Active Medical Devices

Unrivalled expertise from an Active Medical Devices Notified Body

As a manufacturer of an active medical device, you must ensure that you meet the relevant requirements outlined in the Medical Device Regulation (MDR) (EU) 2017/745 before placing your product onto the EU market.

It is critical to work with a notified body that understands the industry and has the experience to review and confirm your products' readiness for market – efficiently, promptly and robustly. As an Active Medical Devices Notified Body our technical specialists have extensive experience and can support you through the process of certifying your active medical device.

BSI has two Notified Bodies, one in the UK (0086) and one in the Netherlands (2797), both of which have full scope designations to the IVDR and MDR.

bsi.

...making excellence a habit.™

Defining active medical devices

An active medical device is defined in the MDR as "any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy."

For further clarity and more information on the definition of an active medical device, please refer to the MDR (EU) 2017/745.

Meet our experienced Active Medical Devices team

Our active medical devices specialists are product experts with a broad range of industry and regulatory experience, including product design and development, manufacturing, testing and regulatory expertise.

Where products require additional expertise, we collaborate with our internal clinicians and in-house technical teams at BSI covering all areas from dental, ophthalmic, orthopaedic and vascular, to active implantable, medicinal substances, devices utilizing animal tissue and sterile devices.

"BSI is justifiably proud of its respected status in the medical devices industry as a designated Notified Body under the MDR, including active medical devices. This is clearly visible in the level of experience and unrivalled expertise of our large specialist team."

Paula Gomes
Global Head of Active Medical Devices, BSI

From the experts

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

Examples of products we cover

- Ablation devices
- Body-worn sensors
- Hearing aids
- Heart-lung machines
- Infusion pumps
- Patient monitors
- Radiation therapy
- Software devices
- Surgical lasers
- Surgical robots
- Ultrasound devices
- Ventilators
- X-ray machines

Reasons to make BSI your Active Devices Notified Body

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 over 700; within that team are our technical experts with experience encompassing the full range of medical devices and management system standards.

BSI Group 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 has two Notified Bodies, one in the UK (0086) and one in the Netherlands (2797), both of which have full scope designations to the IVDR and MDR.

Confidence and robust reviews

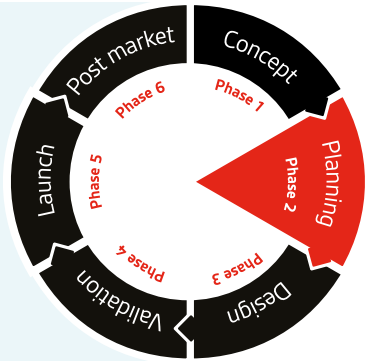
Our comprehensive review process combined with our world-leading experience as a Notified Body will ensure that your conformity assessment process is both efficient and robust.

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 active 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 MDR

The Medical Devices Regulation (EU 2017/745), which replaces the Active Implantable Medical Devices Directive (90/385/EEC) and Medical Devices Directive (93/42/EEC), has a transition period of four years starting from May 2017, after which the Regulation will apply. Manufacturers have the duration of the transition period to update their Technical Documentation and processes to meet the new requirements if they want to place medical devices on the market in the European Union.

The MDR brings with it more scrutiny of Technical Documentation; addresses concerns over the assessment of product safety and performance by placing stricter requirements on clinical evaluation and post-market clinical follow-up; and requires better traceability of devices through the supply chain.

Whether you're starting the certification process, looking to transfer, or just need to discuss options for your organization, we have a range of materials to support you through this regulatory change. Our MDR Best Practices Guidelines (BPG) provide guidance on preparing and structuring your Technical Documentation. Following these will ensure your submission to BSI is complete and thorough.

CE-Excellence: Technical Documentation Review

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

CE-Standard

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

CE-Dedicated

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

Five steps to getting your product to market

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 all 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 Certification Decision team 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 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

Call: **+39 02 66 79 091**

Visit: **bsigroup.com/active**

and start your journey

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