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 info: **NB 3033**

Tasks performed by the Body

Last approval date: 2024-03-07

Product	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 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 assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Class III Excluded
-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)	Class III Excluded, Medical gas pipeline system excluded
-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)	Class III Excluded
-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)	Class III Excluded, Catheter lock solutions excluded, and Solutions for disinfecting contact lenses excluded
-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)	Class III Excluded, Heart-lung-bypass pump /Extracorporeal Membrane Oxygenation (ECMO) excluded, Intra-aorthic Balloon Pump excluded

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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)	Class III Excluded
-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)	Class III Excluded
-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)	Class III Excluded
-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)	Class III Excluded, Short wave diathermy excluded
-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 assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Class III Excluded, Sterilization devices excluded

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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 1205 Non-active non-implantable orthopaedic and rehabilitation 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)	Class III Excluded
-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)	Class III Excluded
-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)	Class III Excluded
-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)	Class III Excluded
-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)	Class III Excluded

Product	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)	Class III Excluded, Restricted to: Periferal vascular catheters and related tools
-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)	Class III Excluded
-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)	Class III Excluded
-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)	Class III Excluded
-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)	Class III Excluded
-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 assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	Class III Excluded

Product	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 0311 Active non-implantable dental 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)	Class III Excluded, Restricted to: Powered dental surgical unit and hand pieces, Surgical suction device for dental use
-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)	Class III Excluded, EEG excluded
-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)	Class III Excluded, Restricted to: Orthopaedic nails, screws, plates, and Sutures, suture anchors, staples for orthopedic surgery
-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)	Class III Excluded
-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)	Class III Excluded

Horizontal technical competences	Limitations
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:	Restricted to: ethylene oxide gas sterilisation (EOG) and radiation sterilisation (gamma, x-ray, electron beam)

Horizontal technical competences	Limitations
MDS 1006 Reusable surgical instruments:	
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:	
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 2006 Devices manufactured using chemical processing:	
MDT 2008 Devices manufactured in clean rooms and associated controlled environments:	
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:	