

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

**From:** ANSM : Agence Nationale de  
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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 info:**

**NB 0333**

**Tasks performed by the Body:**

**Last approval date:** 2024-04-23

Product	Procedures	Articles /Annexes	Conditions
<b>-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE</b> <b>-A. Active devices</b> <b>-2. Active non-implantable devices for imaging, monitoring and/or diagnosis</b> <b>-MDA 0201 Active non-implantable imaging devices utilising ionizing radiation</b>	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)	XI(A) is limited to class Im, Ir, Is & IIa devices
<b>-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE</b> <b>-A. Active devices</b> <b>-2. Active non-implantable devices for imaging, monitoring and/or diagnosis</b> <b>-MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation</b>	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)	XI(A) is limited to class Im, Ir, Is & IIa devices
<b>-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE</b> <b>-A. Active devices</b> <b>-2. Active non-implantable devices for imaging, monitoring and/or diagnosis</b> <b>-MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters</b>	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
<b>-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE</b> <b>-A. Active devices</b> <b>-3. Active non-implantable therapeutic devices and general active non-implantable devices</b> <b>-MDA 0305 Active non-implantable devices for stimulation or inhibition</b>	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)	XI(A) is limited to class Im, Ir, Is & IIa devices
<b>-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE</b> <b>-A. Active devices</b> <b>-3. Active non-implantable therapeutic devices and general active non-implantable devices</b> <b>-MDA 0307 Active non-implantable respiratory devices</b>	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	Limited to hyperbaric chambers

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<b>-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE</b> <b>-A. Active devices</b> <b>-3. Active non-implantable therapeutic devices and general active non-implantable devices</b> <b>-MDA 0312 Other active non-implantable surgical devices</b>	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)	XI(A) is limited to class Im, Ir, Is & IIa devices
<b>-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE</b> <b>-A. Active devices</b> <b>-3. Active non-implantable therapeutic devices and general active non-implantable devices</b> <b>-MDA 0313 Active non-implantable prostheses, devices for rehabilitation and devices for patient positioning and transport</b>	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)	XI(A) is limited to class Im, Ir, Is & IIa devices
<b>-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE</b> <b>-A. Active devices</b> <b>-3. Active non-implantable therapeutic devices and general active non-implantable devices</b> <b>-MDA 0315 Software</b>	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)	XI(A) is limited to class Im, Ir, Is & IIa devices
<b>-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE</b> <b>-A. Active devices</b> <b>-3. Active non-implantable therapeutic devices and general active non-implantable devices</b> <b>-MDA 0316 Medical gas supply systems and parts thereof</b>	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation	Annex IX(I) Annex IX(II)	
<b>-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE</b> <b>-A. Active devices</b> <b>-3. Active non-implantable therapeutic devices and general active non-implantable devices</b> <b>-MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation</b>	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)	XI(A) is limited to class Im, Ir, Is & IIa devices

Product	Procedures	Articles /Annexes	Conditions
<b>-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE</b> <b>-B. Non-active devices</b> <b>-2. Non-active non-implantable devices</b> <b>-MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis</b>	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)	XI(A) is limited to class Im, Ir, Is & IIa devices
<b>-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE</b> <b>-B. Non-active devices</b> <b>-2. Non-active non-implantable devices</b> <b>-MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools</b>	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)	XI(A) is limited to class Im, Ir, Is & IIa devices
<b>-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE</b> <b>-B. Non-active devices</b> <b>-2. Non-active non-implantable devices</b> <b>-MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices</b>	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)	XI(A) is limited to class Im, Ir, Is & IIa devices
<b>-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE</b> <b>-B. Non-active devices</b> <b>-2. Non-active non-implantable devices</b> <b>-MDN 1208 Non-active non-implantable instruments</b>	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)	XI(A) is limited to class Im, Ir, Is & IIa devices

Horizontal technical competences	Limitations
<b>MDS 1005 Devices in sterile condition:</b>	Limited to the following sterilisation processes: ethylene oxide gas (EOG), moist heat, radiation (gamma, x-ray, electron beam)
<b>MDS 1006 Reusable surgical instruments:</b>	
<b>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:</b>	
<b>MDS 1010 Devices with a measuring function:</b>	

Horizontal technical competences	Limitations
<b>MDS 1011</b> <b>Devices in systems or procedure packs:</b>	
<b>MDT 2001</b> <b>Devices manufactured using metal processing:</b>	
<b>MDT 2002</b> <b>Devices manufactured using plastic processing:</b>	
<b>MDT 2003</b> <b>Devices manufactured using non-metal mineral processing (e.g. glass, ceramics):</b>	
<b>MDT 2004</b> <b>Devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper):</b>	
<b>MDT 2005</b> <b>Devices manufactured using biotechnology:</b>	
<b>MDT 2006</b> <b>Devices manufactured using chemical processing:</b>	
<b>MDT 2007</b> <b>Devices which require knowledge regarding the production of pharmaceuticals:</b>	
<b>MDT 2008</b> <b>Devices manufactured in clean rooms and associated controlled environments:</b>	
<b>MDT 2010</b> <b>Devices manufactured using electronic components including communication devices:</b>	
<b>MDT 2011</b> <b>Devices which require packaging, including labelling:</b>	
<b>MDT 2012</b> <b>Devices which require installation, refurbishment:</b>	
<b>MDT 2013</b> <b>Devices which have undergone reprocessing:</b>	