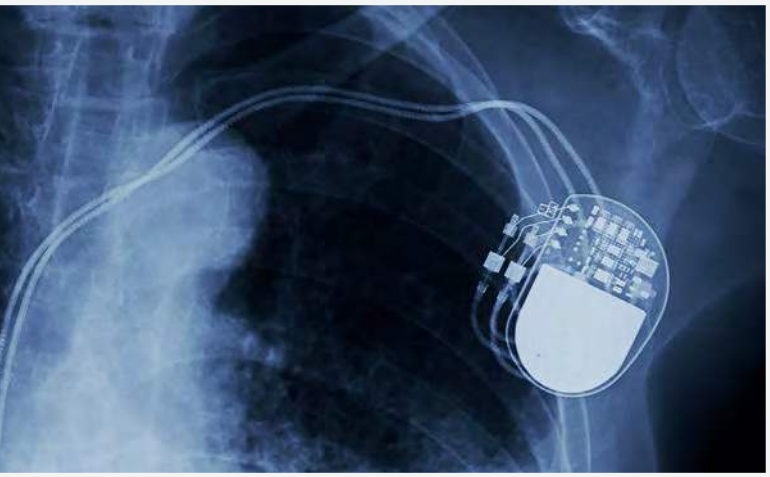
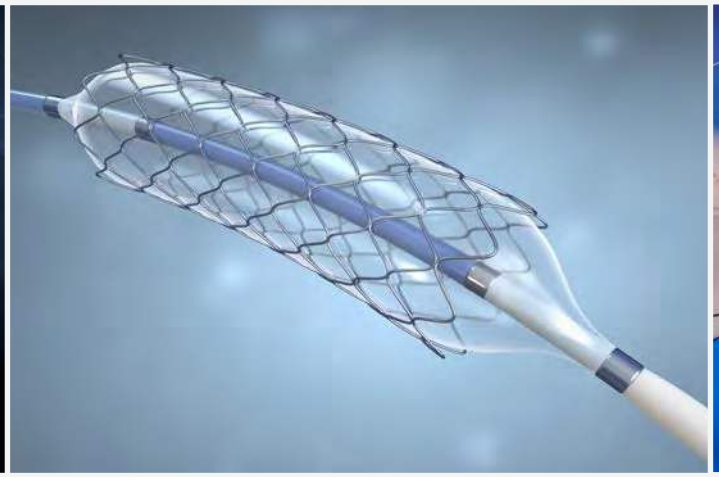
