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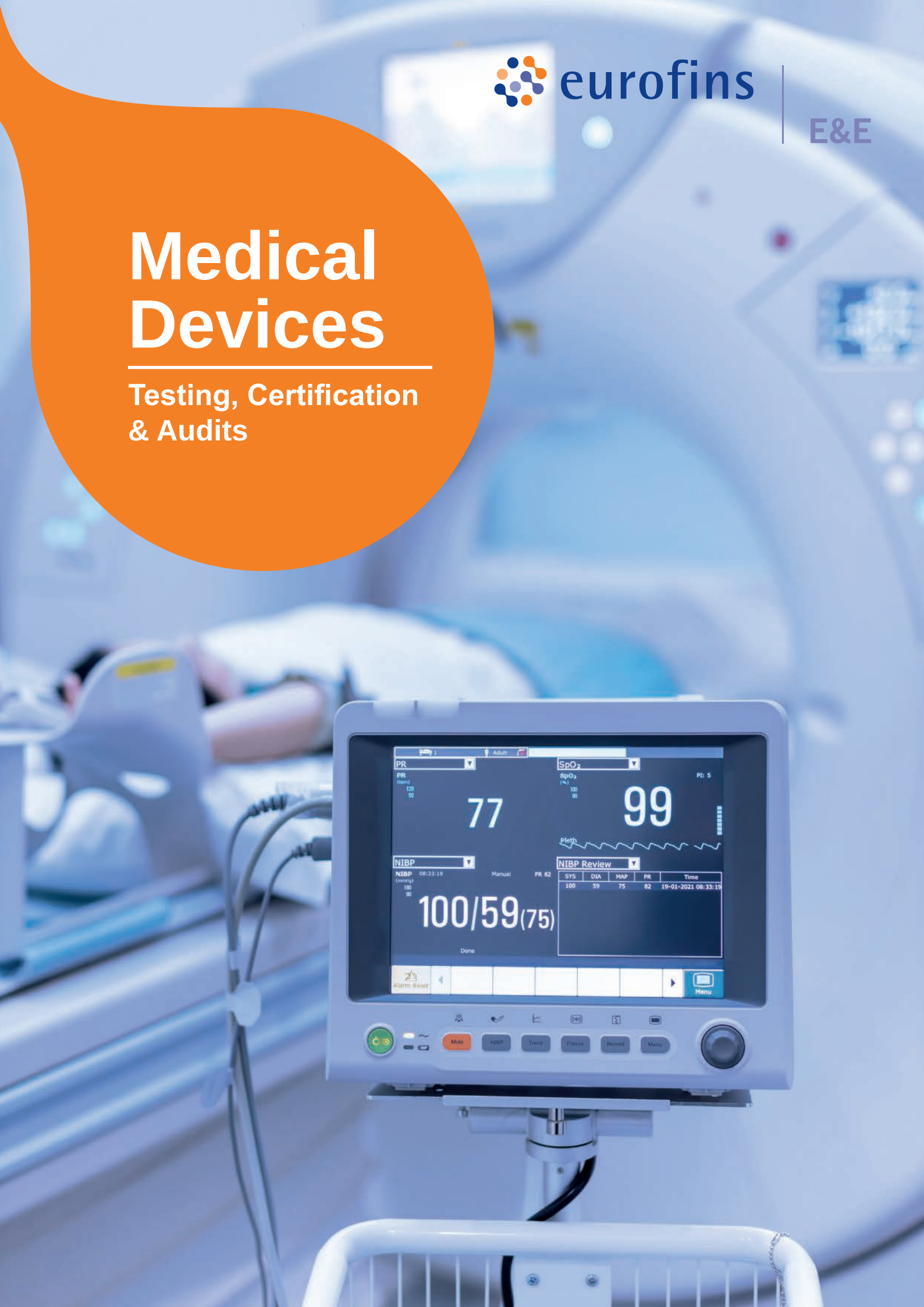
Medical Devices

Testing, Certification & Audits

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Our Services

Eurofins E&E offers a range of testing and certification services to help you get your medical devices to market on time and within 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 give you with the confidence to design, develop and deliver tested and certified products to your chosen markets efficiently and cost-effectively.

