



Medical Electrical Equipment

Worldwide medical devices are controlled by strictly adjusted regional approval procedures, which also typically require testing by approved laboratories. In the field of active medical devices, these requirements are documented and internationally harmonized under the standard family IEC 60601.

Eurofins Medical Device Testing offers an extensive range of product testing and certification that will allow you to access global markets and deliver compliant products to your customers.

Choose Eurofins Medical Device Testing to help you:

- Check basic safety and essential performances
- Ensure conformity to IEC/EN 60601 standards
- Document test results in test reports and certificates
- Get CB test reports and certificates

Testing Available

Product Safety Testing

Safety testing for active medical devices based on the international IEC 60601-1 standards family including, but not limited to:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020
- EN 60601-1:2006 + A1:2013
- AAMI ES 60601-1:2005/(R)2012 + A1:2012
- CAN/CSA C22.2 No. 60601-1:14
- Safety testing for *in vitro* diagnostic medical devices to IEC 61010-2-101 and UL/CAN CSA 22.2 No. 61010-2-101
- EC 62133/UL 1642 safety testing of Lithium-Ion Batteries and UL 2054 safety of household and commercial batteries
- ANSI ISO 14708-3: 2017 for active implantable neurostimulators

CB Scheme

Our Certification Bodies in Germany, Switzerland and the United States are National Certification Bodies (NCB) and the test laboratories are Certification Body Testing Laboratories (CBTL) under the international Certification Body Scheme (CB Scheme).



EMC Testing

Medical EMC testing for active medical devices based on the international IEC 60601-1 standards family including, but not limited to:

- EN/IEC 60601-1-2 4th Edition
- Radio/Wireless Testing
- WLAN, Bluetooth, ZigBee, GSM/GPRS, UMTS, Wireless Power Transfer (WPT), and LTE
- Ultra-low power active medical implants (ULP-AMI)
- Medical device RFID susceptibility testing
- Medical device wireless coexistence testing
- Mechanical & Climatic Environmental Simulation
- Corrosion tests, IP tests, temperature shock, overpressure, temperature and altitude, faster decompression, shock and vibration etc
- Performance Testing
- Functionality, energy efficiency, durability and reliability, performance claims validation
- Other related testing services
- Digital Testing Services (software, functionality, interoperability)
- Cybersecurity testing
- Biocompatibility testing according to the ISO 10993 standards family and microbiological studies (GLP)
- Chemical characterization for materials, extractable and leachable substances evaluation
- Medical device packaging testing with distribution simulation testing, fragility, shock compression testing