Your ally for medical devices testing

A one-stop provider for placing your medical device on the market

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The importance of medical device testing for market access

Bringing a medical device to market requires more than innovation and quality design. Conformity with the applicable legislations is a critical step to ensure safety, performance, and compliance.

Testing by an independent, trusted Certification Body like BSI can streamline your route to market in the UK, EU, and global markets. Medical device testing is important to demonstrate compliance with safety and performance requirements and fosters trust in healthcare professionals, and patients alike.

BSI offers a comprehensive suite of services for electronic medical devices, ranging from initial testing to ongoing compliance support. Our Regulatory Services portfolio matched with our trusted testing services, provides you with an efficient one-stop product-to-market journey.

1 **IEC 60601 Testing:** We perform rigorous electrical and mechanical safety testing against the international IEC 60601 standards series, for your device to meet global requirements for safety and performance.

2 **UKCA and CE Certification:** As a leading full scope UK Approved Body and EU Notified Body, BSI provides conformity assessment and certification, to place your medical device on the UK and EU markets confidently. Your IEC 60601 test report from BSI can be used as supporting compliance evidence as part of your UKCA or CE application.

3 **IECEE CB Scheme Certification:** Building on your IEC 60601 testing, BSI acts as a National Certification Body (NCB) and Certification Body Test Laboratory (CBTL), providing manufacturers with a single test report that facilitates entry into over 50 global markets via the CB Scheme.

4 **MDSAP Certification:** Through the Medical Device Single Audit Program (MDSAP), BSI performs a single regulatory quality management system audit that satisfies the requirements of multiple medical device markets – including the USA, Canada, Japan, Brazil, and Australia – helping streamline global compliance and reduce the need for multiple audits.

‘By working with BSI, you gain access to world-class testing facilities, technical experts, and to a certification provider committed to support you at every stage of the product lifecycle.’

Which products are applicable?

BSI provides testing and certification services for a broad range of electronic medical devices across diagnostic, therapeutic, monitoring, surgical, implantable, and laboratory categories. These include but are not limited to:

- **Diagnostic and monitoring devices** – such as ECG and EEG machines, ultrasound and imaging systems, digital thermometers, pulse oximeters, and wearable health monitors.
- **Therapeutic and respiratory devices** – including defibrillators, infusion and dialysis pumps, ventilators, CPAP machines, and nebulizers.
- **Implantable and assistive technologies** – like pacemakers, ICDs, cochlear implants, and neurostimulators.
- **Surgical and laboratory equipment** – including electrosurgical units, robotic systems, endoscopy tools, and analyzers for blood or genetic diagnostics.

‘If your device is electrically powered and utilized in a medical context, BSI can assess its compliance and market readiness.’

IEC 60601 Testing

Ensure your medical electrical device meets international safety and performance standards

IEC 60601 is the cornerstone international standard for demonstrating the safety and essential performance of medical electrical equipment.

For manufacturers of devices such as ECG machines, ultrasound systems, ventilators, infusion pumps, defibrillators, and many others, compliance with the IEC 60601 series is fundamental to ensuring that products are safe for use in clinical and homecare environments.

Please note: devices intended for use in laboratory settings are not covered under IEC 60601. Instead, these must comply with the IEC 61010 series of standards, which address safety requirements for electrical equipment used in measurement, control, and laboratory use.

If you're unsure which standards apply to your product, BSI can advise on the correct testing and certification pathway to support compliance and market readiness.

This standard is globally recognized and is often a legal or regulatory expectation for market entry. It shapes the foundation for two essential certification pathways:

- **UKCA and CE Certification:** compliance with IEC 60601 is a widely accepted method to demonstrate compliance with some of the General Safety and Performance Requirements (GSPRs) of the EU Medical Device Regulation (MDR) and the Essential Requirements (ER) of the UK Medical Devices Regulations.

- **IECEE CB Scheme:** IEC 60601 testing is the gateway to CB Scheme certification, enabling market access to over 50 countries through mutual recognition of test reports.

