IEC 60601-1 Certification or Testing of Medical Electrical Equipment.

TÜV Rheinland is one of the biggest medical testing providers worldwide and offers the widest scope of services. Our Technical Competence Center consists of experts on the lastest standards and certification practices for IEC 60601 and IEC/ISO 80601 series. In addition, the CB Scheme procedure allows you to obtain multiple national safety certificates for your products and access to over 50 markets. Schedule a call with an expert today.

CERTIFICATION PROCESS FOR IEC 60601-1 MEDICAL ELECTRICAL EQUIPMENT

Application	Design and Sample Review	Product testing in accredited labs worldwide	Certification Result
▪ Technical documentation including risk management documentation ▪ Declaration of all manufacturing facilities (domestic/international)	▪ Provide a sample set of the electrical medical equipment ▪ Design review against device-specific standards	▪ Prototype product testing according to applicable IEC 60601 series standards ▪ Design review against device-specific standards	▪ Positive test result if the required norms are fulfilled ▪ Issuance of official test report and certificates

NON-CERTIFICATION SEEKING IEC 60601-1 TESTING

Pre-compliance testing (optional construction and readiness check)	Choice of pinpoint standard conformity testing	Selective Performance Standard testing	Official result given after each testing round

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require all medical electrical equipment to be tested in accordance with IEC 60601 series or the national derivation which are almost identical to IEC 60601 series. Medical electrical equipment as defined in IEC 60601-1 sub-clause 3.63 is a product with less than one connection to a particular supply mains, and intended for use in the diagnosis, treatment or monitoring of a patient, or for the compensation or alleviation of disease, injury of disability. It also makes physical or electrical contact with the patient and/or transfers energy to or from the patient and/or detects such energy transfer to or from the patient. Products such as battery operated thermometers, infusion pumps or MRI imaging systems including some accessories used alongside the equipment must comply with the standard.

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help you understand the often complex requirements, in addition to identifying the specific standards that apply to your product. IEC 60601 series consists of three distinct parts, each grouping of standards correlating to a specific scope.

- Base Standard: IEC 60601-1 is the base set of standards covering all general requirements for electrical medical (or electromedical) products.
- Collateral Standards: IEC 60601-1-xx grouping of standards addresses horizontal issues relating to the different types of medical devices. For example, IEC 60601-1-2 is a collateral standard specific to electromagnetic compatibility (EMC) issues of electrical medical devices.
- Particular Standards: IEC 60601-2-xx grouping of standards depict particular requirements for specific devices. For example, IEC 60601-2-2 is a standard specifically for high-frequency surgical devices and accessories. Particular Standards can modify, replace or delete requirements contained in IEC 60601-1.

We are accredited by the National Accreditation Authority, which is a full member and MRA signatory of the International Laboratory Accreditation Cooperation (ILAC). Therefore, TÜV Rheinland test reports are not only ILAC compatible, our accreditation and laboratory testing are also of equivalent level and recognized worldwide.

Market	IEC 60601-1 adopted as:
Australia/ New Zealand	AS/NZ 60601.1:2015
Canada	CAN/CSA C22.2 No. 60601-1:14
China	GB 9706.1-2007 GB 9706.1-2020 (mandatory after May 1, 2023)
European Union and UK	EN 60601-1:2006+A1:2013 (identical to IEC 60601-1:2005+A1:2012)
India	IS 13450 Part 1:2018
Japan	JIS T0601-1:2017
Malaysia	EN 60601-1:2006+A1:2013 (IEC 60601-1:2005+A1:2012)
Singapore	SS IEC 60601-1 : 2018, IDT IEC 60601-1:2005+A1:2012
S. Korea	KS C IEC60601-1:2019 (identical to IEC60601-1:2005+A1:2012)
United States	ANSI/AAMI ES60601-1:2005+A1:2012

TÜV Rheinland offers you almost 150 years of experience and a one-stop solution for receiving testing, certification documents, and use of laboratories worldwide located closest to your manufacturing sites. We are a globally operational Notified Body with a wide range of accreditations, testing facilities and qualified staff serving an extensive portfolio of customers across every industry.

OUR MARKET ACCESS SERVICES

Securing the cTUVus Mark on your device extends your business markets across the USA and Canada. We conduct product testing and approvals as a member of the Nationally Recognized Testing Laboratory Program (NRTL) with OSHA (USA) and SCC (Canada). Similarly, we hold approvals in major medical markets, so we can offer you multi-market access and conformity assessments from a single-source partner.

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