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

From:

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To:

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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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NB 0546

Tasks performed by the Body:

Last approval date: 2024-09-17

null	Procedures	Articles /Annexes	null
-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
-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)	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
-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 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
-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 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

null	Procedures	Articles /Annexes	null
-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 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
-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)	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
-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)	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

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-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)	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
-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)	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
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE -B. Non-active devices -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

null	Procedures	Articles /Annexes	null
-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)	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 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
-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)	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)	Exluding devices for in vitro fertilisation (IFV) and assisted reproductive technologies (ART)

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-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:	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:	

Horizontal technical competences	Limitations
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 undergone reprocessing