

# Consulting, Testing & Sterile Packaging

## Consulting Services

**Guiding you through complexity with confidence**

Bringing a medical device to market isn't just about innovation — it's about navigating a complex landscape of regulations, audits, and clinical risks. Whether you're preparing for your first submission or managing post-marketing surveillance, you need a partner who anticipates challenges, bridges knowledge gaps, and keeps your product moving — safely and successfully.

Eurofins Medical Device Services (MDS) combines deep regulatory insight, technical rigour, and a collaborative mindset to support your product through every phase of its lifecycle. Our consulting teams bring years of hands-on experience across device classifications and global markets, helping manufacturers align with evolving markets — without losing momentum.

We provide a custom-made service throughout the entire lifecycle of your product.

- At design validation, we define project plans and manage Verification & Validation (V&V) protocols, execution, and reporting for robust regulatory submissions.
- For technical documentation, we prepare and maintain comprehensive dossiers and quality systems to meet expectations before and after submission.
- Usability and risk analysis are integrated into a broader risk management strategy, ensuring risks from design, use error & ergonomics are well understood & mitigated.
- In the pre-clinical phase, we advise on optimising your testing strategy, including chemical characterisation, biocompatibility, toxicological assessments, and absorption profiling.
- Our clinical evaluation support includes tailored Clinical Evaluation Plans & Reports, presenting your evidence & strategy clearly for regulatory authorities.



- Post-approval, we provide QA/RA support, including system maintenance and audit readiness, keeping your device compliant.

Our services at a glance:

- Strategic & Regulatory Consulting
- Regulatory Submission
- Risk & Gap Assessment
- Biocompatibility
- Preclinical Safety & Clinical Evaluation
- Post-Marketing Surveillance
- Quality Management System
- Software as a medical Device
- Trainings

## Why choose Eurofins Medical Device Consulting?

### • EU-based, globally connected

With a strong foundation in the European regulatory landscape, we support innovators worldwide in navigating diverse market requirements.

### • Real-time submission experience

Our consultants have hands-on expertise with active submissions across MDR, IVDR, FDA, and other global frameworks — bringing practical insights to every project.

### • Integrated consulting approach

We combine strategic foresight, technical depth, and operational know-how to guide your product from concept to compliance — efficiently and confidently.



## Testing Services

### Full-Service Testing for Class I, II, and III Devices

Navigating the medical device regulatory landscape is complex, especially when safety, compliance, and speed to market are on the line. Knowing what will be tested, how long it will take, and just what the regulatory requirements are for each type of device demands special expertise. Whether you're developing a Class I, Class II, or Class III device, test strategies must be robust, precise, and aligned with global standards.

The Eurofins Medical Device Services network of laboratories will verify and validate your product designs, confirm biocompatibility and efficacy, and ensure regulatory readiness. We support developers at every stage – from concept design through to commercialisation – with testing solutions that can be customised to fit each device's class, complexity, and intended use.

For more than 40 years, our scientists and engineers have worked alongside product and device developers of all sizes throughout the world, providing regulatory guidance and executing test plans designed to withstand scrutiny from global regulators.

Our medical device testing facilities are spread over more than 20 sites across Europe, North America and Asia Pacific, and are equipped with leading instrumentation, rapid capacity, and deep scientific expertise in core categories including:

- Accelerated and Real-Time Aging
- Biological Safety and Biocompatibility (ISO 10993 series)
- Chemical and Physical Characterisation
- Combination Product Testing
- Mechanical and Functionality Testing
- Microbiology and Sterility (bioburden, endotoxins, validation)
- Packaging and Seal Integrity (ISO 11607)
- Toxicological Risk Assessment and Cytotoxicity Testing
- Viral Clearance
- Human Factors

### Why choose Eurofins Medical Device Testing?

- **Global expertise, local execution**

With a worldwide network of specialised laboratories, we deliver precise, compliant testing solutions tailored to your device class and market needs.

- **Decades of regulatory insight**

For over 40 years, our scientists and engineers have supported device developers with test plans built to meet the scrutiny of global regulators.

- **Comprehensive, class-specific testing**

From Class I to Class III devices, we offer full-service testing across biological safety, sterility, packaging, and performance, ensuring your product is safe, effective, and market-ready.



Our services include product packaging, cleaning, assembly and engineering, plus sterilisation through our in-house EO sterilisation plant — all of which are fully compliant. In addition, we offer all associated validations and documentation. By consolidating all of these services under one roof, we streamline your supply chain, minimise vendor-related risks, and accelerate your route to market. Our teams ensure full material traceability and remain on-hand to advise you as requirements evolve across global markets. At Eurofins MDS, we help you protect more than your product. We protect your reputation, your compliance status, and your path to market.

Our Sterile Packaging Services include:

- Packaging Design & Manufacturing
- Assembly
- Cleaning
- Packaging
- Sterilisation
- Validations & Documentation
- Procurement Management

## Sterile Packaging Services

### Protecting product integrity

When packaging is the final barrier protecting the sterility, integrity, and performance of your medical device, nothing can be left to chance. It's vital to understand the challenges of regulatory compliance, cost control, and maintaining patient and product safety—particularly when sterile barrier systems must be customised for novel technologies. Add the pressure of material traceability and an increasingly complex supply chain, and it becomes clear: precision, reliability, and speed are essential.

The Eurofins Medical Device Services (MDS) network of laboratories is built to support you at every stage of the sterile packaging process. From concept to commercialisation, our scientists work closely with your teams to deliver fully compliant packaging systems, optimised for both performance and cost-efficiency.

### Why choose Eurofins Sterile Packaging?

- **Tailored, compliant & dependable sterile solutions**

Sterile packaging is the final barrier safeguarding the integrity, sterility, and performance of your medical device. With increasing regulatory demands, complex supply chains, and the need for customised barrier systems, precision and reliability are essential.

- **End-to-end packaging expertise**

Our sites offer fully compliant sterile packaging solutions — including cleaning, assembly, packaging, and sterilisation — all optimised for performance and cost-efficiency.

- **Streamlined, risk-reduced supply chain**

By consolidating services under one roof, we reduce vendor risks, ensure full material traceability, and accelerate your route to market, while maintaining patient and product safety.

#### 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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