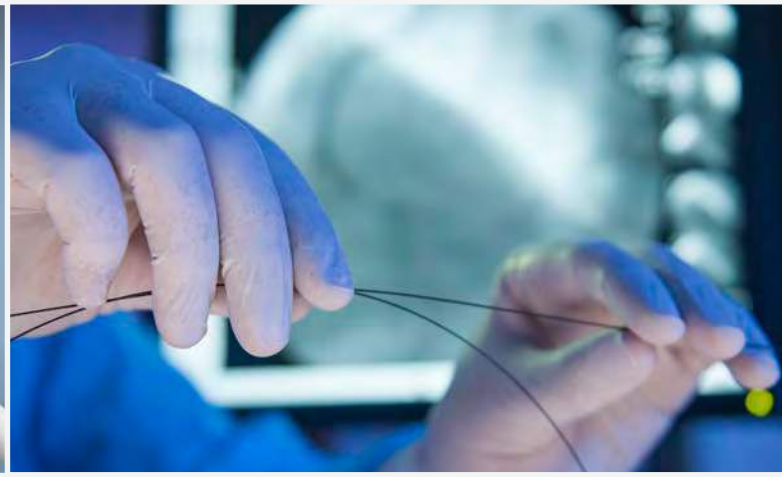
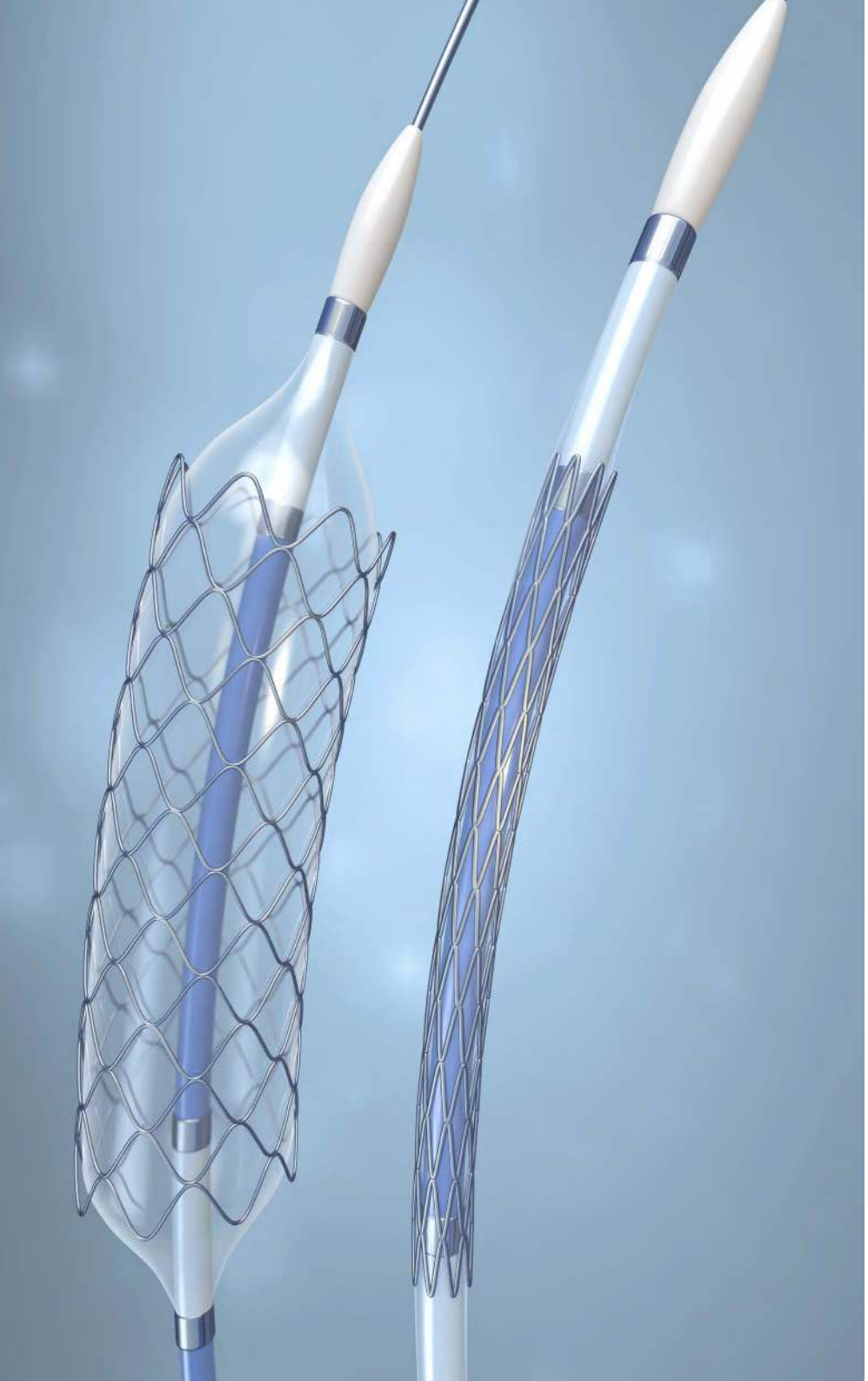




