What is EN 60601?

EN 60601 is a group of standards which cover the basic safety and essential performance requirements of a wide range of medical electrical equipment and their related systems. EN 60601 is widely recognized to ensure general requirements for medical electrical equipment are met. It is equivalent to the international series of standards IEC 60601 and comprises of over 70 individual standards. The standard sets basic safety and essential performance requirements and is recognized as a benchmark for compliance across the Medtech industry.

By Royal Charter

EN 60601 coverage and application

EN 60601-1 applies to all medical electric equipment and medical electrical systems. Medical electrical equipment is defined in the standard as equipment, which:

- Has an applied part – the part of the medical electrical equipment which, in normal use, necessarily comes into physical contact with the patient for the medical electrical equipment or system to perform its function

OR

- Transfers energy to or from the patient

The medical electrical equipment should be provided with only one connection to a particular power supply. The intended use, as described by the manufacturer, should be aimed at the diagnosis, treatment, or monitoring of a patient, or to alleviate or compensate for disability, disease, or injury.

Devices classified as medical electrical equipment include:

- Cardiac defibrillators
- High frequency surgical equipment
- Infant incubators and warmers
- Medical lasers
- Patient monitors
- Patient ventilators
- Ultrasound equipment – diagnostic and therapeutic

Market access through EN 60601

CE/UKCA marking

Manufacturers who wish to place medical electrical equipment onto the European or Great Britain market must obtain **CE** or **UKCA** Certification and apply the CE/UKCA mark to their device to demonstrate compliance with the appropriate legislation.

Compliance with the standards is the preferred method of demonstrating conformity with the applicable General Safety and Performance Requirement (GSPRs) of the **Medical Devices Regulation (MDR) (EU 2017/745)**, or Essential Requirements (ER) of the **UK Regulation**.

Whilst compliance with standards is not mandatory for CE and UKCA marking for medical electrical equipment, it can be the most efficient method to demonstrate compliance with applicable GSPRs/ERs.

IECEE CB scheme

As a National Certification Body (NCB) and Certification Body Test Laboratory (CBTL), BSI offers a simplified approach to obtain multiple national safety certificates via a single test report through the **IECEE CB scheme**. This allows your device to access more than 50 countries with one certificate.

What standards do we test to?

60601-1	General safety and essential performance
60601-1-6	Basic and essential performance, usability
60601-1-8	Alarm systems
60601-2-5	Ultrasonic physiotherapy equipment
60601-2-10	Nerve and muscle stimulators
60601-2-22	Laser equipment
60601-1-11	Home healthcare devices
60601-1-2	Electromagnetic disturbances

Why choose BSI to meet the requirements of EN 60601?

BSI has a global service with world-class expertise and is recognized as global leader in testing and certification services. With more than 300 technical experts located in over 100 countries, we provide the most extensive and efficient testing services.

Our dedicated laboratory in Loughborough (UK) is a world-class facility from where we can provide you with ongoing support. BSI provides you with global reach through local expertise by offering also additional local testing facilities that allow you to save time and resources otherwise needed for overseas or long-distance shipments. Our team of medical devices testing experts collectively hold high-level industry knowledge and technical experience. By working with us, you can be confident in the integrity of the certification and testing services offered.

If you have any questions about certification for your medical electric equipment or electrical systems

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