



# Healthcare and Life Sciences

Supporting confidence  
through experience



Safety. Science. Transformation.™



**Striving for a more  
interconnected,  
patient-centric world**

UL Solutions offers manufacturers of medical devices and health and wellness products guidance to navigate a complex regulatory environment and meet critical patient needs.





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## Product performance and safety testing

# Medical electrical devices and laboratory equipment safety

The growing complexity of medical devices requires more advanced testing and certification to evaluate safety, performance and compliance to regulatory requirements. By developing a comprehensive testing strategy, manufacturers of medical devices and laboratory equipment can streamline testing and certification, save time and simplify compliance.

To help patients, healthcare products and equipment need to demonstrate safety and effectiveness. Regulators update requirements frequently as the healthcare industry adapts to connected and evolving technologies. Safety testing helps medical and laboratory equipment manufacturers stay up to date with complex and evolving standards, regulations and directives.

Electromagnetic incompatibility for healthcare products is prevalent and potentially life-threatening. Products may not be safe or effective if they are not compatible with their intended environment. Electromagnetic compatibility (EMC) testing evaluates the potential interference between nearby products and the risk of injury or damage to persons or surroundings. These tests also determine compatibility between devices within their intended electromagnetic environment.

UL Solutions offers safety and compliance testing to solve these challenges. Our engineers stay current on global regulations and can provide product evaluations and tests such as electrical safety, performance and electromagnetic compatibility.

### Applicable services include testing to:

- IEC/AAMI 60601, Medical Electrical Equipment – General Requirements for Basic Safety and Performance
- IEC 60601-1-2, Electromagnetic compatibility (EMC), Wireless testing, coexistence
- IEC 61010, Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use



- IEC 61326-1, Electrical equipment for measurement, control and laboratory use - EMC requirements – Part 1: General requirements
- IEC 61326-2-6, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment
- UL 1069, the Standard for Hospital Signaling and Nurse Call Equipment
- UL 2560, the Standard for Emergency Call Systems for Assisted Living and Independent Living Facilities
- UL 1431, the Standard for Personal Hygiene and Health Care Appliances

## U.S. Food and Drug Administration (FDA) ASCA Pilot program

The U.S. Food and Drug Administration (FDA) designed its voluntary Accreditation Scheme for Conformity Assessment (ASCA) Pilot program to improve the premarket process. This program was created to increase FDA product reviewers' and device manufacturers' confidence in medical device testing when performed by an ASCA-accredited laboratory and help reduce the need for additional testing or information during the premarket review process.

As an FDA ASCA-accredited testing laboratory, UL Solutions offers manufacturers safety and performance testing required for participation in the Pilot program. Our healthcare experts have a deep understanding of the industry and offer comprehensive testing and certification services throughout the entire production life cycle. With testing services conducted in our laboratories across the U.S., Europe and Asia, we can help you take advantage of this program and build confidence in the process. When using UL Solutions to perform testing, you can reference this testing in your declaration of conformity (DOC).

## Overcome software, usability and connectivity challenges

As healthcare technology evolves, medical devices are deployed for use in an increasingly patient-centric and connected environment, such as healthcare monitoring devices for remote patient monitoring and robotic surgery for a less invasive process to promote faster healing for patients. Manufacturers need to be proactive and tackle key challenges around software quality, usability, interoperability and cybersecurity.

Software is commonly used within medical devices, but what are the impacts of relying on software for basic safety and essential performance? In response to the complexity of software, regulators have developed standards such as IEC 62304 that defines the life cycle requirements for medical device software, providing processes, activities and tasks to help ensure safety.

Usability engineering is a high priority in the medical device industry. Devices that lack an intuitive design and fail to take into account the user-device interaction can jeopardize patient and user safety. The international Standard IEC 62366-1 covers the application of usability engineering to medical devices. This standard helps medical device manufacturers consider human factors by offering a standardized process for analyzing, specifying, developing and evaluating the usability of their medical device.

A number of challenges prevent the healthcare community from realizing the full potential of device interoperability. These challenges include technical issues, systems engineering issues and security challenges. UL Solutions possesses expertise and experience to help manufacturers implement secure medical device interoperability.





The UL Solutions Cybersecurity Assurance Program (UL Solutions CAP) for Network Connectable Components of Healthcare and Wellness Systems helps validate that product and systems offer a reasonable level of protection against risks that may result in unintended or unauthorized access, change or disruption.

**Applicable services include testing to:**

- IEC 62304, the Standard for Medical Device Software – Software Life Cycle Processes
- IEC 60601-1-6, the Standard for Medical Electrical Equipment – Part 1-6: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Usability
- IEC 62366-1, the Standard for Medical Devices – Part 1: Application Of Usability Engineering To Medical Devices
- ANSI/CAN/UL 2900-1, the Standard for Software Cybersecurity for Network-Connectable Products, Part 1: General Requirements
- ANSI/CAN/UL 2900-2-1, the Standard for Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems
- ANSI/AAMI/UL 2800-1, the Standard for Software Cybersecurity for Network-Connectable Products, Part 2-1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems

## Personal health, wellness and hygiene consumer products

In 2021, McKinsey estimated the size of the global wellness market at more than \$1.5 trillion (USD). This boom has spurred health and wellness technology manufacturers to introduce consumer devices such as wearables for personal hygiene and health/wellness monitoring. These innovative products may contain features such as an electrocardiogram (ECG), blood pressure and blood glucose monitoring that cross into regulated medical device categories.

