled environments	
MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin	Devices manufactured using materials of human origin and devices other than intended to come into contact with intact skin only are excluded.
MDT 2010 Devices manufactured using electronic components including communication devices	
MDT 2011 Devices which require packaging, including labelling	
MDT 2012 Devices which require installation, refurbishment	
MDT 2013 Devices which have undergone reprocessing	