The Czech Metrology Institute (CMI) has reached the final phase of preparation for conformity assessment of medical devices under the new Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR - Medical Device Regulation). CMI's application for designation as a notified body under the MDR regulation will be submitted in 2020.

In the field of active medical devices, the CMI application covers the following codes:

* MDA 0201 Active non-implantable imaging devices utilising ionizing radiation
* MDA 0202 Active non-implantable imaging devices utilising non-ionizing radiation
* MDA 0203 Active non-implantable devices for monitoring of vital physiological parameters
* MDA 0204 Other active non-implantable devices for monitoring and/or diagnosis
* MDA 0301 Active non-implantable devices utilising ionizing radiation
* MDA 0302 Active non-implantable devices utilising non-ionizing radiation
* MDA 0305 Active non-implantable devices for stimulation or inhibition
* MDA 0307 Active non-implantable respiratory devices
* MDA 0310 Active non-implantable devices for ear, nose and throat
* MDA 0311 Active non-implantable dental devices
* MDA 0312 Other active non-implantable surgical devices
* MDA 0315 Software
* MDA 0316 Medical gas supply systems and parts thereof
* MDA 0317 Active non-implantable devices for cleaning, disinfection and sterilisation
* MDA 0318 Other active non-implantable devices

In the field of non-active medical devices, these are the following codes:

* MDN 1102 Non-active osteo- and orthopaedic implants
* MDN 1103 Non-active dental implants and dental materials
* MDN 1205 Non-active non-implantable orthopaedic and rehabilitation devices
* MDN 1207 Non-active non-implantable diagnostic devices
* MDN 1208 Non-active non-implantable instruments
* MDN 1209 Non-active non-implantable dental materials
* MDN 1214 General non-active non-implantable devices used in health care and other non-active non-implantable devices

In the field of horizontal codes, the prepared CMI application covers the following medical devices with specific characteristics (MDS codes) and specific technologies or processes (MDT codes):

* MDS 1005 Devices in sterile condition
* 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
* 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
* 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 2010 Devices manufactured using electronic components including communication devices
* MDT 2011 Devices which require packaging, including labelling
* MDT 2012 Devices which require installation, refurbishment

Suggestions and comments from the medical device manufacturers and stakeholders interested in professional cooperation are welcomed. Please, do not hesitate to contact us (mdr@cmi.cz).