Our core services include:

- Medical Device Certification
  - Notified Body Services for the EU
  - Approved Body Services for the UK
  - North American Certification Services
- Quality Management Systems & Audits
- Testing of Medical Devices
  - Product Safety
  - EMC
  - Radio/Wireless
  - Mechanical & Climatic Simulations
  - Performance
  - Cybersecurity

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 do not present a risk to patients or users alike.

These regulatory requirements and approval methods differ between countries and only in a few cases are these mutually recognised.

For example, products must comply with EU Regulations in the European Economic Area, the requirements of the MHRA in the UK, 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 is complex and time-consuming.

Eurofins E&E provides 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.

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Eurofins E&E locations, correct as of the 1st September 2023. Multiple laboratories or offices may be present in one location identified.

Medical Device / IVD Certification

CE Marking & Conformity assessment for EU Markets

In Europe, the use of a Notified Body (NB) is required in the approval or certification process for medical devices.

Our network of accredited laboratories and certification bodies offers 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 MDR (Medical Device Regulation) 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) that can provide conformity assessment to the Medical Device Regulation (MDR) 2017/745.

Medical Device Regulation (MDR) 2017/745

Our certification bodies in Finland (NB No. 0537) and Italy (NB No. 0477) are Notified Bodies under the MDR (2017/745) for both active and non-active medical devices.

In-Vitro Diagnostic Regulation (IVDR) 2017/746

Our certification body in Finland (NB No. 0537) is a Notified Body under the In-Vitro Diagnostic Regulation (IVDR) 2017/746.

Our EU Notified Bodies

Italy
Eurofins Product Testing Italy Srl
NB No. 0477

Finland
Eurofins Electric & Electronics Finland Oy
NB No. 0537

The current scope of accreditation for all EU Notified Bodies can be found on the EU Nando website.

UKCA Marking & Conformity assessment for the UK

Medical Devices placed onto the UK market will need to be UKCA marked and have been subject to Conformity Assessment by a UK Approved Body for Medical Devices.

UKCA Designation for Medical Devices is currently underway for Eurofins E&E CML Ltd UKAS No. 8175.

For more information, talk to our team or contact our UK Medical Device Certification Team via EEinfoUK@eurofins.com

Certification for the US & Canada

To access the United States (US) and Canadian markets, medical devices or equipment need to be certified to the specific requirements of those markets.

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 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).

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).

Testing of Medical Devices

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 standards, including particular and collateral standards:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020
- Risk Management files to ISO 14971
- EN/IEC 62304:2006+AMD1:2015 (Software life cycle processes)
- EN/IEC 62366-1:2015 (Usability of medical devices)
- 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/EN 61010-1:2010+A1:2019+AC:2019
- EN/IEC 61010-2-101 and UL/CAN CSA 22.2 No. 61010-2-101
- EN/IEC 62133:2012 safety testing of Lithium-Ion Batteries
- ANSI ISO 14708-3: 2017 for active implantable neurostimulators

