eurofins

Medical Device Testing

Precision. Proficiency. Proximity.

These three simple words comprise the most important elements of our Medical Device testing services.


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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 68,000 square feet of microbiology lab space worldwide, we offer a full range of standard microbiology services, including validations for terminal sterilization, as well as for reprocessing of reusable devices and environmental monitoring to support your clean manufacturing facilities.

Biocompatibility - Our partner labs in the US and Europe operate AAALAC-accredited vivariums with 42 animal rooms and dedicated supporting laboratory space, including necropsy rooms, surgical rooms, isolated cage wash areas and various sample preparation and procedure rooms totaling 2,000 square meters (21,000 square feet).

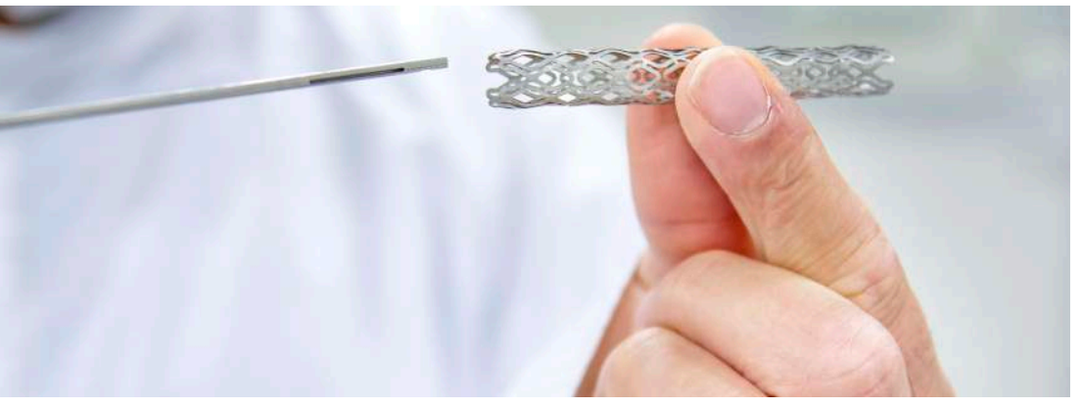
Package Testing: Package Testing: Our new, state-of-the-art package testing facility is equipped to perform functional testing, material testing and aging/stability of primary, secondary and shipping configurations. Our engineers will help you evaluate every aspect of your packaging from sterile seal 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.

Stability Testing & Storage - With more than 5,300 total cubic meters (187,000 cubic feet) of stability space worldwide and a wide range of stability chambers meeting ASTM/ISO/ICH conditions, we have the largest global capacity for accelerated and real-time stability and aging studies.

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:

Chemical / Physical Analysis

- Extractables & Leachables
- Material & Product Stability
- Dissolution
- Raw Materials Purity
- Particle Size Identification
- Residual Ethylene Oxide
- Uniaxial Mechanical Testing

Microbiology & Sterility Testing

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

Medical Electrical Equipment

- Electrical (ISO 60601)

Notified Body Services

- EC Certification

Biocompatibility Testing

- Chemical Characterization
- Toxicological Risk Assessment
- Cytotoxicity
- Hemocompatibility
- Genotoxicity
- Irritation
- Sensitization
- Toxicity

Packaging & Seal Integrity Testing

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

Combination Products

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

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 16 facilities in North America, Europe and Asia Pacific, 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 international presence ensures personal quality service backed by a unique global 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, AAMI standards, as well as custom test methodologies to meet our customers' unique challenges.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