TESTING MEDICAL DEVICES FOR SAFETY, COMPLIANCE AND EFFECTIVENESS

eurofins | EAG Laboratories



Why Choose Eurofins EAG for Medical Device Characterization?

For medical device manufacturers, Eurofins EAG Laboratories offers unmatched capabilities and analytical expertise, a unique range of in-house techniques and instruments, and fast, flexible problem solving.

Our services may be applied to:

- Research and development: the testing of new concepts and material properties
- Process development: to test new processes, designs, and tools
- Production: to qualify incoming materials; monitoring quality control and assurance
- Process improvement: to monitor process changes and subsequent process performance
- Failure analysis: to investigate problems for contamination/defect analysis; to identify contaminant sources; for good/bad comparisons

Experience and Scientific Excellence

- Eurofins EAG has over 40 years of experience in medical device characterization. From a single analytical support partner, clients gain expertise in chemical characterization, surface analysis, and materials chemistry.

- Eurofins EAG offers scientific excellence with highly-educated staff. Our clients have direct access to our expertise in project design and technique selection. Through a consultative approach, these projects utilize the most appropriate techniques and clients get the right answers the first time.

Reliable Support and Shortest Industry Turnaround

- With a strong focus on communication and responsiveness, Eurofins EAG provides the shortest industry turnaround timelines. Clients also gain efficiency from our equipment redundancy and consultative approach.

Risk Mitigation

- Eurofins EAG reduces risk for device companies needing compliance support or facing safety challenges. All medical device characterization is performed at ISO 17025 certified laboratories. By utilizing Eurofins EAG's expertise in the composition of a device, clients confidently assess their product's safety and performance. For clients managing different supply chains, Eurofins EAG reduces risk by providing redundancy of equipment and analytical services from multiple global locations.

Expert Support for Every Stage of Your Medical Device Product

Concept and Research

- Raw Material Testing
- Trace Elemental Analysis
- Microscopic Structure (AFM, TEM, SEM)
- Metallurgical Analysis
- Polymer Chemistry
- Test Proof-of-Concept and Preliminary Performance

Prototype Design Development

- Materials Selection
- Surface Morphology
- Microscopic Structure (AFM, TEM, SEM)
- Analytical Method Development and Validation
- Corrosion Resistance
- Particulate Investigation

Design Verification and Validation

- Supplier Qualification and Selection
- Materials Characterization
- Extractables and Leachables Testing
- Analytical Method Development and Validation
- Surface Chemistry (XPS, Auger, etc.)
- Stability Testing and QC Release
- Reliability Testing

Regulatory Submission

- Extractables and Leachables Testing
- Evaluate Safety, Qualify Suppliers and Demonstrate Control of Manufacturing (ISO 10993-18)
- Evaluate compliance according to ISO 18562

Post Market Surveillance

- Lot Release Testing
- Impurity ID and Characterization
- Particulate Investigation
- Contaminant Identification
- Failure Analysis
- Surface Chemistry (XPS, Auger, etc.)
- Stability Testing and QC Release
- Material and Vendor Change (incl. ISO 10993-19)

Extractables & Leachables

Within the Eurofins network there is vast experience with the materials that go into medical devices to assist our clients in performing the necessary chemical characterization studies per ISO 10993-18 and the EU MDR. We can identify bioavailable chemicals released from a product through simulated use or exaggerated conditions.

- Part 18 testing program
  - Validated methods for use across a wide variety of materials/extractables
  - Driven by a protocol unique to each device
  - Performed using extractions based upon 10993-12 and using the Analytical Evaluation Threshold (AET) as a sensitivity target

- Extracts are analyzed by the following techniques
  - Non-volatile residues (NVR) with FTIR characterization
  - Volatiles and semi-volatiles by Headspace GC-MS and GC-MS
  - Metals by ICP-MS
  - Non-volatiles by LC-MS
  - Other techniques as required by our clients (Raman, IC-MS, HPLC-UV, Thermal Desorption, etc.)

- Our state-of-the-art Q-TOF LC-MS systems facilitate improved sensitivity and mass accuracy, which support achieving lower AETs and improved unknown ID

- We use a combination of internal and external mass spectral databases as well as a robust and rigorous science-based review to evaluate data and identify the compounds present. This process ensures that the assignments make sense and provide our clients with the best data so they can make informed decisions about their devices.

- With access to a wide range of polymer grades and disinfection and cleaning agents of global players, Eurofins EAG experts can carry out a pre-study to make a preselection of suitable solvents for ISO 10993-18 studies. This increases the success rate and improves turnaround times.

- Our Eurofins experts can also support toxicological evaluations.

Emissions and Leaching in Breathing Gas Pathways

ISO 18562 describes biocompatibility evaluation of breathing gas pathways of medical devices. Eurofins EAG provides expertise in the testing, identification, characterization, and data interpretation of emissions of particulate matter and volatile organic compounds from gas pathways, which are intended to provide respiratory care or deliver substances via the respiratory tract to a patient. In addition, substances leached by liquid water condensing into gas pathways of a medical device can be evaluated.

