We deliver nonclinical testing solutions for medical devices

Nonclinical testing evaluates factors outside of a clinical setting that can affect device accuracy and impact patient safety.

At UL Solutions, we provide testing solutions in areas such as transportation, storage, biocompatibility, microbiology and sterilization to help our clients ensure their healthcare products meet state-of the-art requirements and are compliant to applicable standards before they are introduced into a clinical setting.

We provide testing services for your technical documentation submissions for regulatory approvals.

What makes UL Solutions different?

- We are a strong team of professionals in diversified domains building on our 25 years of expertise in non-clinical medical device testing.
- We have experience working with multiple of regulatory bodies worldwide.
- Our senior toxicologists are American board-certified.
- Our scientists participate in developing the standards related to ISO 10993 and ISO 18562.
- We have a presence in more than 100 countries.

UL Solutions

Testing

Biocompatibility testing and evaluation of medical devices

- ISO 10993 Series, additional tests on request
- ISO 10993-1, biological evaluation of medical devices (BEP, TRA, BER)
- ISO 10993-5, Test for in vitro cytotoxicity
- ISO 10993-17, Toxicological risk assessment (TRA) of medical device constituents
- ISO 10993-18, Chemical characterization of medical device materials
- ISO 18562 VOC, particles and leachables in breathing gas pathways

Reprocessing of reusable medical devices

- ISO 17664, Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices (Parts 1 and 2)
- FDA Guidance on Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
- AAMI TIR30, A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- ISO 17665-1, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

Process control and validation-related testing

- ISO 11607, Packaging for terminally sterilized medical devices (Part 1 and Part 2)
- ISO 11737, Sterilization of health care products — Microbiological methods (Part 1 Bioburden and Part 2 Test of sterility)
- ANSI/AAMI ST72, PhEur, USP & FD Guidance - Bacterial Endotoxin Testing (BET)
- USP<788>, Ph.Eur chapter 2.9.19 & 2.9.20 - Particle Determination

Learn more at UL.com/Solutions.

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Safety. Science. Transformation.™

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