

**bsi.**

● Active  
Medical Devices



By Royal Charter



# ● EU Notified Body, UK Approved Body and Auditing Organization 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 (MDR)(EU) 2017/745

**Great Britain:** Medical Devices Regulations (UK MDR 2002)

**Global Medical Device Single Audit Program (MDSAP)**

- It is critical to work with a trusted EU Notified Body or UK Approved Body or Auditing Organization 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 full-scope 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 full-scope UK Approved Body that provides Conformity Assessments under the UKCA scheme.

**BSI Group America Inc.** is a recognized Auditing Organization.

## 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.

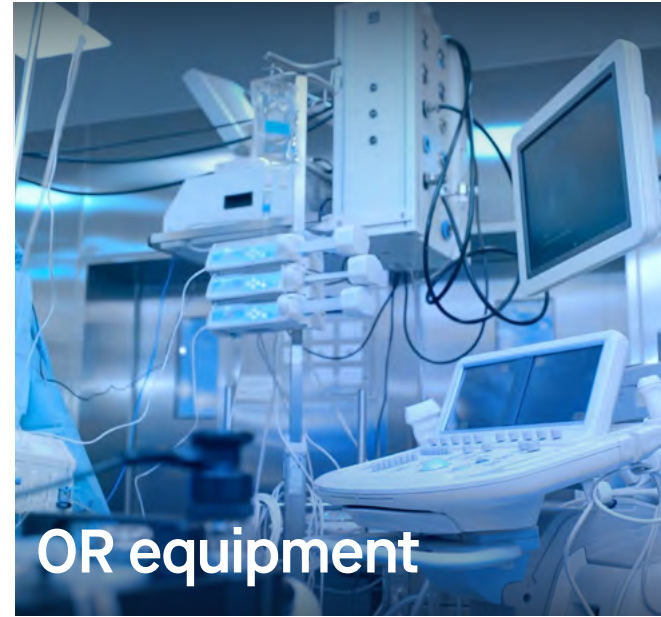
For more clarity on active and related medical devices, please refer to the [MDR \(EU\) 2017/745](#).



# ● Product range covered and more



X-Ray machines



OR equipment



Surgical robots



Ultrasound scanners



Software devices



Infusion pumps



Surgical drills



Ventilators

# ● 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.

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"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



Over **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 1000 professionals including technical experts and internal clinicians 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.

## Trusted 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 UKCA scheme.

BSI is a recognized Auditing Organization, providing Quality Management System certification through Medical Device Single Audit Program (MDSAP).

## Thorough and responsive 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

## 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.

1

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.

## 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.

3

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.

## 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.

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# ● How BSI supports your market readiness

## 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.

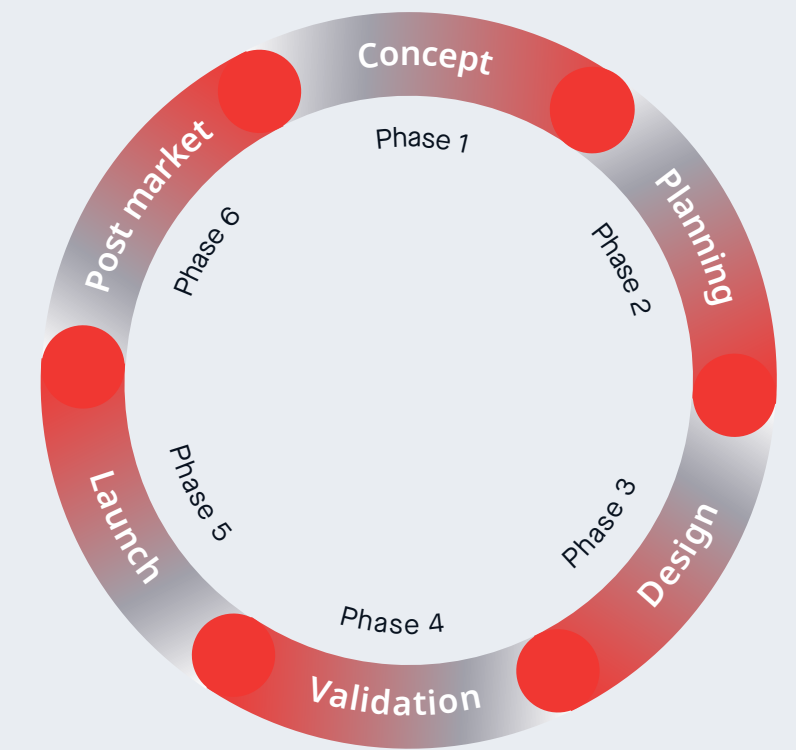
## BSI Transfer

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 must 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 to ensure timely compliance with the Regulation.



**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 access to our technical experts throughout your submission

## CE/UKCA Excellence

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

### Standard

Access to technical review timeline after Technical Documentation submission.

### Dedicated

Technical review planned up-front to Technical Documentation submission.

### Talk to BSI today

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[bsigroup.com/active](https://bsigroup.com/active)

and start your journey







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