bsi.

Medicinal and biologics 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 medicinal and biologics 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.

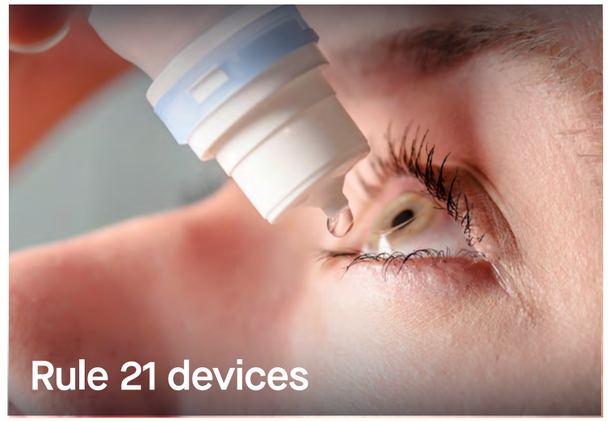
  BSI UK (0086) is a full-scope UK Approved Body that provides Conformity Assessments under the UKCA scheme.

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

Defining medicinal and biologics medical devices

The medicinal and biologics team cover a broad range of medical devices, including devices utilising non-viable human or animal tissue or their derivatives, devices incorporating ancillary medicinal substances, Article 117 drug-device combinations, devices used for the processing and preservation of human tissues, organs and cells, including in vitro fertilisation (IVF) and assisted reproductive technologies (ART), and devices composed of substances or combinations of substances.

Medicinal and biologic medical devices



Medical devices with ancillary medicinal substances

Classification

Early classification of medical products containing or delivering drug substances is essential in order that the appropriate regulatory path is determined:

- Medical products designed to deliver drugs, supplied without the drug itself are regulated as medical devices (e.g. infusion pump)
- Medical products designed to deliver drugs, supplied with the drug combined, are regulated as medicinal products (e.g. sub-dermal contraceptive implants and insulin-filled syringes)
- Medical products which incorporate as an integral part a substance which, if used separately, can be considered to be a medicinal product and which have action ancillary to that of the device, are regulated as medical devices (e.g., catheters coated with heparin)

To ensure an accurate classification you must consider the following questions:

- Whether any constituents, if used separately, may be considered to be a medicinal product (e.g. silver, some herbal ingredients, analgesics, etc)
- What claims are made for the product – what is the intended purpose?
- The method by which the principal intended action is achieved – mode of action?

Medicinal Consultations

During the certification process for devices with an ancillary medicinal substance, the Notified Body must review device aspects and seek the opinion of a European Competent Authority in relation to the ancillary medicinal substance incorporated in the device.

Prior to seeking the opinion of the Competent Authority, BSI must verify the usefulness of the medicinal substance incorporated in the device.

The Competent Authority will provide the Notified Body with a scientific opinion on the quality and safety of the substance taking in to account the clinical benefit/risk profile of the incorporation of the medicinal substance into the device.

The review of the medicinal substance by the Competent Authority may take up to 210 days and usually runs in parallel with the review of the device by the Notified Body.

Experience in Device Drug Consultation

Antimicrobial woundcare

Sutures with antimicrobial coating

Drug coated PTCA balloon catheters

ART Media with ancillary human blood derivative

Steroid coated cardiac pacing leads

Devices utilizing materials of animal origin

BSI is one of a few Notified Bodies designated to certify devices manufactured utilizing materials of animal origin including those derived from Transmissible Spongiform Encephalopathy (TSE) susceptible species. Our large in-house team of experts understand the challenges in gaining successful certification for your products.

Our auditors are qualified to conduct assessments at slaughterhouse facilities, tissue processors and all the way through the manufacturing chain to the finished product.

