



The Czech Metrology Institute, as **notified body NB 1383**, offers **conformity assessment** of medical devices under Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices (**MDR**), and also offers **QMS certification** according to **ISO 13485**.



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**WE ARE YOUR
CENTER FOR
CERTIFICATION
OF MEDICAL
DEVICES**

 **CZECH
METROLOGY
INSTITUTE**

WE ARE ASSESSING THE CONFORMITY OF THESE CODES OF MEDICAL DEVICES

ACTIVE DEVICES:

Active non-implantable devices for imaging, monitoring and/or diagnosis

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

Active non-implantable therapeutic devices and general active non-implantable devices

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 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

NON-ACTIVE DEVICES:

Non-active implants and long term surgically invasive devices

MDN 1102 Non-active osteo- and orthopaedic implants

MDN 1103 Non-active dental implants and dental materials

Non-active non-implantable devices

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 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing

MDN 1214 General non-active non-implantable devices used in health care and other nonactive non-implantable devices

We are currently in the process of obtaining designation for the following codes:

MDA 0303, 0304, 0306, 0313, 0318

MDN 1201, 1202, 1203, 1204, 1213

CONFORMITY ASSESSMENT PROCEDURES:

Annex IX, Chapters I and III MDR

Is, Im, Ir

Quality management system assessment

EU quality management system certificate

Annex IX, Chapter II MDR

Ila, Ilb

Assessment of the technical documentation

EU technical documentation assessment certificate

Annex XI, Part A MDR

Is, Im, Ir, Ila

Conformity assessment based on product conformity verification

Production quality assurance

EU quality assurance certificate