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

**From:**

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**To:**

European Commission
GROWTH Directorate-General
200 Rue de la Loi,
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**Other Member States**

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

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## Body info:

**NB 0333**

**Body:**

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

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

| Products | Procedures | Articles /Annexes | Conditions |
|---|---|---|---|
| **-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE**<br>**-B. Non-active devices**<br>**-2. Non-active non-implantable devices**<br>**-MDN 1202 Non-active non-implantable devices for administration, channelling and removal of substances, including devices for dialysis** | Conformity assessment based on a quality management system<br>Conformity assessment based on assessment of technical documentation<br>Conformity assessment based on product quality assurance | Annex IX(I)<br>Annex IX(II)<br>Annex XI(A) | XI(A) is limited to class Im, Ir, Is & IIa devices |
| **-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE**<br>**-B. Non-active devices**<br>**-2. Non-active non-implantable devices**<br>**-MDN 1203 Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools** | Conformity assessment based on a quality management system<br>Conformity assessment based on assessment of technical documentation<br>Conformity assessment based on product quality assurance | Annex IX(I)<br>Annex IX(II)<br>Annex XI(A) | XI(A) is limited to class Im, Ir, Is & IIa devices |
| **-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE**<br>**-B. Non-active devices**<br>**-2. Non-active non-implantable devices**<br>**-MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices** | Conformity assessment based on a quality management system<br>Conformity assessment based on assessment of technical documentation<br>Conformity assessment based on product quality assurance | Annex IX(I)<br>Annex IX(II)<br>Annex XI(A) | XI(A) is limited to class Im, Ir, Is & IIa devices |
| **-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE**<br>**-B. Non-active devices**<br>**-2. Non-active non-implantable devices**<br>**-MDN 1208 Non-active non-implantable instruments** | Conformity assessment based on a quality management system<br>Conformity assessment based on assessment of technical documentation<br>Conformity assessment based on product quality assurance | Annex IX(I)<br>Annex IX(II)<br>Annex XI(A) | XI(A) is limited to class Im, Ir, Is & IIa devices |

| Horizontal technical competences | Limitations |
|---|---|
| **MDS 1005 Devices in sterile condition:** | Limited to the following sterilisation processes:ethylene oxide gas (EOG), moist heat, radiation (gamma, x-ray, electron beam) |
| **MDS 1006 Reusable surgical instruments:** | |
| **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:** | |

| Horizontal technical competences | Limitations |
|---|---|
| **MDS 1011 Devices in systems or procedure packs:** | |
| **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 2007 Devices which require knowledge regarding the production of pharmaceuticals:** | |
| **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:** | |
| **MDT 2013 Devices which have undergone reprocessing:** | |