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 60601-1-2:2015+A1:2020

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

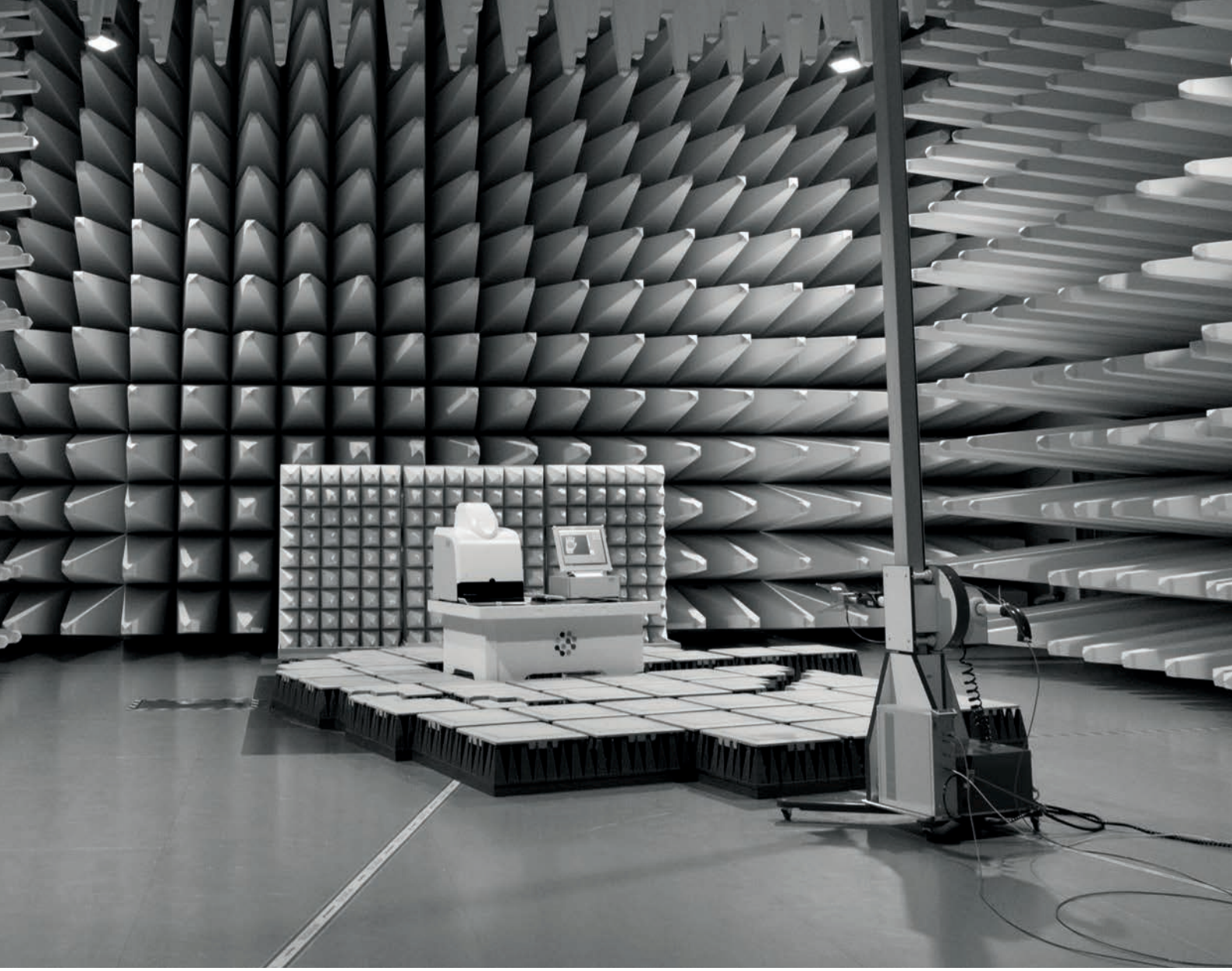
Cybersecurity Testing

- EU MDR Annex I
- MDR and IVDR requirements MDCG 2019-16
- IEC 81001-5-1
- IEC 62304

Other related testing services

- 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

1. 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



Quality Management Systems & Audits

ISO 13485 Quality Management System (QMS)

The global standard ISO 13485 stipulates the quality management requirements for regulatory purposes for all actors involved in the life cycle of medical devices (manufacturers, suppliers, distributors, etc.) and is the certified quality management system that is most broadly recognised in the medical sector.

Eurofins E&E has four 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
- UK
  Eurofins E&E CML Ltd UKAS No. 8175

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).

ISO 9001 Quality Management System (QMS)

In addition to the ISO 13485 services, Eurofins E&E can also offer certification to ISO 9001:2015.

Although ISO 13485 Certification is a real asset for most areas of Medical Device manufacturing, for companies with additional products or services that fall outside the scope of ISO 13485, a QMS certified to ISO 9001:2015 demonstrates a commitment to product quality.

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Due to the ever-changing international regulatory scenario, the information displayed on this flyer may be subject to changes should any of the regulatory authorities publish an update after the date of issue. Please check with our product experts or with the relevant authorities, prior to using these contents for your testing plan.

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