

TOTAL QUALITY ASSURANCE FOR MEDICAL DEVICES

Product assurance, testing, inspection and certification

Intertek has the solutions and expertise to support you with your medical devices in major markets around the world.

From standards interpretation to risk management, testing and certification, Intertek provides Total Quality Assurance throughout the product lifecycle.



The status of IEC 60601-1 Ed. 3 Amendment 1

With the publication of IEC 60601-1 Ed.3 Amendment 1 (AMD1) in 2012, the global adoption process has started and is still ongoing. However, transition times in some major markets such as the USA and EU have already ended, meaning manufacturers must ensure compliance with the latest applicable requirements. Many existing particular standards (part 2-x) have already been revised so that they can be used in conjunction with IEC 60601-1 Ed.3 including AMD1.

Country	Standard	Mandatory from
US*	ANSI AAMI ES 60601-1:2005/ (R)2012 And A1:2012 (FDA)	01/08/2016
Canada	CAN/CSA C22.2 NO 60601-1-14:2014 / IEC 60601-1:2012-Ed.3.1 (Health Canada)	31/08/2015
EU**	EN 60601-1:2006/ A1:2013 (Official Journal)	31/12/2017
Japan	JIS T 0601-1:2014	01/06/2017

Brazil	ABNT NBR IEC 60601-1:2010 + Emenda IEC:2012	25/09/2015
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* OSHA lists the US versions of the IEC 60601 Ed.2 and Ed.3 including AMD1 on their list of recognized standards.

**Compliance with standards is not mandatory in the EU; medical devices must comply with the essential requirements of the applicable directive(s).

Standards development: Outlook on future changes

The application of IEC 60601-1 Ed.3 AMD1 by manufacturers and test laboratories resulted in a number of issues which have been collated and are now being considered in the development of Amendment 2 and Edition 4.

Amendment 2, with a forecast publication date of April 2020, is intended to address high-priority issues only, such as corrections of technical errors, removal of inconsistencies and updates of standard references. One topic which is being addressed and is of high importance for manufacturers is the incorporation of requirements of IEC 62368-1 to demonstrate means of operator protection. This standard replaces IEC 60950-1 which is no longer being maintained. This will eventually lead to the lack of components (e.g. power supplies) on the market which comply with IEC 60950-1 as new components will be designed to meet requirements of IEC 62368-1 instead. This

standard is currently not referenced in IEC 60601-1.

Edition 4 may possibly include more significant changes including revised and/or new requirements. A re-structuring of the standard may be a possible consequence of the feedback received so far. Edition 4 is likely to not be published before 2026.

New particular standards

As the implementation of new technologies in health care continues, new particular standards are being developed which address the specific hazards relevant to the new applications, helping manufacturers make key decisions that have an impact on the design of their device. Examples of standards which are targeted to be published in 2019 or 2020 include the following:

Standard	Particular requirements for the basic safety & essential performance of:
IEC 80601-2-77	Robotically assisted surgical equipment
IEC 80601-2-78	Medical robots for rehabilitation, assessment, compensation or alleviation
IEC 60601-2-83	Home light therapy equipment
ISO 80601-2-84	Emergency and transport ventilators
ISO 80601-2-85	Cerebral tissue oximeter equipment

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IEC 80601-2-86	Electrocardiographs including diagnostic equipment, monitoring equipment, ambulatory equipment, electrodes, cables and leadwires
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Intertek offers manufacturers choice in testing & certification

Intertek is a leading medical electrical equipment and systems provider across a global network of laboratories. Our compliance expertise uniquely qualifies us to guide your medical devices through product development and launch to global markets.

From pre-compliance checks and process evaluations to independent testing, Intertek provides services to address the needs of manufacturers, contractors, facility managers and distributors.

Our state-of-the-art laboratories and equipment provide manufacturers with confidence that products perform as they should; and deliver faster time-to-market through innovative and expert testing and Total Quality Assurance solutions.

Decades of expertise

We have the capabilities to offer a wide range of services for medical devices including:

- ETL Listed, Recognized or Classified Mark
- IEC CB Scheme Certification
- Process Evaluations – Risk Management, Programmable Electrical Medical Systems, Usability
- S-mark and BEAB-mark for product safety
- Evaluation, Testing and Certification of Components and Sub-assemblies (Batteries, LEDs, Power Supplies, Transformers, etc.)
- Laser Products Evaluation and Testing
- EMC and Wireless Testing and Certification
- Environmental Testing
- Functional Safety Evaluation & Certification
- Cybersecurity
- Global Market Access including country-specific directives and requirements

The Intertek advantage

We are committed to providing you with quality testing and verification services to help you reach your target market quickly.



The acceptance of IEC 60601-1 Edition 3, and the transition to Amendment 1 helped ensure medical device safety via a more enlightened approach to risk management.

However, the complexity of the IEC 60601 series of standards, different transition times in certain target countries and new and revised standards being published requires manufacturers to plan their activities thoroughly to achieve compliance with the current and future requirements.

Intertek will partner with you, help you to determine the appropriate standards

We work with you to develop ongoing compliance-testing programs to ensure that new product components do not compromise the quality and performance of medical robots and robotic devices.

From complete testing and verification through post-launch we will help you identify the options and alternatives that are right for you.

Intertek will partner with you to identify and mitigate risk throughout every phase of the product lifecycle.

About Intertek

Intertek is a leading Total Quality Assurance provider to industries worldwide. Our network of more than 1,000 laboratories and offices and over 44,000 people in more than 100 countries, delivers innovative and bespoke Assurance, Testing, Inspection and Certification solutions for our customers' operations and supply chains. Intertek Total Quality Assurance expertise, delivered consistently with precision, pace and passion, enabling our customers to power ahead safely.

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