Our full scope covers the entire spectrum of devices in combination with:

- Regulation (EU) 722/2012
- EN ISO 22442 and all other aspects related to your certification needs across a wide range of device technologies
- Sourcing and processing controls
- Inactivation and elimination of viruses and TSE agents
- Quality System assessments

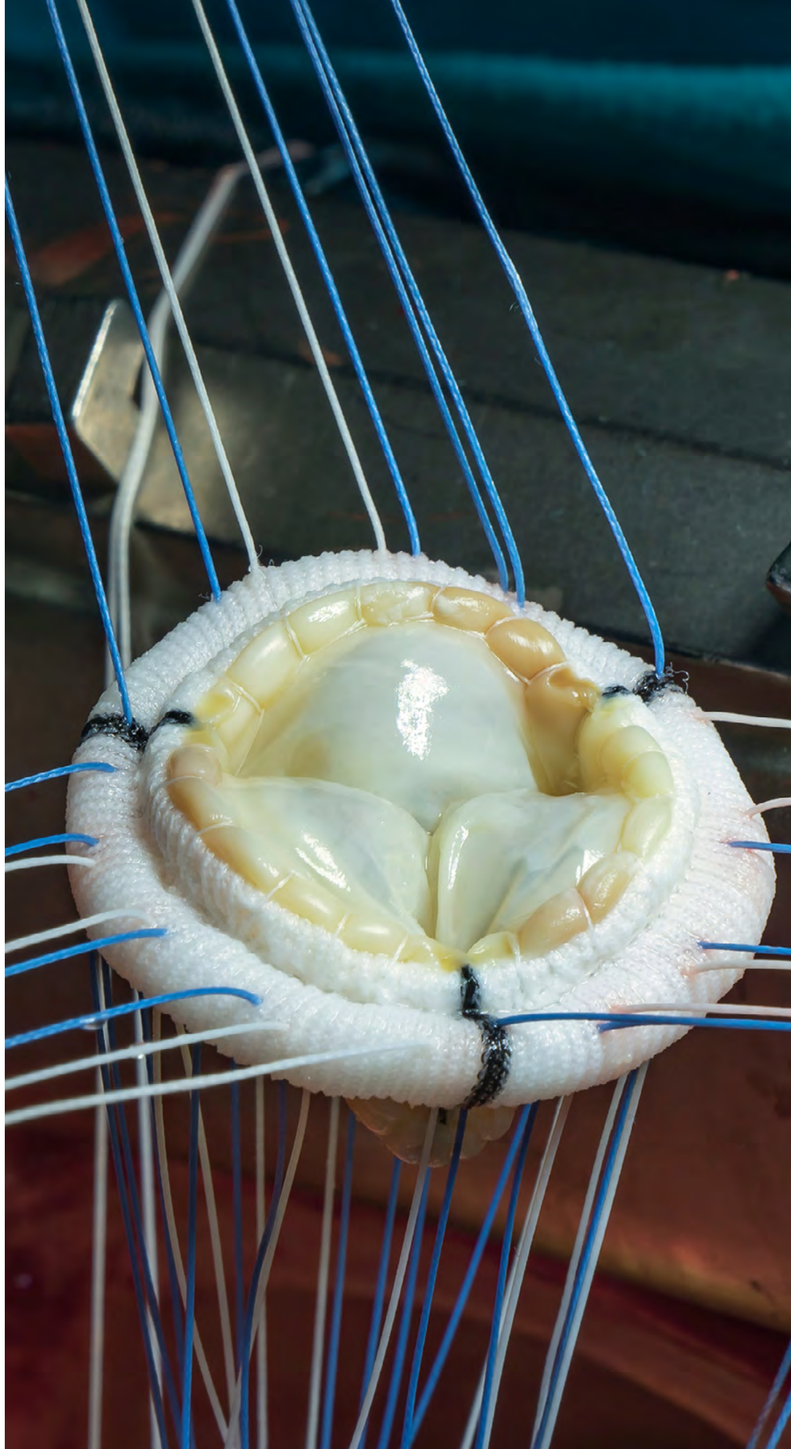
Suppliers of materials of animal origin can also apply to BSI for EN ISO 13485 certification which may provide a competitive advantage when seeking to do business with device manufacturers. Certification will include a review against relevant requirements of EN ISO 22442 and may be taken into consideration by Notified Bodies during conformity assessments.