Emissions of particulate matter (ISO 18562-2):

- Particle counting, sizing, and morphology
- Particle isolation by filtration or impactor
- Chemical characterization of particles by means of SEM/EDX, FTIR, Raman and LC-MS

Emissions of Volatile Organic Compounds (VOCs) (ISO 18562-3):

- Measurement by GC-MS
- Determination of exposure dose to patient

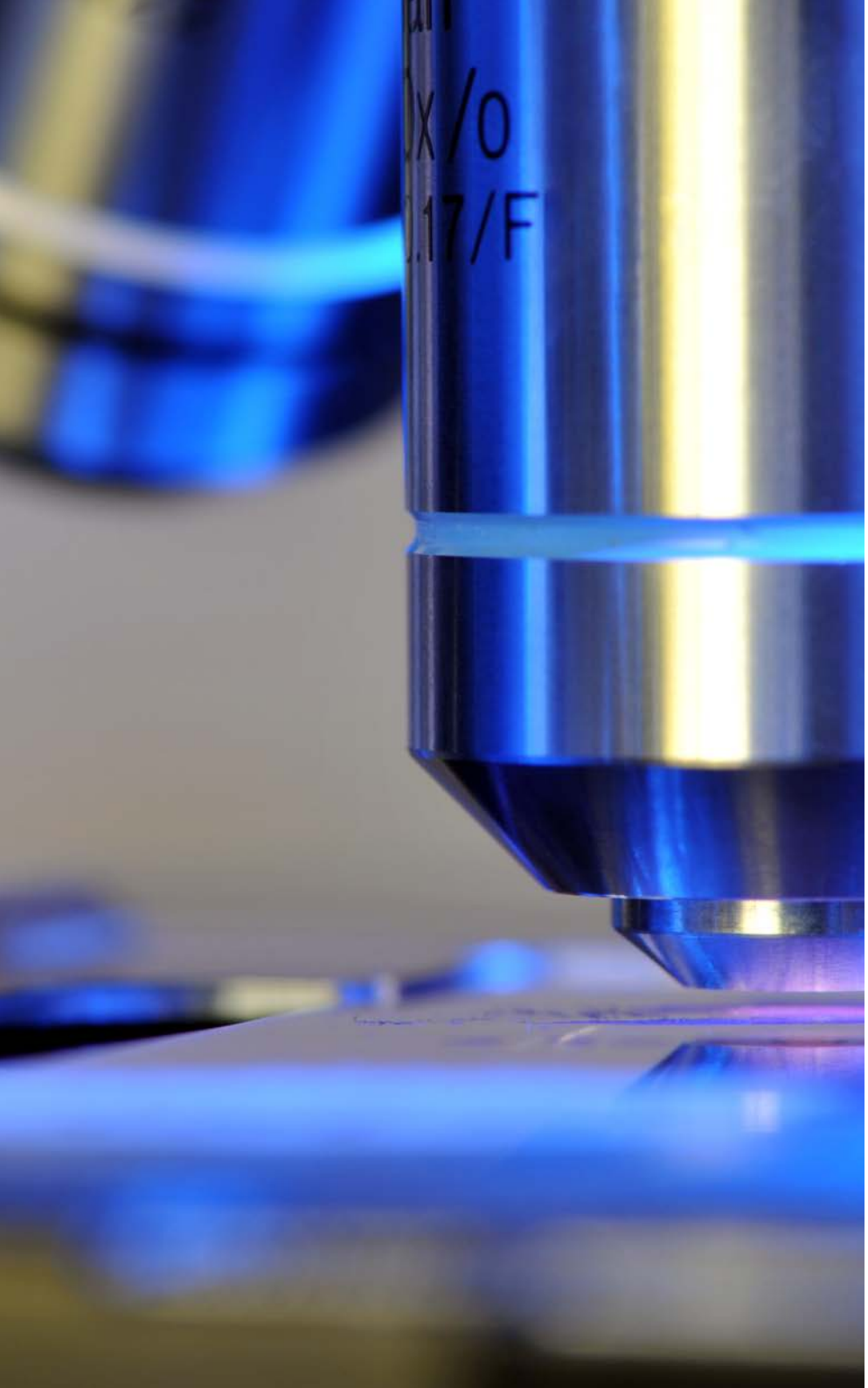
Leachables in condensate (ISO 18562-4):

- Measurement of metals in extract by ICP-MS and anions and cations by IC-MS
- Measurement of organic impurities in extract by GC-MS and LC-MS
- Determination of exposure dose to patient

Particulate & Particle Analysis

Eurofins EAG has developed expertise in identifying and characterizing particles of an unknown origin with individual and combined compositional analysis techniques in conjunction with expert data interpretation.

