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

From : Ministry of Health and Welfare,
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To : **European Commission**
GROWTH Directorate-General
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Other Member States

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

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Body : **NB 1912**

Tasks performed by the Body :

Last approval date : 05/11/2019

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 0202 Active non-implantable imaging devices utilising non-ionizing radiation	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)	
- 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 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)	
- 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 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)	
- 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 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)	
- 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 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	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
	verification		
- 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 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)	
- 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 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)	Limited to devices for administration and removal of substances
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0307 Active non-implantable respiratory 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)	Excluding inhalation anaesthesia devices, lung ventilators and heart-lung machines
- 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 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)	
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0309 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)	
- 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 type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(B)	
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0311 Active non-implantable dental 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)	
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0312 Other active non-implantable surgical 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)	
- 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 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)	
- 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	Annex IX(I) Annex IX(II)	
- 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 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)	
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0318 Other active non-implantable devices	Conformity assessment based on type-examination Conformity assessment based on a quality management system	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	

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	Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance Conformity assessment based on product conformity verification	Annex XI(B)	

Horizontal technical competence	Conditions
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	Limited to ethylene oxide gas sterilisation and radiation sterilisation
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	Only for active devices
MDS 1010 Devices with a measuring function	
MDS 1011 Devices in systems or procedure packs	Only devices in systems, procedure packs are excluded
MDS 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745	Only for active devices. Code will be only applicable as of the date of application of the relevant common specifications referred to in Article 1(2) of the MDR.
MDT 2001 Devices manufactured using metal processing	
MDT 2002 Devices manufactured using plastic 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	