

Chemical Characterisation & Physical Analysis

We recognise the needs of our customers are as unique as the medical devices they produce. With a broad range of equipment, including over 500 chromatography systems, our highly trained chemists provide customers the opportunity to leverage our extensive analytical resources and expertise to develop customised testing programs, within a riskbased approach, for chemical characterisation of their products and materials.

Eurofins Medical Device Testing offers comprehensive chemical characterisation services according to ISO standards, including:

- Chemical Characterisation of Materials (ISO 10993-12, 18, 19)
- Identification and Quantification of Degradation Products (ISO 10993-13, 14, 15)
- Determination of Tolerable Intake for Extractable Substances (ISO 10993-17)
- Ethylene Oxide Sterilisation Residuals (ISO 10993-7)

Choose Eurofins Medical Device Testing to help you:

- Confirm the purity of raw materials
- Characterise the degradation and dissolution of resorbable polymer devices or bone ingrowth coatings
- Ensure the safety profiles of processing aids or additives used in plastic devices
- Assess the impacts of changes to raw material suppliers, processing techniques or sterilisation methods
- Ensure products are free of processing contaminants and residuals, such as machining oils and cutting fluids



Extractables & Leachables / Residuals Testing

Ensuring the safety of materials used in the construction of medical devices includes a critical assessment of the additives, colorants, and processing aids that are compounded into the resins or inadvertently incorporated during the manufacturing process. This also includes degradation products generated through harsh processing and sterilisation methods or through aging.

Our team of expert chemists utilise a vast array of analytical equipment and techniques to determine what compounds may leach from your products over time. Accelerated or simulated use extractions are followed by detailed identifications using our extensive database of known additives, or through analytical determination of breakdown or degradation profiles.



Shelf-Life and Product Stability Testing

With more than 180 chambers and nearly 5,300 m³ (187,000 ft³) of storage space across more than 20 locations, we offer the largest stability and storage facilities for Medical Device Testing worldwide. Our chambers are housed in secured areas, continuously monitored by our validated monitoring systems and supported by a fully-validated computerised stability laboratory information managements systems (LIMS) to manage and ensure proper execution of your studies.

We perform accelerated and real-time aging studies, along with coldchain testing, and environmental conditioning for package transit testing according to standard environmental specifications or custom temperature and humidity condition defined by our customers.

Dissolution Testing

We perform standard dissolution methods, as well as custom *in vitro* and *in vivo* models to support your specific needs for elution characterisation of combination products and medical devices.

Raw Materials Testing

Whether you need QC confirmation of incoming raw materials, qualification of new suppliers or investigations of a questionable batch of material, our team of chemists and polymer scientists can help assure you of the purity and composition of your raw materials. Our characterisation of resins, metals, elastomers and finished components include:

- Compendial Analysis
- Residual Solvents
- Elemental Analysis / Trace Metals
- Thermodynamic Properties
- Molecular Weight / Crosslinking / Crystallinity
- Partical Size Characterisation

Residual Ethylene Oxide Testing

As a complement to our sterility validation services, we offer residual ethylene oxide analyses per part 7 of ISO 10993. Through GC/FID, we will analyse for:

- Ethylene Oxide (EO)
- Ethylene Chlorohydrin (ECH)
- Ethylene Glycol (EG)

Mechanical Testing

Equipped with several mechanical test frames, our engineers and scientists can help you evaluate the functionality or mechanical integrity of your products or materials. Whether comparing different materials for a new component, or assessing the durability of a finished product design, we provide a range of static and low frequency dynamic tests, including:

- Syringe Testing
- Packaging Seals
- Part Design Functionality
- Standard Mechanical Characterisation (for uniaxial and torque) per ASTM, ISO, or custom methods

Testing Services

Biocompatibility & Toxicology • Cleaning & Reprocessing Validations
Chemical & Physical Analysis • Distribution & Package Integrity
Performance Testing • Human Factors & Usability • Microbiology &
Sterility Mechanical & Functionality • Viral Safety

Flexible Models

Fee For Service (FFS)
Full-Time-Equivalent (FTE)
PSS Insourcing Solutions®

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