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

From : Finnish Medicins Agency
P.O. Box 55
FI-00034 FIMEA
Finland

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 :

SGS FIMKO OY
Takomotie 8
00380 HELSINKI
Finland
Phone : +358 9 696 361
Fax :
Email : nb.fimko@sgs.com
Website : www.sgs.fi

Body : **NB 0598 (ex-0403)**

Tasks performed by the Body :

Last approval date : 09/01/2021

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 0201 Active non-implantable imaging devices utilising 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)	Up to class IIb
- 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)	Up to class IIb, excluding ultrasound 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 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)	Up to class IIb
- 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)	Up to class IIb, excluding audiometers
- 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 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)	Up to class IIb

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 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 verification	Annex X Annex IX(I) Annex IX(II) Annex XI(A) Annex XI(B)	Up to class IIb, excluding blood warmers
- 3. Active non-implantable therapeutic devices and general active non-implantable devices - MDA 0304 Active non-implantable devices for shock-wave therapy (lithotripsy)	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)	Up to class IIb, limited to extracorporeal shockwave therapy of limbs and joints and shockwave HIFU
- 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)	Up to class IIb
- 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)	Up to class IIb, excluding hyperbaric chambers
- 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)	Up to class IIb, excluding surgical devices
- 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	Annex X Annex IX(I) Annex IX(II) Annex XI(A)	Up to class IIb

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
	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 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)	Up to class IIb, limited to hospital beds, physiotherapy equipment, rehabilitation, patient positioning and transport 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 Conformity assessment based on product conformity verification	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 0317 Active non-implantable devices for cleaning, disinfection and sterilisation	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)	Up to class IIb, limited to autoclaves
- 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 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)	Up to class IIb
- 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)	Up to class IIb
- 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	Annex IX(I) Annex IX(II) Annex XI(A)	Up to class IIb

Product family, product /Intended use/Product range	Procedure/Modules	Annexes or articles of the directives	Conditions
	on assessment of technical documentation Conformity assessment based on product quality assurance		
- 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)	Up to class IIb
- 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)	Up to class IIb
- 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)	Up to class IIb

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	Aseptic Processing, Ethylene Oxide gas sterilization, Low temperature steam and formaldehyde sterilization, Low temperature H2O2 sterilization, Moist heat sterilization, Radiation sterilization (gamma, x-ray, electron beam)
MDS 1007 Devices incorporating or consisting of nanomaterial	Up to class IIb
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 1012 Products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745	
MDS 1014 Devices incorporating as an integral part an in vitro diagnostic device	
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	