Understanding the IEC 60601 standard suite for medical devices

The IEC 60601 family includes both general, collateral, and particular standards, which can apply in various combinations depending on the design, function, and intended use of the medical device. These include:

- **60601-1:** General safety and essential performance
- **60601-1-2:** Electromagnetic disturbances (EMC)
- **60601-1-6:** Usability and human factors engineering
- **60601-1-8:** Alarm systems
- **60601-1-11:** Home healthcare environments
- **60601-2-5:** Ultrasonic physiotherapy equipment
- **60601-2-10:** Nerve and muscle stimulators
- **60601-2-22:** Laser equipment

BSI offers complete and comprehensive testing to the full IEC 60601 standard suite. Our experts conduct detailed risk-based assessments, simulate real-world conditions, and apply deep knowledge of medical device technologies to ensure your device meets all relevant requirements.

Key benefits of partnering with BSI for IEC 60601 testing:

- Streamline your route to CE and UKCA certification, and CB Scheme Certification, enabling you to enter global markets.
- Gain access to globally recognized and trusted expertise in medical electrical equipment testing.
- Comply with safety and performance requirements and standards.
- Leverage BSI's world-class testing laboratories and local market knowledge.
- Access BSI comprehensive, streamlined, predictable and transparent processes throughout the testing, documentation, and conformity assessment phases.
- Minimize delays and reduce risks through our robust reviews and assessments.

UKCA and CE Certification

Demonstrate compliance and gain access to the UK and EU medical device markets.

To place medical electrical equipment in the UK or EU markets, manufacturers must ensure their products comply with the applicable requirements and obtain a CE/UKCA certificate from a designated EU Notified Body or UK Approved Body. Once the certification is successfully issued, the manufacturer can proceed in:

- **UKCA marking devices to be placed on the market in Great Britain**
- **CE marking devices to be placed on the European Union market**

CE/UKCA marking is the medical device manufacturer's claim that a product meets the General Safety and Performance Requirements (GSPR) of all relevant European Medical Device Regulations/Essential Requirements (ER) of the UK MDR 2002, as amended, and is a legal requirement to place a device on the EU/GB market.

'BSI is a leading full scope Notified Body (NB) designated to issue CE certification in the EU and an Approved Body (AB) designated to issue UKCA certification in Great Britain.'

As a trusted and independent third-party certifier, BSI provides thorough technical documentation conformity assessments to ensure your device compliance against the applicable legislations by offering a range of flexible certification services, providing you with efficient pathways to bring your product to market.

Why IEC 60601 testing is the most efficient route to compliance

Although not mandatory, testing to recognized standards such as IEC 60601 – which BSI offers in-house – is considered the most efficient and reliable route to demonstrate compliance with some GSPRs/ER. These standards comprehensively address electrical safety, electromagnetic compatibility, performance, and usability. Our experienced teams guide manufacturers through the entire conformity assessment process, simplifying complexity and helping you meet agreed timelines and market expectations.

Key benefits of partnering with BSI for UKCA and CE certification:

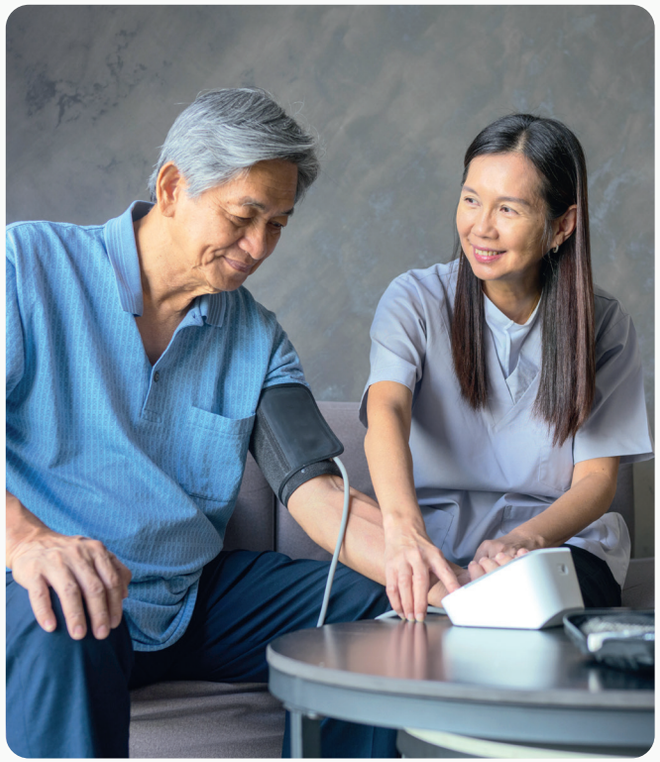
- Benefit from BSI's extensive experience as a Notified Body and Approved Body for medical devices.
- Gain IEC 60601 Certification with BSI to as solid basis to input into your UKCA and CE Certification journey.
- Access expert technical support for navigating UK and EU medical device regulations.
- Use your IEC 60601 Certification to access more than 50 countries worldwide, as well as being able to apply for UKCA and CE marking.

