Mobile Medical Devices

Unrivalled expertise from an EU Notified Body and UK Approved Body

As a manufacturer of a mobile medical device, you must ensure that you meet the relevant regulatory requirements before placing your product onto the market; for the EU, these are outlined in the Medical Device Regulation (MDR) (EU) 2017/745 and, for the UK, the UK Medical Devices Regulations (UK MDR) 2002.

It is critical to work with an EU notified body or UK approved body that understands the industry and has the experience to review and confirm your product's readiness for market – efficiently, reliably and promptly. Our technical specialists have extensive experience in certifying mobile medical devices and can support you through the process of certifying your device.

BSI The Netherlands (2797) is a leading Notified Body; we review medical devices to ensure that they conform to the requirements of the European Directives and Regulations. BSI UK (0086) is a UK Approved Body able to provide conformity assessments under the new UKCA scheme.

bsi.

Inspiring trust for a more resilient world.

Defining mobile medical devices

We are witnessing an explosive growth in medical devices that use wireless technologies. Some devices are implanted and some are worn on the body to control bodily functions and to measure an array of physiological parameters. The data from these sensors and monitoring equipment, together with patient observations of daily living, can be transmitted wirelessly to another location for review by relevant specialists.

Mobile devices allow for remote management of patients with a range of chronic diseases or patients recovering at home. Mobile medical applications are also transforming healthcare. Examples include apps that measure heart rate and blood pressure, perform an ECG, manage the delivery of insulin, take patient-specific information and provide a clinician with radiation dosage calculations, and allow doctors to view X-rays or other imaging on smart phones and tablets.

A device falls under the scope of the EU MDD or MDR, or the UK MDR (2002), if it has a medical purpose as defined in the Directive or Regulations; please note that products without a medical purpose need to meet separate requirements. Areas for consideration:

- Risks associated with design, manufacture and use should be managed as part of a comprehensive quality management system by, ideally, applying ISO 14971
- Data integrity and security are concerns particularly when the data is transmitted wirelessly
- Usability compliance can most easily be demonstrated by meeting the requirements in the standard EN 62366 in the design process. If the device is for home use, studies should be carried out on samples of target users
- Software lifecycle processes become an important part of the design process. An applicable standard in this area is EN 62304
- Electromagnetic compatibility should be considered as an integral part of the development lifecycle. Wireless devices also fall under the scope of the Radio Equipment Directive (RED) so the EN 301 489 and EN 60601-1-2 series of standards will likely apply
- You should also ensure that the device complies with the safety and essential performance requirements contained in the EN 60601 family of standards
- When designing any medical device, you must perform extensive clinical data evaluations to ensure patient safety

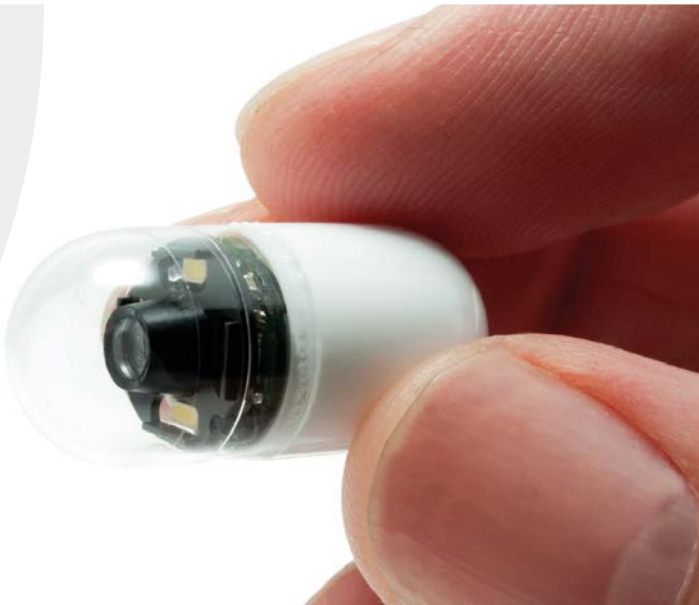
Unless the regulatory framework and requirements are taken into account in the early stages of the design process, you could find yourself needing to invest significant additional time and resources to obtain regulatory approval.

From the experts

The process of CE or UKCA marking a mobile medical device requires that you, as a manufacturer, fully understand the requirements applicable to your device and have clear, compliant and complete documentation. For CE marking, we have developed MDR Best Practices Guidelines to assist with this.

BSI's mobile device experience includes:

- Integrated device recognition using RFID
- Video capsule endoscopy
- Devices to assist movement of artificial limbs
- Mobile medical device apps
- Ingestible sensors
- Implanted wireless sensors and devices
- Wearable wireless sensors and devices



Reasons to work with BSI Medical Devices

Experience and product expertise

The benefits of having experienced, professional and well-qualified technical specialists cannot be overstated in the complex and ever-changing medical device industry. BSI Medical Devices has a team of more than 750; within that team are our technical experts with experience encompassing the full range of medical devices and management system standards

BSI is a global network of over:

5,000 people **supported by** **12,000** industry experts **in more than** **193** countries

Focus on service

Clients work with us because we understand the challenges medical device manufacturers face in bringing compliant products to market efficiently and safely. We offer a range of flexible product review services providing you with efficient pathways to bring your product to market.

