



Your partner  
in progress

# Active Medical Devices



# EU Notified Body, UK Approved Body and Auditing Organization Expertise

As a manufacturer of a active medical device, 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** and In Vitro Diagnostic Regulation (**IVDR**) (**EU**) **2017/746**

**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 Group The Netherlands B.V. (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 Group Assurance UK Ltd. (0086)** is a full-scope UK Approved Body that provides Conformity Assessments under the UKCA scheme.

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



Active Medical Devices

## 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.

“ 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  
Devices, BSI



# Why choose BSI



## 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 Medical Devices consists of a team of over 1000 professionals including technical experts and internal clinicians with expertise 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.

## Thorough and responsive service

We truly understand the challenges medical devices manufacturers face in bringing compliant products to market efficiently and safely.

We offer standard and dedicated review services providing you with the efficient pathways to bring your device 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 UKCA scheme.

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

BSI is a Conformity Assessment Body for EN ISO 17021-1 (EN-ISO 9001, ISO 14001, ISO 13485) as accredited by the Dutch Accreditation Council (RvA) and the UK Accreditation Service (UKAS).

## 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.

# Five steps from product-to-market



# 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. BSI is an accredited Conformity Assessment Body for Quality Management Systems against ISO 17021-1 with ISO 13485, ISO 9001 and ISO 14001 in its scope.

BSI Group The Netherlands B.V. (2797) is a leading Notified Body achieving full-scope designation under MDR and IVDR.

We are a recognized certification body in Japan, Malaysia, Singapore. BSI Group The Netherlands B.V. (2797) is a recognized "Notified Body partner" in Taiwan's Technical Cooperation Programme (TCP), and a recognized MDSAP auditing organization for all participating regulatory authorities.

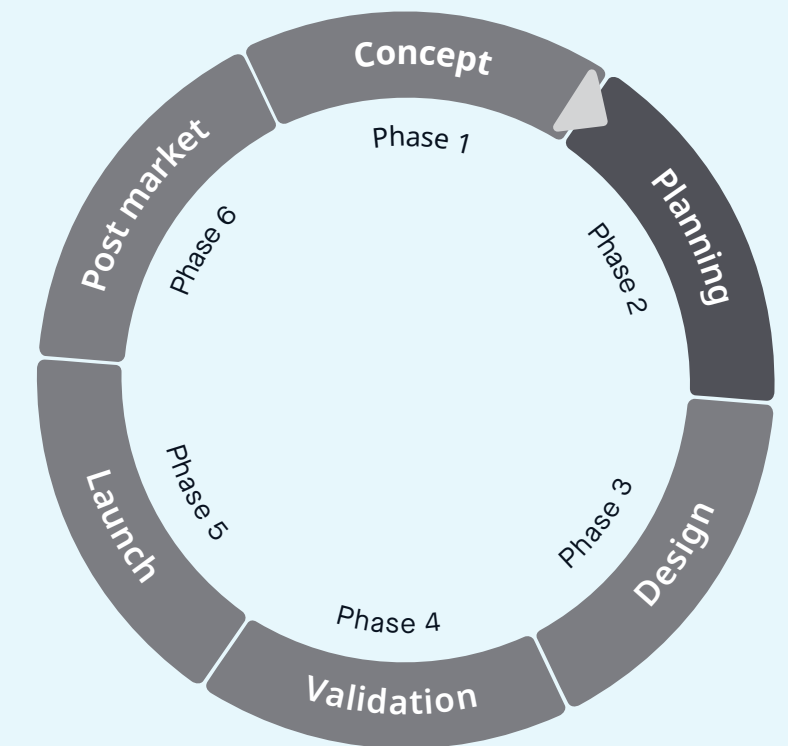
## BSI Transfer

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

Manufacturers of medical devices and IVDs have to ensure their technical documentation and processes meet MDR and IVDR requirements before placing their products on the EU Market.

Manufacturers are invited to apply to a Notified Body as soon as possible to ensure compliance with the Regulations.

Starting the certification process?

Transitioning to MDR?

Transferring to BSI 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 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.

## Interactive Dedicated

Technical review planned up-front to Technical Documentation submission.

## Talk to BSI today and start your journey

### Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

**Talk to us** 



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