- ISO 7 clean room with an ISO 5 zone
- Sample filtration and particle isolation
- Particulate analysis per USP<788> and USP<789>
- Advanced Microscopy to optically characterize particles using various contrast methods (fluorescence, phase contrast, bright/dark field, interference contrast)
- Particle counting, sizing, and morphology
- Characterization of particles and bulk materials by SEM-EDX, FTIR, Raman and LC-MS
- EDS mapping to observe spatial orientation of elements
- 3D imaging to examine surface topography by optical profilometry



Medical Device Material Characterization

Eurofins EAG Laboratories uses over 30 different characterization methods to provide answers to our customers. As ISO 10993-19 continues to evolve, we have pioneered the utilization of these techniques.

Advanced Microscopy (FIB, SEM, TEM, SAM, X-Ray CT)

- Crystallographic and morphological properties
- Sub-monolayer analysis
- Failure analysis (defect, fatigue, fracture, wear, corrosion, adhesion and bonding)
- Surface modifications, changes and degradation

Surface and Thin film (XPS, TOF-SIMS, AFM, Profilometry, Ellipsometry, XRD, UV-VIS, FTIR, Raman)

- Surface characterization of organic and elemental materials
- Mapping distributions of surface species
- Identification of contaminants, stains, discolorations, and hazes
- Evaluation of cleaning processes
- Determination of oxidation state and oxide thickness of alloys and semiconductors
- Analysis of carbon (et al.) functionality of polymers and low k dielectrics
- Depth profile analysis to study composition in depth and near interfaces
- Surface roughness, resistance and topography
- Evaluate crystallinity of materials
- Failure analysis

Compositional Analysis and Material Identification (XRF, ICP-MS, GD-MS, GD-OES, FTIR)

- Determine the identity or source of a material
- Characterize a material from a potential competitor or vendor

Mechanical and Physical properties

- Examining damage in structure, microstructure, and morphology by fractography and X-Ray CT
- Tensile, compression, bend, impact, hardness testing
- Thermal properties (TGA, DSC, Emissivity)
- pH and conductivity
- Curing of materials (polymers, hydrogels, etc), hardness and modulus

Impurity investigation

- Isolation and characterization of visible contaminants by optical microscopy, FTIR and SEM-EDX
- In organic materials by GC-MS, HPLC and Q-TOF LC-MS
- In inorganic materials by ICP-OES, ICP-MS, GD-OES and GD-MS

Material Degradation and Reliability Testing

Eurofins EAG has experts in testing and predicting behavior during the complete lifecycle of a medical device and its interaction with the environment or various chemicals applied. Eurofins EAG supports clients with the design and execution of test plans to verify the expected lifetime of the device. By exposure to environmental stress (UV, heat, humidity, vibration, drop) component or design weaknesses and reliability issues can be assessed (including HALT and MEOST testing).

Cleaning Validations

Cleaning validation verifies that a process will consistently result in devices that meet a predetermined level of cleanliness. Our analysis focuses on the residue remaining on the devices including, chemicals or substances the cleaning step intended to remove, residue from the cleaning process (detergents, solvents, etc.), and other potential contamination residue. The test method may include target specific techniques (i.e. LC-MS, GC-MS and ICP-MS) and non-target specific techniques (i.e. UV-Vis, Conductivity, TOC).

