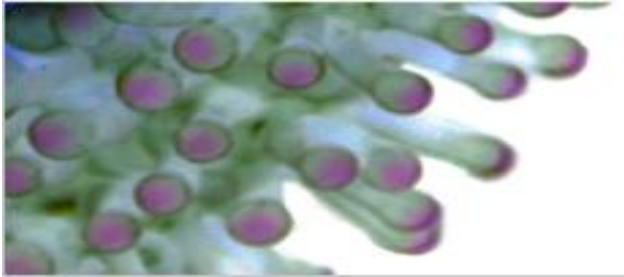


Reaching the market in time

A global approach on medical devices safety and functional tests



Safety and Functional Testing of Medical Devices*



Biocompatibility Testing

- Cytotoxicity
- Sensitization
- Irritation
- Systemic Toxicity
- Subchronic Toxicity
- Genotoxicity
- Pyrogenicity
- Implantation
- Haemocompatibility
- Chronic Toxicity

Gemar is an independent Medical Device Consulting firm, operating worldwide with extensive Regulatory Compliance Experience.

Global Medical Device Registration and Medical Device Approval

Gemar - Your US Agent and Correspondent

Gemar - Your European Authorized Representative (EAR)



Microbiological Testing

- Sterility Test Validation and Routine Testing
- Endotoxins tests
- Bio-burden validation and routine monitoring testing
- Test for Specified Microorganisms/ Microbial Limit Test
- Test for Antimicrobial Preservation
- Validation of Test Methods/Suitability Tests
- Identification of Microorganisms
- Test for Antimicrobial Efficacy
- Evaluation of Reusables for the intended Reprocessing Procedure (Cleaning, Disinfection, Sterilization)
- Environmental Monitoring
- Process Water Testing
- Analysis of Bio-indicators
- Sterilization Processes: Microbiological Studies within Performance Qualification
- Validation of ETO sterilization, irradiation, steam, plasma sterilization Processes
- Validation of Depyrogenation Processes
- Identification of Microorganisms

Functional Testing

- Electrical Safety testing (IEC 60601)
- Tests Design according to ISO or national standards,
- Tests Design according to USP and Ph. Eur.

Additional Services

- Functional Implantation studies (ISO 10993-6)
- Identification and quantification of degradation products (ISO 10993-15)
- Packaging validation (ISO 11607)
- EO residue determination (ISO 10993-7)
- Ophthalmic Implants -Intraocular lenses (ISO 11979-5)
- USP Plastic Class I-VI (USP 87, 88)
- Various Test Designs according to ISO standards, USP and Ph. Eur.
- Transport stability studies
- Quality Controls of Raw Materials According to Official Standard Methods
- Heavy Metals and Phthalates
- Shelf Life/Accelerated Aging Studies
- Particles and microbiological Environmental controls

*partnered service

