

QACS LAB

QUALITY ASSURANCE & CONTROL SYSTEMS

The Challenge Test Laboratory



MEDICAL DEVICES TESTING

Medical Devices should be safe to use
& not pose health risks

Plan | Evaluate | Report

BIOCOMPATIBILITY SERVICES

BIOCOMPATIBILITY EVALUATION (ISO 10993)

- ◆ Cytotoxicity
- ◆ Sensitization
- ◆ Irritation (i.e., Dermal, Ocular, Vaginal)
- ◆ Inhalation test (EpiAirway)
- ◆ Phototoxicity
- ◆ Genotoxicity
- ◆ Chronic and sub-chronic studies

CHEMICAL CHARACTERIZATION (ISO 10993)

- ◆ Chemical characterization of materials
- ◆ Ethylene oxide sterilization residuals
- ◆ Extractables & Leachables

MICROBIAL CHARACTERIZATION

- ◆ Characterization of Sterility
- ◆ Microbial identification
- ◆ Environmental Monitoring with NGS

PACKAGING EVALUATION (ISO 11607)

- ◆ Aging studies
- ◆ Physical properties
- ◆ Mechanical properties

STABILITY (ASTM F1980)

- ◆ Real-time
- ◆ Accelerated aging



REGULATORY SERVICES

BIOLOGICAL EVALUATION PLAN

TOXICOLOGICAL RISK ASSESSMENT

- ◆ Toxicological Risk Assessment of individual components
- ◆ Determination of Tolerable Intake for Extractable Substances

BIOLOGICAL EVALUATION REPORT

- ◆ Risk Analysis, Assessment & Management

EQUIVALENCY ASSESSMENT

CLINICAL EVALUATION REPORT

LABEL REVIEW

INSTRUCTIONS FOR USE (IFU) REVIEW

CLASSIFICATION OF MEDICAL DEVICES



QACSLAB

QUALITY ASSURANCE & CONTROL SYSTEMS

At QACS Lab, we provide accurate and reliable Biocompatibility, Microbiological, Chemical and Packaging testing, along with regulatory solutions to businesses worldwide.

Laboratory testing services are conducted in cutting-edge facilities & equipment, to assist you with Product Safety, Quality Control, Regulatory Compliance & Performance Testing.

Our comprehensive range of accredited solutions makes QACS, the Challenge Test Lab, your ideal testing partner.



ONE
STOP SHOP



100+
SCIENTISTS



24H
EU PICK UP



WORLDWIDE
TESTING



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