Corrosion Testing

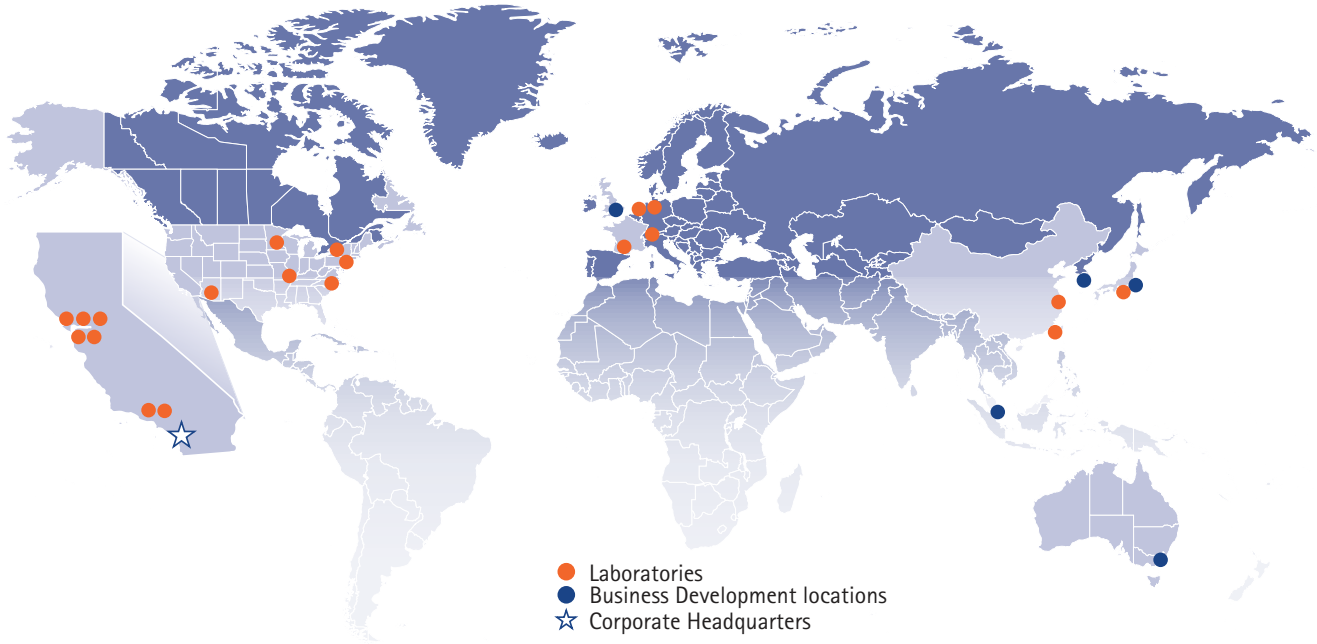
Corrosion testing provides critical insights throughout the medical device product lifecycle, from materials selection early in the design process to quality control and failure analysis. Eurofins EAG is equipped to evaluate the composition, microstructure, surface features and corrosion performance. Corrosion potential, corrosion rate and pitting susceptibility are also measurable. The standard approach of ASTM F2129 applies cyclic potentiodynamic polarization to small medical implant devices (stents, filters, endovascular grafts, cardiac occluders, etc.) in the final form and finish.

Electronics Testing

Our engineering support services for medical devices include failure analysis and electronic troubleshooting, fault localization and root cause determination. Electrostatic discharge (ESD) testing ensures that medical device chips will withstand events that may occur during handling and assembly.

Intellectual Property and Product Liability Support

Our scientists provide expertise, technical consulting, data interpretation, analytical support, and expert testimony in product liability, intellectual property, and other cases.



About Eurofins EAG Laboratories

When it comes to understanding the physical structure, performance, chemical properties and composition of materials, no other scientific services company offers the breadth of experience, diversity of analytical techniques or technical ingenuity of Eurofins EAG Laboratories. We don't just perform testing, we drive commercial success—through thoughtfully designed investigations, technically superior analyses, and expert interpretation of data.

We deliver multi-disciplinary, problem-solving expertise to help our customers accelerate innovation, ensure quality and safety, and protect intellectual property. Whether you are seeking to reduce time-to-market, solve manufacturing problems or ensure regulatory compliance, turn to Eurofins EAG. We know how to bring the power of science to every phase of your product lifecycle.

- 20+ facilities located in the US, Europe, and Asia
- 2,500+ instruments
- 600+ highly-educated employees
- Serving more than 4,000 clients worldwide
- Revenue sourced from more than 50 countries

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Complete Lifecycle of Services

- PRODUCT INNOVATION & IMPROVEMENT
- INVESTIGATION & TROUBLESHOOTING
- QUALITY ASSURANCE
- MANUFACTURING SUPPORT
- FAILURE ANALYSIS
- REGULATORY COMPLIANCE
- MANUFACTURING & SUPPLY CHAIN SUPPORT
- CONSULTING & LITIGATION

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