Regulators define regulated medical devices and general wellness products differently, and regulatory requirements vary significantly across different markets. Manufacturers must comply with these requirements in order to sell their products in their target markets.

**Applicable services include testing to:**

- UL 1431, the Standard for Personal Hygiene and Health Care Appliances
- UL 60335-2-52, the Standard for Household and Similar Electrical Appliances – Safety – Part 2-52: Particular Requirements for Oral Hygiene Appliances

# Customized verification testing to standards or internal specifications

Medical device design and development is complex. Engaging a trusted third-party certifying organization like UL Solutions with deep technical knowledge of the healthcare and life sciences industries to customize validation and verification testing will help you identify potential design issues early in the product development stage.

## Applicable services\* include testing to:

- AAMI EC12, Disposable ECG electrodes
- AAMI EC53, ECG trunk cables and Patient Lead-wires
- AAMI/CR504, emergency use resuscitator systems (EURS)
- ASTM E1112, Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature

\*UL Solutions capabilities and competencies cover various industry recognized standards, not limited to the above.

AI has been introduced to medical devices to enhance ease of use. However, manufacturers need to instill confidence in consumers that their AI-enhanced products work as reliably as claimed. UL Solutions AI Algorithm Reproducibility Process Claim Verification Program is the first independent claim assessment focused on evaluating whether a specific algorithm is capable of consistently producing a specified outcome.

UL Solutions Marketing Claim Verification makes objective, science-based assessments to evaluate the accuracy of marketing claims. Our independent Marketing Claim Verification process scrutinizes the validity of specific advertising or promotional statements.

## Applicable services include testing to:

- Algorithm Reproducibility Process (for medical AI)
- UL Solutions Marketing Claim Verification





## Medical regulatory compliance



Navigating regulatory compliance can be challenging, particularly in the healthcare and life sciences industries. As technologies and devices evolve, global standards will change. As regulations around the world evolve, manufacturers must stay in tune with current requirements to get medical devices to your target markets.

Active, inactive and in-vitro diagnostic (IVD) medical device manufacturers will often require third-party regulatory approvals, product testing, certification and auditing to support their compliance challenges.

We help global medical device manufacturers by evaluating their products for compliance to applicable standards and regulatory requirements so that they can access their target markets.

### **Applicable services include:**

- CE Compliance – MDD, MDR, and IVDD certifications
- Medical Device Single Audit Program (MDSAP) certification
- Quality management system (QMS) registration and certification for medical device manufacturers include ISO 13485 and ISO 9001
- Brazil INMETRO certification
- ISO 14971, risk management for medical devices registration
- IEC 62304, medical device software – software life cycle processes registration





## Other healthcare industry testing solutions

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

Our solutions cover areas such as transportation, storage, biocompatibility, microbiology and sterilization to help ensure healthcare products meet state-of-the-art requirements and are compliant to applicable standards before they are introduced into a clinical setting.

We generally provide testing services conducted within an ISO 17025 compliant management system and are also partly available in Good Laboratory Practice (GLP) compliance for your technical documentation submissions for regulatory approvals.

### Applicable services include testing to:

- Biocompatibility testing and evaluation of medical devices
  - ISO 10993-1
  - ISO 10993-17
  - ISO 10993-18
  - ISO 10993-5
  - ISO 10993 Series
- Reprocessing of reusable medical devices
  - ISO 17664
  - FDA Guidance on Reprocessing Medical Devices in Healthcare Settings: Validation Methods and Labeling
  - AAMI TIR30
- Process control and validation related testing
  - ISO 11607
  - ISO 11737
  - ISO 17665-1
- Ophthalmic implants – intraocular lenses
  - ISO 11979-2
  - ISO 11979-3
  - ISO 11979-5
  - ISO 11979-6



Let's get started



Dedicated to healthcare industry innovation, we leverage decades of technical, regulatory and clinical expertise to help you manage regulatory challenges and help you bring your products to market faster.

Our testing and compliance engineers work closely with standards committees to stay up to date on all the new amendments and upcoming changes. These committees include the American National Standards Institute (ANSI) and the International Electrotechnical Commission (IEC).

We provide a single source for your needs, helping you save time and cost. Our comprehensive suite of services includes end-product testing, certification, verification (EMC, wireless, safety, interoperability, cybersecurity, biocompatibility), and Global Market Access.

To learn more, contact us at [UL.com/contact-us](https://www.ul.com/contact-us)





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