eurofins | Medical Device Testing



Reprocessing Validations

The importance of ensuring your products and instruments are clean and sterile every time they come into contact with a patient or end user cannot be overstated. The burden of responsibility falls on the manufacturers of finished medical devices to provide clear, understandable and reproducible cleaning and sterilization protocols that have been validated to be effective.

With more than 30 years of experience in this field, Eurofins Medical Device Testing network of laboratories offers a broad range of microbiological, bio-/chemical and toxicological testing to examine products for the intended reprocessing procedures according to AAMI ST 12, AAMI ST98, ISO 17664-1 and ISO 17664-2 to validate procedures for manual and automated cleaning, disinfection and sterilization.

Choose Eurofins Medical Device Testing to help you:

- Evaluate the effectiveness of your cleaning, disinfecting and sterilization protocols
- Select the most appropriate test soil or organism to simulate practical use
- Identify inoculation sites on your instruments which represent worst case challenges (Consulting Service)
- Optimize your Instructions for Use (Consulting Service)
- Complete your regulatory dossiers with proven validation reports (Consulting Service)

Testing Available

- Simulated Use Cycles
- Manual Cleaning
- Automated Cleaning
- Chemical Disinfection
  - Low Level Disinfection
  - Intermediate Level Disinfection
  - High Level Disinfection
- Thermal Disinfection
  - Manual Thermal Disinfection
  - Automated Thermal Disinfection

- Sterilization
  - Dynamic Air Removal
  - Gravity Displacement
- Analysis of Chemical Residual
- Analytes
  - Visual Evaluation
  - Protein
  - Hemoglobin
  - Total Organic Carbon (TOC)
  - Cytotoxicity

Instrumentation

- Shakers
- Ultrasound Baths
- Washer Disinfectors
- Moist Heat Sterilizers
- TOC Analyzers
- Microplate Readers