Certification of medical devices

As a Notified Body with the EU/EEA for Medical Devices Directive (MDD), we cover your compliance needs for product requirements (IEC 60601 series) as well as Quality Management System requirements (ISO 13485).

We are accredited according to ISO/IEC 17065 and ISO/IEC 17025.

Product certification

Nemko provides international CB certificates for medical devices.

Medical device certification for Europe

- Medical Device Directive, Class I-m (measuring), I-s (sterile), IIa, IIb, III
- EC Declaration of Conformity; compiling of test reports and required documentation for the technical file (MDD Annex VII)
- EC Type Examination Certificate (MDD Annex III)
- Full Quality Assurance with reference to EN ISO 13485 (MDD Annex II)
- Production Quality Assurance with reference to EN/ISO 13485 (MDD Annex V)
- Product Quality Assurance with reference to MDD Annex VI
- EC Verification MDD Annex IV
