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Medical Devices

Testing, Compliance & Certification

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Eurofins E&E offers a range of testing and certifications services to help you get your medical devices to market on-time and on budget.

Our international network of accredited electrical and electronics (E&E) laboratories and certification bodies offer a comprehensive range of testing and certification services for active and non-active medical devices and In Vitro Diagnostic Medical Devices (IVDs).

Our experience and expertise provide you with the confidence to design, develop and deliver tested and certified products to your chosen markets, efficiently and cost-effectively.

Meet the demands of global markets

The market for medical devices is global and in all important markets, regulatory requirements are in place to ensure that products meet the highest standards and that they do not present a risk to patients or users alike.

Unfortunately, these regulatory requirements and the methods of approval differ between countries and only in a few cases are these mutually recognised.

For example, products must comply with EU Directives in the European Economic Area, the FDA's requirements in the United States, Health Canada's requirements in Canada, JPAL regulations in Japan and TGA requirements in Australia.

In addition to these markets, many important countries globally have their own regulatory systems for medical devices and managing these requirements complex and time-consuming.

Eurofins E&E provides you with a single point of contact for the testing and certification of your medical devices, allowing you to access your chosen markets, quickly, easily and cost-effectively.

Conformity assessment for EU markets

Our network of accredited laboratories and certification bodies offer a comprehensive range of testing and certification services for both active and non-active medical devices and *in vitro* diagnostic medical devices in line with the requirements of the MDD (medical device directive), MDR (medical device regulation) and the IVDD (*in vitro* diagnostic devices directive) for EU markets.

To assist you in placing your medical devices onto the EU market, Eurofins E&E has a number of Notified Bodies (NB) who can provide conformity assessment to:

- Medical Device Regulation 2017/745
- Medical Device Directive 93/42/EEC
- IVD Directive 98/79/EC

Certification for the US & Canada

To access the United States (US) and Canadian markets, medical devices or equipment needs to be certified.

For the US, this should be undertaken by a Nationally Recognised Testing Laboratory (NRTL) and for Canada, a Standards Council of Canadian (SCC) Certification Body.

Eurofins E&E North America is both an NRTL recognised by OSHA and a Certification Body accredited by the SCC and can provide the MET NRTL mark to demonstrate compliance with these requirements.

Medical Device Testing

The Eurofins E&E network of laboratories offers a range of testing services for medical devices.

We can also offer an extensive range of additional testing, certification and approval services for products that fall outside of the scope of medical devices.

Our range of services for medical devices includes but is not limited to:

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 + A1:2012+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
- IEC 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
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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 characterisation for materials, extractable and leachable substances evaluation
- Medical device packaging testing with distribution simulation testing, fragility, shock compression testing

* Where IEC standards are referred to, national and regional variations are also applicable including, but not limited to; ANSI/AAMI, UL, ISO, CAN/CSA, JIS, EN, ENV, BS EN, DD ENV and BS IEC. Please enquire on a case by case basis.

Medical Device Certification

Notified Body Services for the EU

In Europe, the use of a Notified Body (NB) is required in the approval or certification process for medical devices. To assist you in placing your medical devices onto the EU market, Eurofins E&E has a number of Notified Bodies (NB) who can provide conformity assessment to:

- Medical Device Regulation 2017/745
- Medical Device Directive 93/42/EEC
- IVD Directive 98/79/EC

Medical Device Regulation (MDR) 2017/745

Our certification body in Finland (NB No. 0537) is a Notified Body under the MDR (2017/745) for both active and non-active medical devices.

Medical Device Directive (MDD) 93/42/EEC

Our certification bodies in Finland (NB No. 0537), Germany (NB No. 0681) and Italy (NB No. 0477) are Notified Bodies under directive 93/42/EEC for both active and non-active medical devices.

In Vitro Diagnostic Devices to the IVD Directive (98/79/EC)

For *in vitro* diagnostic medical devices, our certification body in Finland is a Notified Body (NB No. 0537) under the IVD Directive 98/79/EC.

North American Services

For the North American markets, an NRTL mark demonstrates compliance with the required standards for workplace safety which include hospitals, clinics, therapy centres and similar facilities.

Eurofins E&E North America is both an NRTL recognised by OSHA and an SCC Certification Body and can provide the MET NRTL mark to demonstrate compliance with the requirements of both of these bodies for medical devices.

The Eurofins MET-certified products certification mark is universally accepted in both the US and Canada for medical equipment.

FDA Submissions

All medical devices in the United States are regulated by the Food and Drug Administration (FDA) under the Center for Devices and Radiological Health (CDRH).

If you are introducing a new device to the US market, Eurofins can help you navigate the FDA submission process.

Eurofins can also offer expert services to help you gain FDA approval covering Pre-Sub (formerly called Pre-IDE), US FDA 510(k) Premarket Notification submission, “De Novo” and Premarket Approval (PMA).

Quality Management Systems & Audits

ISO 13485 Quality Management System (QMS)

The global standard ISO 13485 stipulates the quality management requirements for regulatory purposes for medical device manufacturers and is the certified quality management system that is most broadly recognised in the medical sector.

Eurofins E&E has three ISO 13485 QMS Certification Bodies to assist in your compliance process:

- Finland
  Eurofins Expert Services, No. S021
- Germany
  Eurofins Product Service GmbH, D-ZM-12092-01-00
- Italy
  Eurofins Product Testing Italy s.r.l., No. 133A

Medical Device Single Audit Program (MDSAP)

Our certification body in Finland acts in cooperation with an MDSAP recognised auditing organization, DQS Medizinprodukte GmbH, and can provide your organisation with MDSAP certification.

Please note that this service is only available in conjunction with the Notified Body services provided by Eurofins Expert Services in Finland (NB No. 0537).

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