Global market access

We are a global organization, trusted and recognized around the world. BSI The Netherlands (2797) is a leading Notified Body; we review medical devices to ensure that they conform to the requirements of the European Directives and Regulations. BSI UK (0086) is a UK Approved Body able to provide conformity assessments under the new UKCA scheme.

Confidence and robust reviews

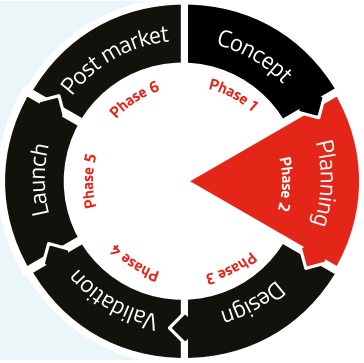
Our comprehensive review process combined with our world-leading medical device and regulatory experience will ensure that your conformity assessment process is both efficient and robust.

Passion for patient safety

Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, robust conformity assessments, evaluations and certifications.

The Product Lifecycle: when to consider clinical and regulatory requirements

An understanding of the complex clinical and regulatory requirements early in the product lifecycle could ensure you gain the competitive advantage needed to bring your product to market. Consolidated clinical and regulatory planning will assist you in maximizing resources and reducing the risk of costly redevelopments later in the lifecycle.
Visit our website for more information about the product lifecycle.



How can BSI support your medical device launch?

Be prepared

In the competitive medical device marketplace, ensuring that product development meets all regulatory requirements is essential. We provide guidance and training to support you through the application process.

Worldwide access

We offer a wide range of proven regulatory and quality management programs that work together for full international compliance. Our Quality Management System (QMS) solutions include ISO 13485, ISO 9001, ISO 14001 and many more.

We are a recognized Certification Body in Hong Kong, Japan, Malaysia, Singapore and Taiwan, and a recognized MDSAP Auditing Organization for all participating Regulatory Authorities.

Seamless transfer to BSI

We can offer a seamless service with comprehensive support and the absolute minimum level of disruption.

Certification support and additional services

We offer continual support throughout the certification process and beyond; we also offer:

- **access to more than 34,000 standards** and related products, as well as online guidance documents
- **expert training** delivered online or face-to-face, either in-house or through our public training courses
- **regulatory updates** and a newsletter service focusing on industry changes, helping you to plan for the future
- **webinars** delivered by our experts on complex regulatory issues
- **comprehensive whitepapers** providing the latest insights on key industry topics

Navigating your transition to the IVDR and MDR

The Medical Devices Regulation (MDR) (EU) 2017/745 has a transition period of four years starting from May 2017, after which the Regulation will apply. The In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746 entered into force on the 25 May 2017 marking the start of a five-year transition period.

Manufacturers have the duration of the transition periods to update their Technical Documentation and processes to meet the new requirements if they want to place medical devices and in vitro diagnostic medical devices on the market in the European Union.

The MDR brings with it more scrutiny of Technical Documentation, addressing concerns over the assessment of product safety and performance by placing stricter requirements on clinical evaluation and post-market clinical follow-up. The IVDR brings with it significant changes to the regulatory requirements for IVD medical device manufacturers and introduces a new rule-based classification system with stricter notified body oversight, as well as significant changes to the depth and requirements of the associated Technical Documentation.

Visit our website for more information: bsigroup.com/medical

Technical Documentation Review

Our Technical Documentation Review services deliver the efficiency you need to be both competitive in the market and maintain confidence through our robust technical reviews.

Standard

Our standard service reviews are completed by experienced BSI Product Experts, giving you confidence in the review.

Dedicated

This service allows you to schedule your Technical Documentation review with a dedicated BSI Product Expert.

Five steps to CE or UKCA marking your product

Step 1

BSI prepares a quotation

A BSI representative meets with your organization to discuss your needs and the available solutions. We will also discuss the best service for your requirements.

Step 2

BSI performs a conformity assessment

A dedicated BSI scheme manager will be assigned to you, supporting your organization throughout the process. A QMS audit will then be performed and Technical Documentation reviewed by one of our experienced technical experts.

Step 3

Certification decision

Successful assessment leads to your BSI scheme manager recommending certification of your product. The BSI Certificate Decision Maker will then review the recommendation and, if satisfactory, approve certification.

Step 4

Issue certificate

Upon successful certification, you will be issued with a certificate. You will then be able to CE or UKCA mark your product and launch to market.

Step 5

Certification maintenance

On-going surveillance audits and reviews are required to monitor for continued compliance. Your BSI scheme manager will be able to support you with any queries you might have.

Talk to BSI today

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Visit: **bsigroup.com/moviles/**
and start your journey

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