eurofins | Medical Device Testing

From our testing lab...

to the operating room.

It's where experience, quality and accuracy matter the most.

With a strategic focus on quality and personal service, we help our clients ensure the safety and efficacy of their products by delivering unparalleled testing services with complete, compliant and accurate data.

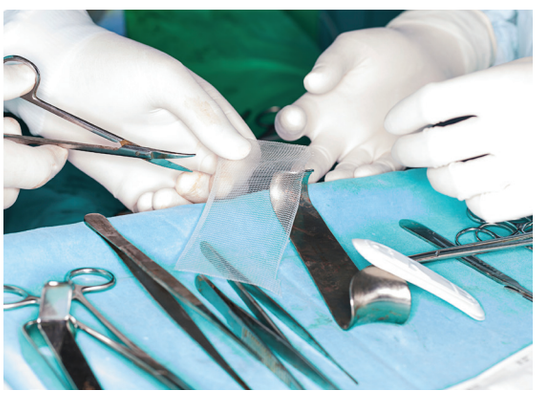
As a trusted partner for over 40 years, let our experience and global reach work for you.


!FRAGILE!
THIS CRATE CONTAINS DELICATE LABORATORY TEST EQUIPMENT AND ELECTRONIC INSTRUMENTS
DO NOT DROP, KEEP DRY & HANDLE WITH EXTREME CARE
Pack-Vac Leak Detector
HAUG

Proficiency

Thorough testing of your medical device and/or component can help to identify unforeseen challenges early in the development process, and ultimately avoid costly delays.

With more than 120 experienced PhDs specializing in chemistry, microbiology, toxicology, and bioengineering, you can rely on our extensive knowledge of analytical methods, regulatory requirements and scientific trends in the Medical Device industry to keep your product moving smoothly through the development pipeline.



Our experienced teams of more than 850 chemists, 160 microbiologists and 22 toxicologists worldwide deliver a comprehensive scope of testing services, including standardized testing, as well as customized test designs.

Chemical / Physical Analysis

- Extractables & Leachables
- Material & Product Stability
- Dissolution
- Raw Materials Purity
- Particle Characterization
- Residual Ethylene Oxide
- Mechanical Testing
- Method Development/ Validation

Microbiology & Sterility Testing

- Sterilization Validations
- Sterility
- Bioburden
- Endotoxins
- Antimicrobials / Infection Control
- Cleaning & Reprocessing Validations
- Microbial Identification

Biocompatibility Testing

- Chemical Characterization
- Toxicological Risk Assessment
- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Subacute / Subchronic / Chronic Toxicity
- Genotoxicity
- Implantation
- Hemocompatibility

Packaging Testing

- Sterile Barrier / Seal Integrity Testing
- Package & Transit Testing
- Shelf Life: Real Time & Accelerated Aging
- Label Durability

Combination Products

- Drug Release and Dissolution
- Chemical Compatibility
- Container & Closure Integrity
- Syringe Testing

Certification Services

- Notified Body Services
- NRTL & SCC
- CB Scheme
- Global Market Access
- ISO 13485

Electrical Medical Equipment

- Cyber Security
- Safety & Performance Testing

Precision

Accuracy in testing is paramount to ensuring product safety and efficacy. And fast turnaround times are critical to keeping your project on schedule.

With the highest level of instrument technology available in the industry, Eurofins Medical Device Testing utilizes the most state-of-the-art instrumentation to deliver accurate and timely test results, including:

Analytical Chemistry: Our chemistry laboratories are equipped with nearly 400 HPLCs and 100 GCs with more than 600 detectors to characterize the chemical constituents of materials used throughout the development process.

Microbiology: With more than 6,300 m^2 (68,000 ft^2) of microbiology lab space worldwide, we offer a full range of standard microbiology services, including six clean room suites for validations of terminal sterilization, as well as for validation of reprocessing procedures of reusables and environmental monitoring to support your clean manufacturing facilities.

Biocompatibility: We offer a variety of cell-based alternative *in-vitro* methods, including standard tests and tailor-made studies, under GLP, GMP and ISO 17025 to examine the hazardous effects of medical devices. In addition, our partner labs in the US and Europe support *in-vivo* testing in AAALAC-accredited vivariums with 60 animal rooms and dedicated supporting laboratory space, including necropsy rooms, surgical rooms, isolated cage wash areas and various sample preparation and procedure rooms, totaling 2,929 m^2 (31,500 ft^2).

Package Testing: Our new, state-of-the-art package testing facility is equipped to perform functional testing, material testing and aging/shelf-life primary, secondary and shipping configurations. Our engineers will help you evaluate every aspect of your packaging from sterile seal integrity through distribution and transit testing of full pallet-sized loads, and durability of your labels. We also have a wide range of material property testing equipment to ensure packaging materials perform consistently before and after sterilization.