Animal origin technologies

- Bone
- Heart valves
- Hyaluronic acid
- Collagen
- Wool fat and derivatives

Device technologies

- Gelatin sealed grafts
- Pericardical patch
- Cartilage repair
- Wound dressings



Meet our Medicinal and Biologics Team

Our Medicinal and Biologics team has a broad range of industry and regulatory experience, including product design and development, manufacturing, testing and regulatory expertise. With more than 200 years of overall combined experience, our team provides guidance on ancillary medicinal substances and blood derivative devices, as well as conformity assessments for MDR (Rule 18) and UK MDR 2002, Part II (MD) (Rule 17) for medical devices utilizing non-viable tissues or cells of human or animal origin and their derivates. BSI Medicinal and Biologics team also offers expertise on IVF/ART devices and devices for processing and preservation of human tissues and cells, Rule 21 devices and emerging technologies related to medicinal, animal origin and biological substances.

"The Medicinal and Biologics team focuses on some of the most challenging areas of EU and UK legislations and it's a privilege to lead a team of such talented individuals. Our dedicated in-house experts have the knowledge to guide you efficiently through the regulatory process."

Dr Jennifer Durrant, Global Head of Medicinal and Biologics, BSI

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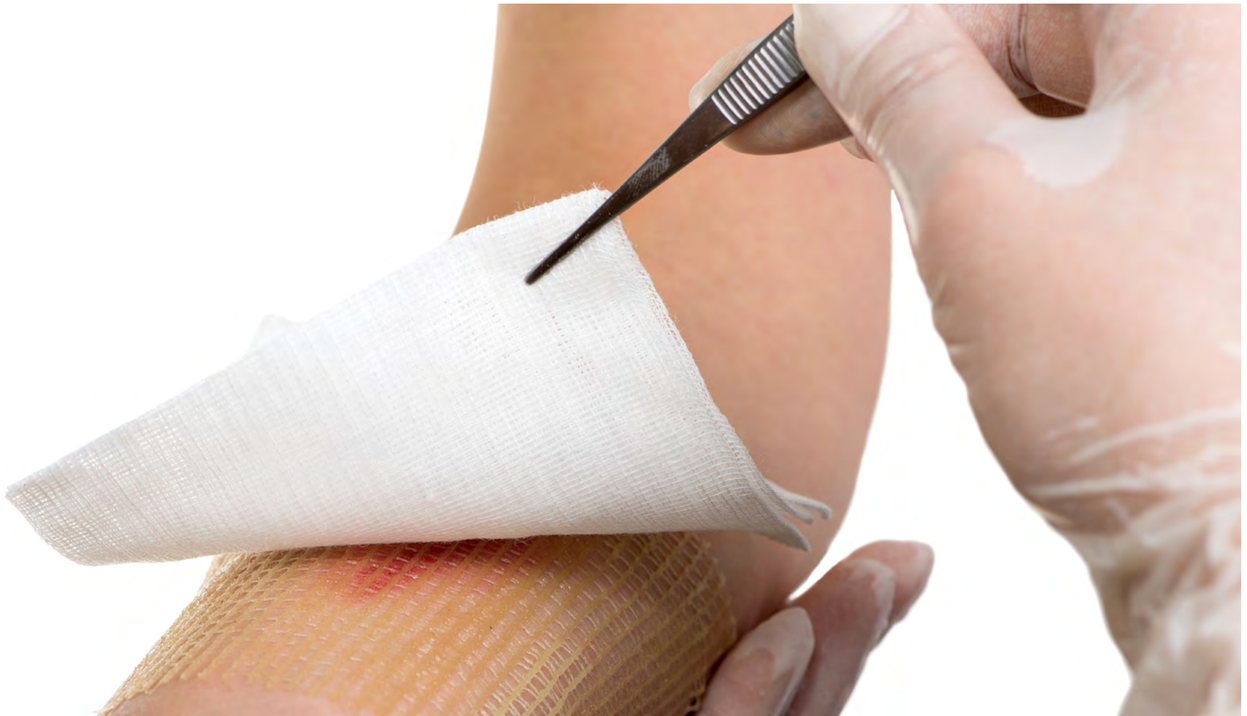
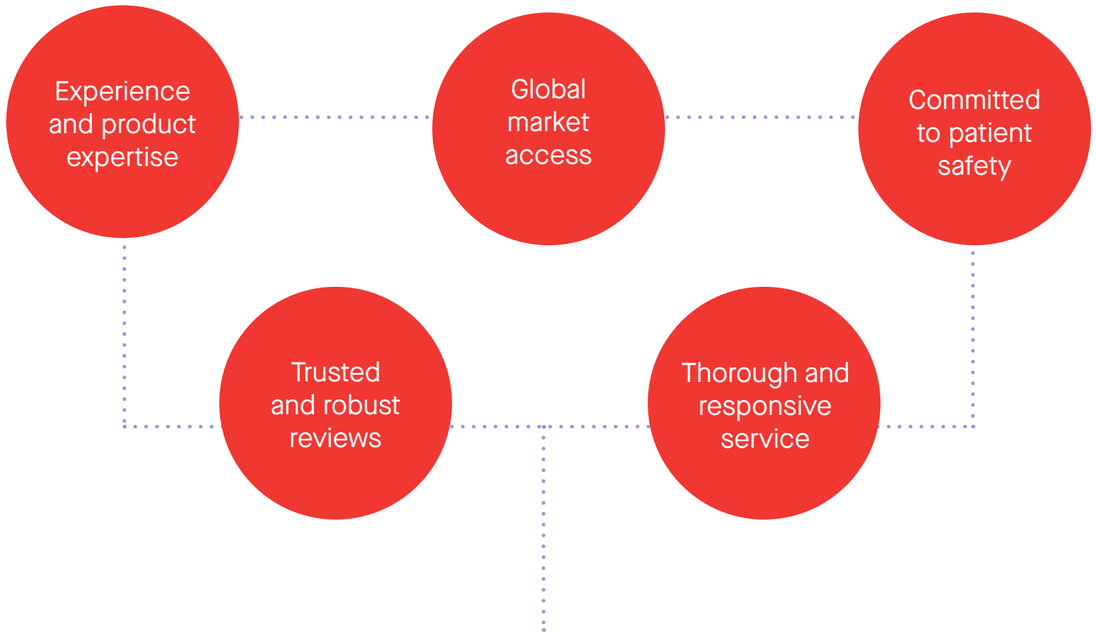


