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

From:

Lægemiddelstyrelsen / Danish Medicines Agency
Axel Heides Gade 1
DK-2300 København S
Denmark

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 :

TÜV SÜD Danmark
Strandvejen 125
2900 Hellerup
Denmark
+45 4477 0010

info.dk@tuvsud.com
https://www.tuvsud.com/en-gb/country/denmark

Body info:

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Body:

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Products	Procedures	Articles /Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-A. Active devices** **-1. Active implantable devices** **-MDA 0101 Active implantable devices for stimulation/inhibition/monitoring**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-A. Active devices** **-1. Active implantable devices** **-MDA 0102 Active implantable devices delivering drugs or other substances**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-A. Active devices** **-1. Active implantable devices** **-MDA 0103 Active implantable devices supporting or replacing organ functions**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
-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	Annex IX(I) Annex IX(II)	
-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	Annex IX(I) Annex IX(II)	Limited to ultrasound technology
-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	Annex IX(I) Annex IX(II)	

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-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	Annex IX(I) Annex IX(II)	
-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	Annex IX(I) Annex IX(II)	
-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	Annex IX(I) Annex IX(II)	Limited to infusion systems
-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	Annex IX(I) Annex IX(II)	
-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	Annex IX(I) Annex IX(II)	Limited to hearing aids

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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 0312 Other active non-implantable surgical devices**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	Excluding surgical robotic
-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	Annex IX(I) Annex IX(II)	Excluding active limb prosthesis
-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	Annex IX(I) Annex IX(II)	
-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	Annex IX(I) Annex IX(II)	
-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 1101 Non-active cardiovascular, vascular and neurovascular implants**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
-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	Annex IX(I) Annex IX(II)	Excluding bone substitutes and bone cements

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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 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	Annex IX(I) Annex IX(II)	
-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	Annex IX(I) Annex IX(II)	
-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	Annex IX(I) Annex IX(II)	
-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	Annex IX(I) Annex IX(II)	

Horizontal technical competences	Limitations
MDS 1001 Devices incorporating medicinal substances:	
MDS 1002 Devices manufactured utilising tissues or cells of human origin, or their derivatives:	
MDS 1003 Devices manufactured utilising tissues or cells of animal origin, or their 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):	

Horizontal technical competences	Limitations
MDS 1005 Devices in sterile condition:	Including aseptic processing, ethylene oxide gas sterilisation (EOG), low temperature steam and formaldehyde sterilisation, moist heat sterilisation, radiation sterilisation (gamma, x-ray, electron beam), sterilisation with hydrogen peroxide, sterilisation with liquid chemical sterilising agents, thermic sterilisation with dry heat
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 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:	
MDS 1013 Class III custom-made implantable devices:	
MDT 2001 Devices manufactured using metal processing:	
MDT 2002 Devices manufactured using plastic 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 2010 Devices manufactured using electronic components including communication devices:	
MDT 2011 Devices which require packaging, including labelling:	
MDT 2012 Devices which require installation, refurbishment:	