

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

From : Ministero dello Sviluppo
Economico - Direzione Generale
per il Mercato, la Concorrenza, il
Consumatore, la Vigilanza e la
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To : **European Commission**
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Other Member States

Reference :

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

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NB 0546

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			
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0303 Active non-implantable devices utilising hyperthermia/hypothermia	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC Excluding all devices depending on a source of electrical energy
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0308 Active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC Excluding all devices depending on a source of electrical energy
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0310 Active non-implantable devices for ear, nose and throat	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC Excluding all devices depending on a source of electrical energy
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0316 Medical gas supply systems and parts thereof	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
- B. Non-active devices			
- 1. Non-active implants and long term surgically invasive devices - MDN 1102 Non-active osteo- and orthopaedic implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
- 1. Non-active implants and long term surgically invasive devices - MDN 1103 Non-active dental implants and dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
- 1. Non-active implants and long term surgically invasive devices - MDN 1104 Non-active soft tissue and other implants	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
- 2. Non-active non-implantable devices - MDN 1202 Non-active non-implantable devices for	Conformity assessment based on a quality management	Annex IX(I) Annex IX(II)	Excluded Class III Medical Devices Except those

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administration, channelling and removal of substances, including devices for dialysis	system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex XI(A)	classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
- 2. Non-active non-implantable devices - MDN 1204 Non-active non-implantable devices for wound and skin care	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	
- 2. Non-active non-implantable devices - MDN 1206 Non-active non-implantable ophthalmologic devices	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
- 2. Non-active non-implantable devices - 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)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
- 2. Non-active non-implantable devices - MDN 1208 Non-active non-implantable instruments	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices
- 2. Non-active non-implantable devices - MDN 1209 Non-active non-implantable dental materials	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluded Class III Medical Devices Except those classified in Class III only as incorporating medicinal substances, according to Directive 2001/83/EC and/or utilising biological active coatings and/or materials or being wholly or mainly absorbed
- 2. Non-active non-implantable devices - MDN 1211 Non-active non-implantable devices for 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)	Excluded Class III Medical Devices
- 2. Non-active non-implantable devices - MDN 1212 Non-active non-implantable devices for processing and preservation of human cells, tissue or organs including in vitro fertilisation (IVF) and assisted reproductive technologies (ART)	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Excluding devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART)
- 2. Non-active non-implantable devices - MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route	Conformity assessment based on a quality management system Conformity assessment based	Annex IX(I) Annex IX(II) Annex XI(A)	

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	on assessment of 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)	

Horizontal technical competence	Conditions
MDS 1001 Devices incorporating medicinal substances	Excluding plasma and blood derivatives
MDS 1004 Devices which are also machinery as defined in point (a) of the second paragraph of Article 2 of Directive 2006/42/EC of the European Parliament and of the Council (1)	
MDS 1005 Devices in sterile condition	Including: - aseptic processing - ethylene oxide gas sterilisation (EOG) - low temperature steam - moist heat sterilisation - radiation sterilisation (gamma-ray, x-ray, electron beam)
MDS 1006 Reusable surgical instruments	
MDS 1008 Devices utilising biologically active coatings and/or materials or being wholly or mainly absorbed or locally dispersed in the human body or are intended to undergo a chemical change in the body	
MDS 1010 Devices with a measuring function	
MDS 1011 Devices in systems or procedure packs	
MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745	
MDT 2001 Devices manufactured using metal processing	
MDT 2002 Devices manufactured using plastic processing	
MDT 2003 Devices manufactured using non-metal mineral processing (e.g. glass, ceramics)	
MDT 2004 Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper)	
MDT 2005 Devices manufactured using biotechnology	
MDT 2006 Devices manufactured using chemical processing	
MDT 2007 Devices which require knowledge regarding the production of pharmaceuticals	
MDT 2008 Devices manufactured in clean rooms and associated controlled environments	
MDT 2009 Devices manufactured using processing of materials of human, animal, or microbial origin	
MDT 2011 Devices which require packaging, including labelling	
MDT 2012 Devices which require installation, refurbishment	
MDT 2013 Devices which have undergone reprocessing	Limited to reusable devices which have to undergo reprocessing