Why choose BSI



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 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 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 conformity 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 17021-1with ISO 13485, ISO 9001 and ISO 14001 in its scope.

We are a recognized certification body in Japan, Malaysia, Singapore. BSI NL (NB2797) a recognised "Notified Body partner" in Taiwan's Technical Cooperation Programme (TCP), and a recognized MDSAP auditing organization for all participating regulatory authorities.

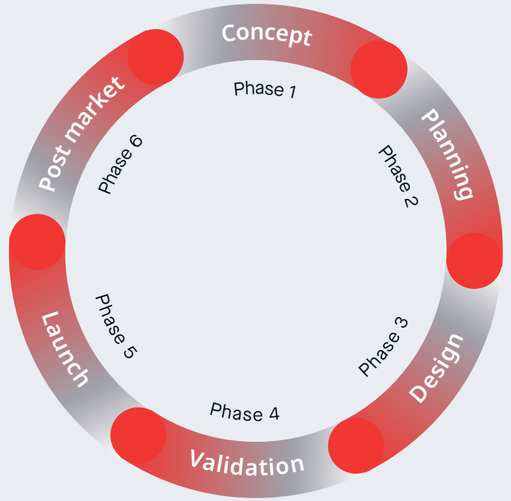
BSI Transfer

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 to BSI your existing certification?

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 process of CE or UKCA marking for devices within the scope of the medicinal and biologics team can be challenging, especially considering the borderline with other legislation such as medicines, cosmetics, human and animal tissues and cells. Engaging with us early will ensure the successful outcome of your application.

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/medicinal

and start your journey

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