Active Medical Devices

By Royal Charter

EU Notified Body and UK Approved Body Expertise

- As a manufacturer of active medical devices, you must ensure that you meet the relevant regulatory requirements before placing your product onto the market.

  Europe Medical Device Regulation (EU MDR) 2017/745

  Great Britain 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, promptly and robustly.

  Our Technical Specialists have extensive experience in active 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 that provides Conformity Assessments under the UKCA scheme.

Defining active medical devices

An active medical device is defined 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 more clarity on active and related medical devices, please refer to the MDR (EU) 2017/745.

Product range covered and more

Meet our Active 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.

We are experienced in working with manufacturers of ablation devices, body-worn sensors, hearing aids, infusion pumps, ventilators, software devices, surgical robots and lasers as well as, radiation therapy, ultrasound and x-ray machines and many others.

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

"We are proud to provide our combined expertise to assess compliance on the complete range of active medical devices. This enables our clients to place onto the market safe and effective diagnostic and therapeutic solutions which benefit clinicians and patients".

Paula Gomes,
Global Head of Active Medical Devices

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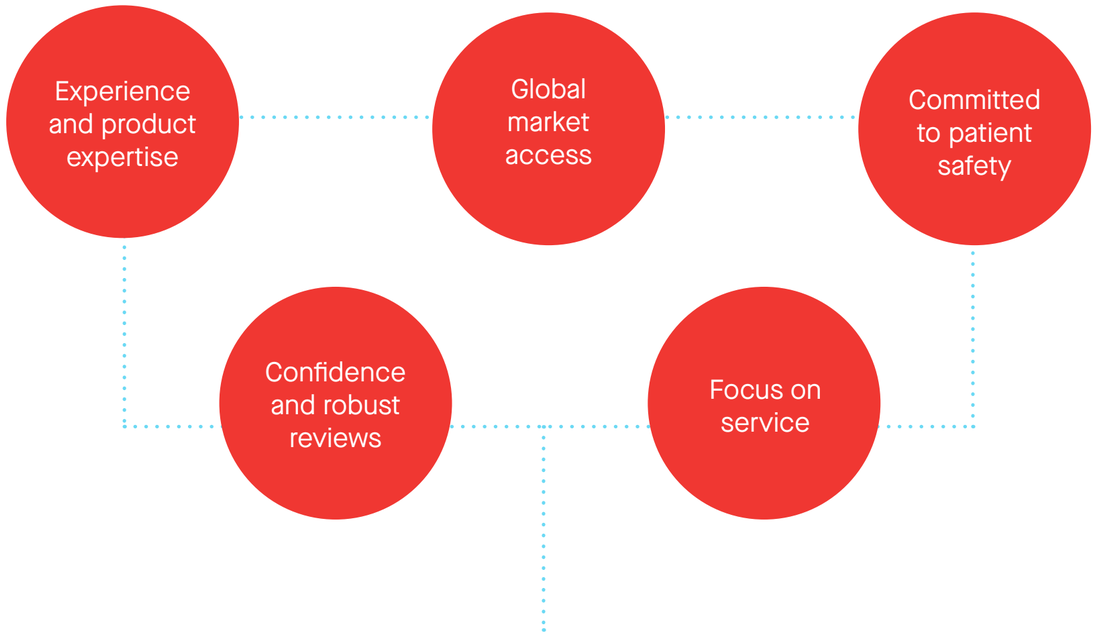
Why choose BSI



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

Experience and product expertise

In the complex and ever-changing medical device industry, support from experienced, professional and well qualified technical specialists is critical.

BSI's medical devices consists of a team of over 900 professionals including technical experts competent in encompassing the full range of medical devices and management system standards.

Committed to 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 and robust conformity assessments, evaluations and certifications.

Confidence and robust reviews

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

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.

Focus on service

We truly understand the challenges medical devices 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.

Five steps from product-to-market

1

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.

2

Conformity assessment

A dedicated BSI scheme manager will be assigned to you, supporting your company throughout the process.

A QMS Audit will then be performed and all Technical Documentation reviewed by one of our experienced technical specialists.

3

Certificate 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.

4

Issue certificate

Upon successful certification, you will be issued with a certificate.

You will then be able to CE/UKCA mark your product and launch to market.

5

Certificate maintenance

On-going surveillance audits and reviews are required to monitor for persistent compliance.

Your BSI scheme manager will support you with any queries you might have.

How BSI supports your Medical Devices launch

Readiness

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

Worldwide Access

We offer a wide range of regulatory and quality management programs that work cohesively for 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 Japan, Malaysia, Singapore and Taiwan, and a recognized MDSAP auditing organization for all participating regulatory authorities.

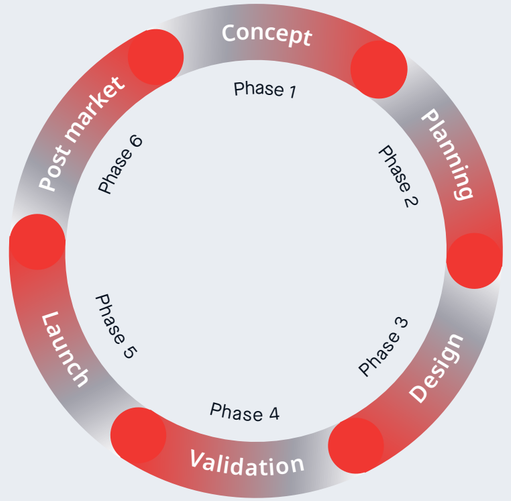
BSI Transfer

We offer a seamless transfer to our services providing comprehensive support to ensure minimal disruption to your company.

Additional Services

- Access to more than 34,000 standards and related products, as well as online guidance documents
- Expert training online or face-to-face through our public training courses
- Regulatory updates and newsletters focusing on industry changes, helping you to plan for the future
- Webinars delivered by our experts on regulatory issues
- Comprehensive whitepapers providing the latest insights on key industry topics

The product lifecycle



Considering 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.

Our consolidated clinical and regulatory planning will support 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

Navigating your compliance to the MDR

The MDR (EU 2017/745), which replaced the AIMDD (90/385/EEC) and MDD (93/42/EEC), applied on May 2021. Manufacturers have until May 2024 to ensure their Technical Documentation and processes meet the new requirements for placing medical devices on the EU market.

Manufacturers are invited to apply to a Notified Body for MDR as soon as possible and well in advance of the end of the transition period (at least 1 year before the expiry date of the MDD/AIMDD certificate) to ensure timely compliance with the Regulation by 26 May 2024.

Starting the certification process?

Transitioning to MDR?

Transferring your existing certification?

From the experts

The process of CE or UKCA marking for active medical devices can be challenging. Strong and statistically relevant clinical evidence, demonstrating the safety and performance of your device, is essential to ensure a successful outcome of your MDR/UKCA application.

MDR Best Practices Guidelines to support you

Conformity Assessment guidance to meet MDR requirements

Continued support from our technical experts through– your submission

CE/UKCA Excellence

Technical Documentation Review Services deliver the efficiency you need to be competitive in the market and maintain trust.

Standard

Our standard service reviews are completed by experienced BSI Product Experts.

Dedicated

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

Talk to BSI today

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bsigroup.com/active

and start your journey

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