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

From:
Czech Office for Standards,
Metrology and Testing
Biskupský dvur 1148/5
110 00 Praha 1
Czech Republic

To:
European Commission
GROWTH Directorate-General
200 Rue de la Loi,
B-1049 Brussels.

Other Member States

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

Body name, address, telephone, fax, email, website :

CESKY METROLOGICKY INSTITUT
Okruzni 31
638 00 BRNO
Czech Republic
+420:545:555111
+420:548:523049
cmi@cmi.cz
www.cmi.cz

Body info:

NB 1383

Body:

Created: 2023-03-13

Last update: 2023-10-24

Tasks performed by the Body:

Last approval date: 2023-12-21

Products	Procedures	Articles /Annexes	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 assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI(A)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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 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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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 0301 Active non-implantable devices utilising ionizing radiation**	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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices

Products	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 0302 Active non-implantable devices utilising non-ionizing radiation**	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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices

Products	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 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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices

Products	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 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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class 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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices
-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)	except IIIrd class devices, annex XI (A) only Is, Im, Ir, IIa class devices, only devices intended for

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:	assesptic processing, ethylene oxid gas sterilisantion (EOG), moist heat sterilisation, radiation sterilisation (only gamma), thermic sterilisation with dry heat
MDS 1006 Reusable surgical instruments:	
MDS 1007 Devices incorporating or consisting of nanomaterial:	
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:	

Horizontal technical competences	Limitations
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:	Including only for products with high intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment
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 2010 Devices manufactured using electronic components including communication devices:	
MDT 2011 Devices which require packaging, including labelling:	
MDT 2012 Devices which require installation, refurbishment:	