IECEE CB Scheme

Use one test report to unlock market access in over 50 countries worldwide.

BSI is also a National Certification Body (NCB) and Certification Body Test Laboratory (CBTL) under the internationally recognized IECEE CB Scheme. Specifically tailored for medical electrical equipment, this scheme allows manufacturers to achieve multiple national safety certifications using a single, harmonized test report. It provides an efficient and internationally accepted route for demonstrating compliance with some of the European legislation GSPRs and UK legislation ER requirements.

BSI conducts comprehensive testing to IEC 60601 and related standards, covering general safety, electromagnetic compatibility (EMC), usability, alarms, and home healthcare environments. We also test device-specific requirements for medical lasers, nerve stimulators, and ultrasonic physiotherapy equipment.



The IECEE CB Scheme gives manufacturers access to over 50 countries, including:

United States (via OSHA-recognized NRTLs), Canada, European Union member states, United Kingdom, Japan, China, South Korea, India, Brazil, Mexico, Australia, South Africa, Singapore, Malaysia, and other Southeast Asian nations, as well as Gulf Cooperation Council (GCC) countries.

This extensive coverage streamlines the path to market by reducing the need for re-testing or obtaining country-specific approvals for each region.

‘Once testing is complete, BSI issues a CB Test Certificate and Report that can be recognized by over 50 national Certification Bodies worldwide.’

Key benefits of partnering with BSI for IECEE CB Scheme testing:

- Access multiple regulated markets through a single BSI-issued CB test report.
- Couple BSI's IEC 60601 testing services, with UKCA and CE certification services, for a seamless product-to-market compliance journey with a one-stop provider. Avoid redundant testing and reduce compliance costs.
- Streamline time-to-market across global healthcare systems.
- Leverage BSI's medical sector expertize to manage, handle complex technical and regulatory challenges.
- Strengthen the trust in your medical devices through internationally recognized certifications.

Medical Device Single Audit Program (MDSAP)

Streamline global compliance with one audit for five regulatory markets.

The Medical Device Single Audit Program (MDSAP) allows a single audit of your Quality Management System (QMS) to meet the requirements of multiple major medical device markets.

Recognized by five participating Regulatory Authorities – including the US FDA, Health Canada, Brazil's ANVISA, Japan's PMDA, and Australia's TGA – MDSAP is a powerful tool to reduce audit fatigue, demonstrate compliance, and expand your global reach.

MDSAP assessments are based on the internationally recognised ISO 13485 standard, with additional country-specific requirements layered on where applicable. This provides manufacturers with a unified yet adaptable approach to global QMS compliance.

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How does MDSAP work?

Audits are performed by authorised Auditing Organizations (AOs) such as BSI, helping you align with the specific QMS expectations of participating countries under a single, harmonized framework. Whether you're entering one or multiple MDSAP markets, BSI's technical expertise ensures your audit journey is efficient, robust, and aligned with international best practice.

MDSAP can support market access in:

- **USA** – FDA accepts MDSAP audits in place of routine inspections
- **Canada** – Health Canada mandates MDSAP certification for medical device manufacturers
- **Australia** – TGA uses MDSAP audit reports as part of market authorization evidence
- **Japan** – MHLW/PMDA integrate MDSAP audits into their QMS oversight
- **Brazil** – ANVISA uses MDSAP results for both pre-market and post-market assessments

The program is especially valuable for global manufacturers looking to consolidate compliance activities and reduce audit-related disruptions across multiple jurisdictions.

Key benefits of partnering with BSI for MDSAP certification:

- One audit covers five major markets, reducing duplication and audit fatigue.
- BSI is an authorized MDSAP Auditing Organization with deep experience since the pilot phase.
- Gain support from BSI's global network of regulatory and technical specialists.
- Improve risk management and demonstrate stronger regulatory compliance.
- Access expert auditors worldwide, supporting both global enterprises and SMEs.

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