Shelf-Life & Product Stability Testing: With more than 5,300 m^3 (187,000 ft^3) of stability space worldwide and a wide range of environmental chambers meeting ASTM/ISO/ICH conditions, we have the largest global capacity for accelerated and real-time aging studies.

Proximity

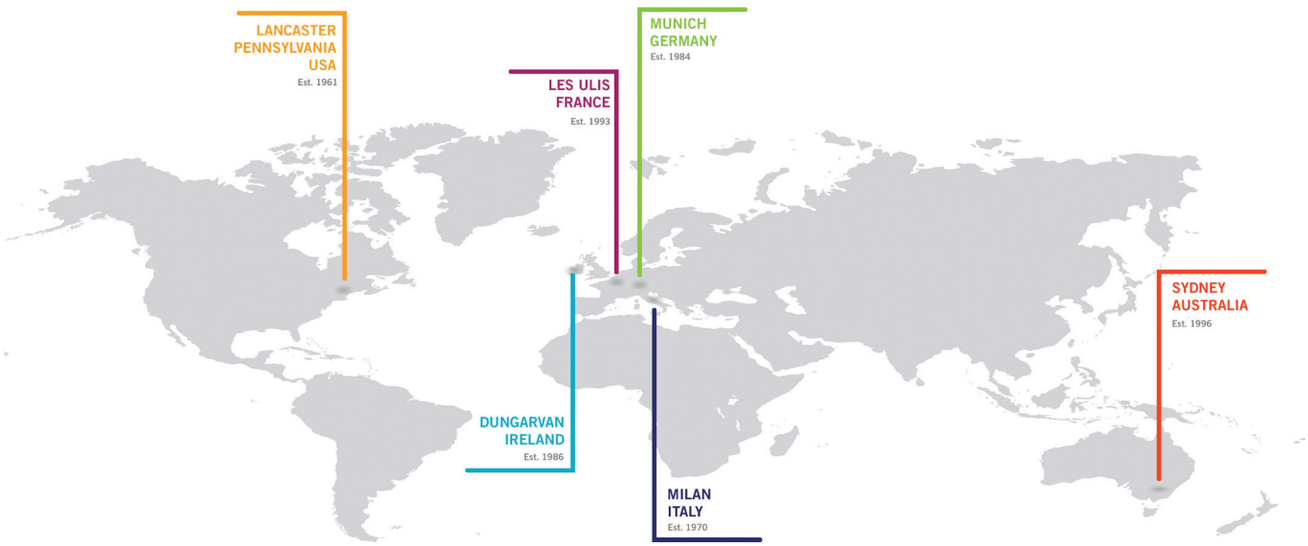
Partnering with the right laboratory to troubleshoot your product challenges fosters the ability to accelerate your global market approval.

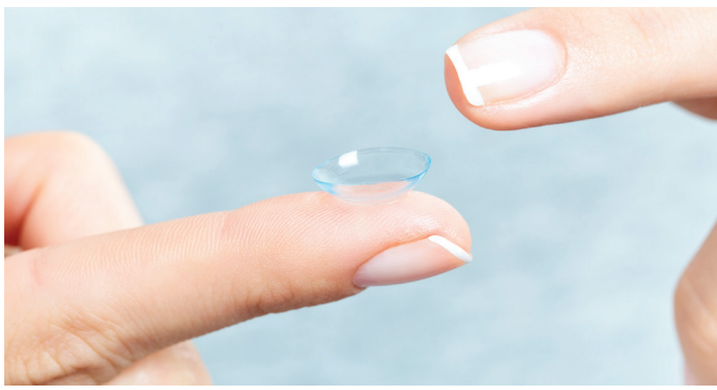
With testing and regulatory expertise across > 20 labs worldwide, Eurofins Medical Device Testing can help develop and execute your test plans, and navigate the regulatory pathway to market anywhere in the world while delivering a true local laboratory experience.

Our global presence ensures personal quality service backed by a unique breadth of harmonized capabilities to solve all of your testing challenges.

Our facilities maintain quality systems compliant with cGMP, GLP and ISO 17025, and conduct testing in accordance with ISO, ASTM, ANSI, ISTA, AAMI, AAALAC standards, as well as custom test methodologies to meet our customers' unique challenges.

A global network of more than 20 laboratories, including 6 flagship sites with a comprehensive offering and over 40 years of laboratory testing expertise.






INSTRON
100 N

eurofins | Medical Device Testing

Eurofins.com/Medical-Device | Medical-Device@Eurofins.com

Australia	Denmark	Germany	Netherlands	Switzerland
Belgium	Finland	Ireland	Spain	United Kingdom
China	France	Italy	Sweden	United States