What is EN 60601?

IEC/EN 60601 is a group of standards which cover the safety, essential performance and electromagnetic comparability of a wide range of medical electrical equipment and their related systems. EN 60601 is widely recognized for ensuring general requirements are met for medical electrical equipment. It is equivalent to the international standard 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 industry.

Who is EN 60601 for and what it covers?

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

- has an applied part – the part of the medical electrical equipment that, in normal use, necessarily comes into physical contact with the patient for the medical electrical equipment or system to perform its function
- transfers energy to or from the patient or detects such energy transfer to or from the patient

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

Examples of devices classed 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 using EN 60601

CE/UKCA marking

Manufacturers who wish to place medical electrical equipment into the European market must apply CE (European Union) or UKCA (United Kingdom) marking to their device to indicate compliance with the Medical Device Regulation.

Compliance with the standards is the preferred method of demonstrating conformity with the applicable General Safety and Performance Requirement (GSPR) of the Medical Devices Regulation (MRD)(EU) 2017/745.

Whilst compliance with standards is not mandatory for CE and UKCA marking for medical electrical equipment under the MDR, it can be the most efficient conformity assessment route to achieve compliance.

IECEE CB scheme

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

What products do we test?

- **60601-1** – general safety and essential performance;
- **60601-1-6** – basic and essential performance; usability;
- **60601-1-8** – alarm systems;
- **60601-2-5** – ultra sonic physiotherapy equipment;
- **60601-2-10** – nerve and muscle stimulators;
- **60601-2-22** – laser equipment;
- Devices for the home healthcare environment
- EMC testing to **IEC 60601-1-2**

Why choose BSI to meet the requirements of EN 60601?

BSI have a global service with world-class expertize and are recognized as the global-leader in testing and certification. With more than 270 technical experts located in over 100 countries, we provide the most extensive and efficient testing services, accelerating time to market and giving you a head start on the competition.

Our dedicated laboratory in Loughborough, UK, is a world-class facility from where we can provide you with ongoing support. Our team of gas testing experts collectively hold 127 years of industry knowledge and technical expertize, and with us you can be confident in the integrity of the certification and testing services we offer. Plus, we provide innovative and efficient testing and a unique blend of certification solutions for market access, saving you time and money.

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

Call: **+44 (0)345 0765 606**
Email: **product.certification@bsigroup.com**
Visit: **bsigroup.com**

BSI Group
Kitemark Court
Davy Avenue, Knowlhill
Milton Keynes MK5 8PP

T: +44 (0)345 0765 606
F: +44 (0)1908 814920
bsigroup.com