eurofins | Medical Device Testing

Microbiology & Sterility Testing

Choose Eurofins Medical Device Testing to help you:

- ✓ Validate the sterilization of your terminally sterilized devices
- ✓ Conduct routine sterility testing for batch release testing or quarterly dose audits
- ✓ Validate cleaning and reprocessing procedures for reusable devices and instruments
- ✓ Evaluate water quality and/or environmental monitoring for your clean room operations
- ✓ Conduct routine endotoxin, bioburden and microbial identification
- ✓ Assess the effectiveness of your antimicrobial device

Microbiology & Sterility Testing

With 10 microbiology laboratories and six cleanroom sterility suites operating on three continents, Eurofins Medical Device Testing is positioned to respond rapidly to your microbiological testing needs. Our highly experienced team will provide guidance and direction to ensure your product development testing and sterilization validations are ready for international regulatory submissions. We will also provide the capacity and rapid turnaround needed to support ongoing quality and product release testing, including environmental monitoring of your clean room operations.

Whether we are providing standardized testing or a tailor-made study to fulfill special requirements, we will work with you to identify the most appropriate test procedure for each device, according to its specific characteristics and international regulatory requirements. We can also help to create individual testing strategies as requested for new biomaterials and manufacturing methods.

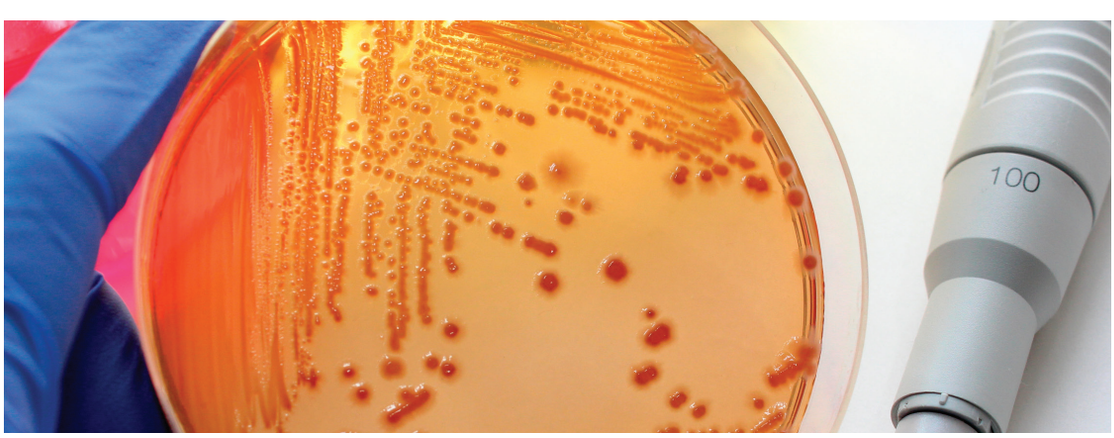
Our deep knowledge of the current guidelines (ISO, EN, pharmacopeia, AAMI, ANSI, ASTM, etc.) and regular participation in international working groups and congresses keep our scientists up-to-date with current trends and regulatory issues to deliver comprehensive microbiology services to the medical device industry, including:

Bioburden

- Aerobic/Anaerobic Bacteria, Yeasts and Molds
- Identification of Microorganisms (Bacteria and Fungi)
- Characterization and Validation of the Method for Bioburden
- Gram Stain

Pyrogen & Endotoxin Testing

- LAL Test (Kinetic Chromogenic, Kinetic Turbidimetric and Gel Clot)
- Pyrogen



Sterility Tests

- Sterility Validation [Method Suitability (Bacteriostasis/Fungistasis) Testing]
- Production Lot Release Testing

Sterilization Verification

- Ethylene Oxide, Gamma Radiation, E-beam, Dry Heat, Moist Heat, etc.
- Process Validation using Bio-indicators (Eto, Dry Heat) or through Bioburden and Sterility Testing (Irradiation)

Analysis of Bioindicators

Identification of Microorganisms

With a proprietary database containing more than 8,450 validated sequences, we perform:

- Sequencing of DNA for Bacteria - using long sequencing to amplify more than 1,350 base pairs of the 16S rRNA gene
- Sequencing of DNA for Fungi - using PCR to amplify the first 500 base pairs of the 28S gene for fungal identifications

Environmental Monitoring

- Establishing the Monitoring and Sampling Plan
- Sampling
- Particle Counting
- Viable Air Contamination
- Microbial Contamination of Personnel and Surfaces
- Identification of Microorganisms (Microbes and Fungi)

Water Production Analysis

- Microbiological Control
- Specific Pathogens
- LAL Test - Endotoxins
- TOC Analysis, Heavy Metals, Conductivity, Nitrates, Aluminum

Antimicrobial Effectiveness Test

- Bactericidal/Bacteriostatic Activity of Surfaces and Materials

Evaluation of the Cleaning, Disinfection and Sterilization of Reusable Devices

- Manual Cleaning / Manual Disinfection
- Manual Cleaning / Automatic Disinfection
- Validation of Sterilization Processes

eurofins | Medical Device Testing

Eurofins.com/Medical-Device | Medical-Device@Eurofins.com

Australia	France	Italy	Sweden
Belgium	Germany	Netherlands	Switzerland
Denmark	Ireland	Spain	U.S.

10002 0323