

Biological Safety Assessment & Biocompatibility Testing

Choose Eurofins Medical Device Testing to help you:

- ✓ Evaluate the biocompatibility of your new device
- ✓ Assess the impact of a design change or new manufacturing process on your device's safety
- ✓ Evaluate new raw material suppliers
- ✓ Consider effects of sterilization techniques or long-term material stability
- ✓ Generate toxicology reports
- ✓ Review the biocompatibility evaluations for your international regulatory submissions
- ✓ Establish biological safety plans and conduct gap analysis of existing biocompatibility dossiers

Biological Safety Assessments

Eurofins Medical Device Testing has expertise in a wide range of products and manufacturing processes to help assess the risks of a new device design or process change, and develop an appropriate testing program for assessing the safety of your products.

From chemical characterization of degradation products and extractables and leachables testing, to toxicological risk assessments and biological evaluations, our veterinarians, chemists and toxicologists can facilitate the appropriate testing to best support your international regulatory submissions.

Chemical Characterization

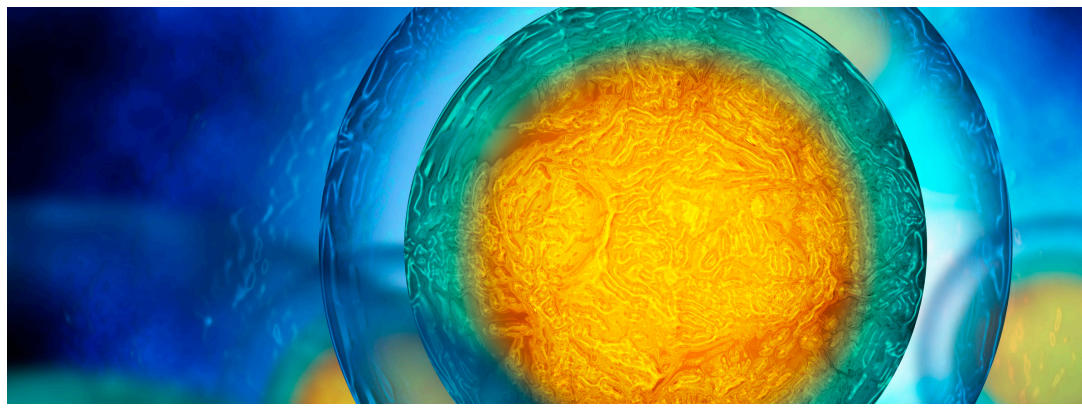
With more than 500 state-of-the-art chromatographic analyzers and 187,000 cubic feet of environmental chambers, operated by our global team of highly trained chemists and PhDs, Eurofins Medical Device Testing provides unparalleled capabilities for all your chemical characterization testing needs, including:

- Chemical Characterization 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)

Toxicology

Our Toxicologist perform risk and toxicological assessments, including Genetic Toxicology, Alternative Toxicology and Toxicological Risk Assessments to help understand the safety profile of medical devices. Based on ISO 10993-17, our methods will identify and evaluate any existing toxicity and human exposure risks for the final medical devices, as well as on individual chemical compounds, additives, colorants, processing aids and other potential leachables. Once identified, we use these profiles to determine additional analytical testing needs for further investigations of unknown entities.





Biocompatibility Testing

Eurofins Medical Device Testing offers the full range of Biocompatibility Testing required by the medical device industry. In addition to conducting biological studies according to the matrix of ISO 10993-1, MHLW requirements, USP classification of plastics, including Class VI and other international guidelines, we have established a variety of cell-based alternative methods or models under GLP to examine the hazardous effects of medical devices. The suitable customized test strategy design is chosen depending on the material of the product, manufacturing methods and the aim of the study.

Our services include standard testing methods and tailor-made studies, as well as alternative, *in vitro* testing methods or comprehensive histopathological services, including:

Cytotoxicity

- Growth Inhibition
- Direct Cell Contact
- Agar Diffusion Test
- Colony Forming Assay

Hemocompatibility

- Dynamic Test Designs
- Chandler-Loop Design
- Agitation Model
- Static Test Designs
- Haemolysis
- Platelet Count
- Thrombogenicity
- Complement Activation

Genotoxicity

- Bacterial Mutation - Ames Mutagenicity
- Mammalian Mutation Assay: Mouse Lymphoma Assay
- Micronucleus Assay (Chinese Hamster Cell)
- Micronucleus Assay (Human Lymphocyte)
- Chromosome Aberration Test (Chinese Hamster Cell)
- Chromosome Aberration Test (Human Lymphocyte)

Irritation

- Dermal Irritation
- Intracutaneous Irritation
- Ocular Irritation
- Oral Mucosa Irritation Test
- Penile Irritation Test
- Rectal Irritation Test
- Vaginal Irritation Test

Sensitization

- Maximization Test (Magnusson & Kligman)
- Closed Patch Test (Buehler)
- Local Lymph Node Assay (LLNA)

Toxicity

- Single Dose Toxicity
- Repeated Dose Toxicity (Subacute, Subchronic and Chronic)
- Reproductive Toxicity
- Inhalation Toxicity
- Carcinogenicity

In vivo testing is performed by our partner labs.



Medical Device
Testing

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