General medical devices

By Royal Charter

EU Notified Body, UK Approved Body and Auditing Organization expertise

As a manufacturer of a 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 an EU Notified Body, UK Approved Body or Auditing Organization that understands the industry and has the experience to review and evaluate your product's readiness for market - efficiently, promptly and robustly. Our technical specialists have extensive experience in these 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.

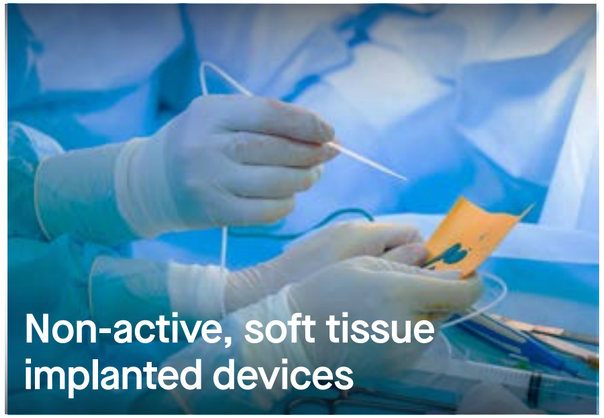
BSI Group America Inc. is a recognized MDSAP auditing organization.

General medical devices

BSI Medical Devices has a team of technical specialists with expertise across all types of medical devices. These are just some of the devices the General team supports:

- Non-active, soft-tissue implanted medical devices
- Wound and skin care medical devices
- Ophthalmic medical devices
- Medical devices for infusion and transfusion
- Medical devices for anesthesia, emergency, and intensive care
- Medical devices for contraception
- Regulation (EU) 2017/745 Annex XVI devices

Medical devices our general team supports



Meet our General Team

Our General team of highly trained technical specialists are product experts who work with device manufacturers and understand the specifics of complex medical devices.

The team has an average of 20 years' industry and regulatory experience, and we are able to provide conformity assessments under the EU MDR and UK MDR 2002.

Where products require additional expertise, we collaborate with our in-house clinicians and other technical teams.

"It is an honour to lead the General Devices Team at BSI. Our highly skilled team covers the broadest range of medical devices from the simplest Class I sterile devices to the highest risk most scrutinised Class III devices on the market. The team works with manufacturers and regulators to ensure safe effective devices are available to patients"

Neill Bannister, Global Head of General Medical Devices, BSI

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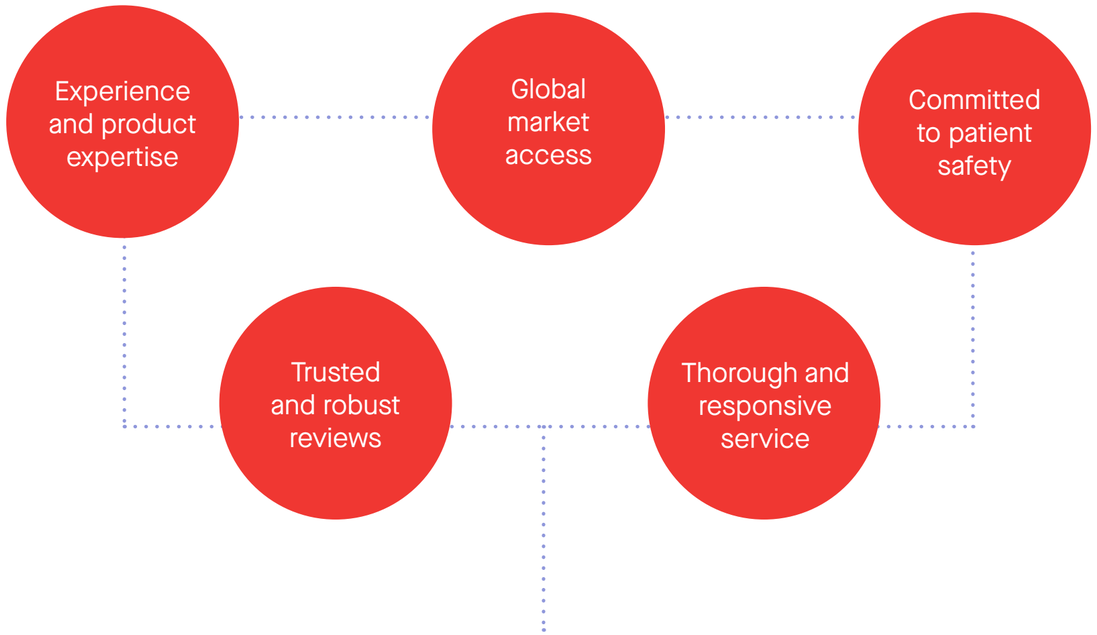
Why choose BSI



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 expert 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).

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).

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.

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 the Technical Documentation reviewed by our experienced QMS auditors and 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 assessment, 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 continued compliance.

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

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.

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

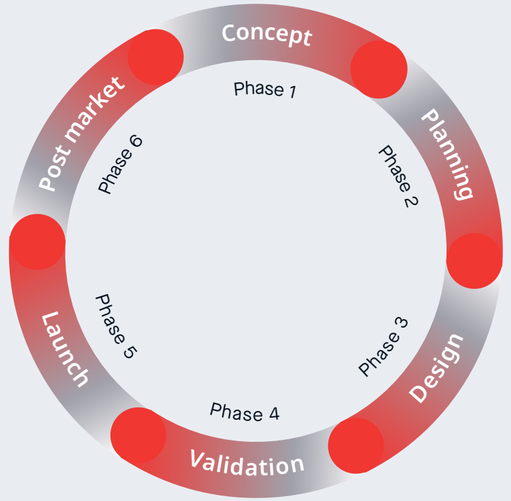
BSI Transfer

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 regulations

Starting the certification process?

Transitioning to MDR/IVDR?

Transferring your existing certification to BSI?

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 timely compliance with the Regulations.

From the experts

The challenges presented to manufacturers by the introduction of the EU MDR/IVDR and UK MDR 2002 are significant, particularly for those manufacturing implantable devices. Our experienced General team provides the guidance and resources manufacturers need to support them on their journey to bringing their product onto the market.

- **MDR** and **IVDR** Best Practices Guidelines to support you
- **MDR** and **IVDR** 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

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/general

and start your journey

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