



Your partner  
in progress

# Medicinal and biologics medical devices



# 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 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 these 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.

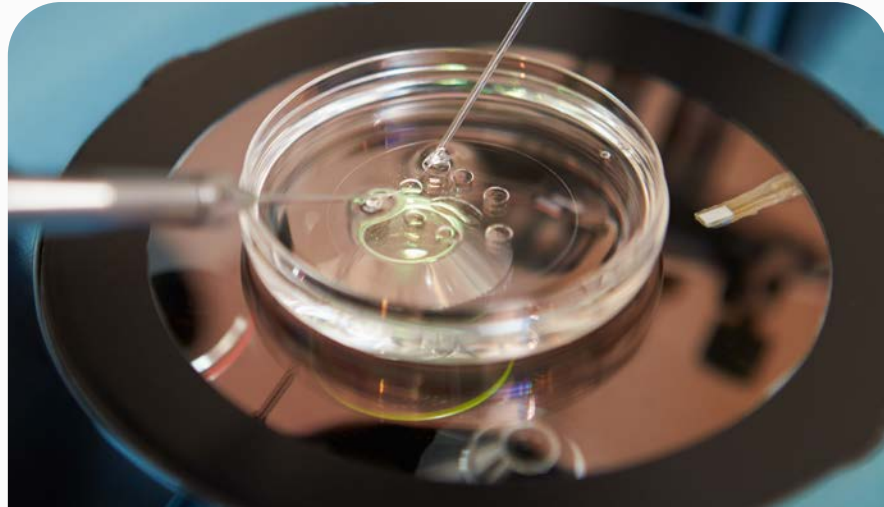
## Defining medicinal and biologics medical devices

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 biologics medical devices



In vitro fertilization



Animal tissue devices



Rule 21 devices



Article 117 devices



Rule 14 devices



Organ preservation

# 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.

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.

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

## 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 derivatives. 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.

“ It is such a privilege to lead the widely diverse group of professionals in BSI’s Medicinal and Biologic team.

As a specialised team we have extensive experience in the delivery of MDR Conformity Assessment services to the medical device sector, spanning MDR Rules 14, 18 & 21, devices for ART/ IVF and organ preservation, with expertise in borderlines classification issues and novel devices. We also are the leading Notified Body for the provision of MDR Article 117 Notified Body Opinion (NBo) to the Pharmaceutical sector.

I look forward to further develop Medicinal & Biologics service offering while delivering excellence to our clients.



**Theresa Jeary**

Global Head of Medicinal and Biologics,  
Regulatory Services, 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 Group The Netherlands B.V. (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 Group Assurance UK Ltd (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.

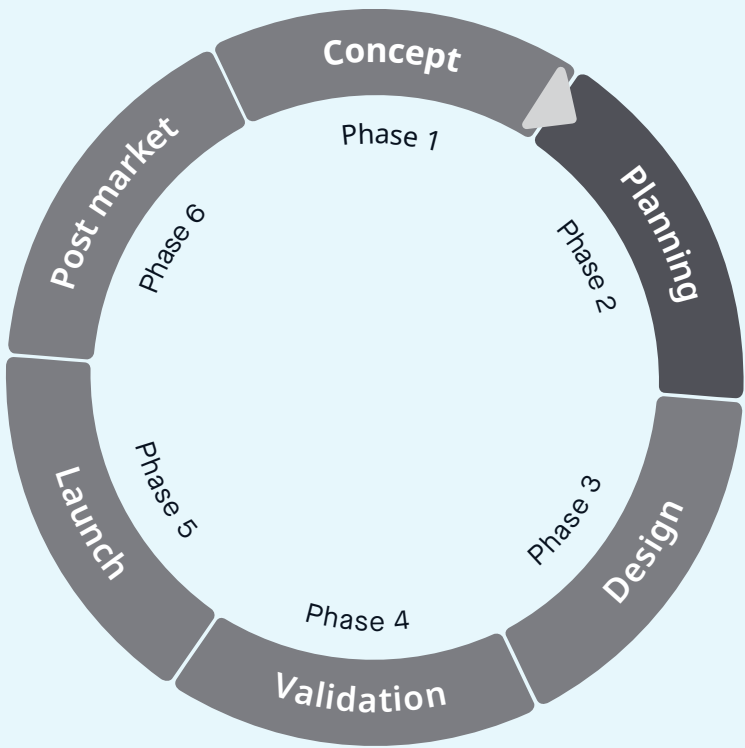
## BSI Transfer

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 regulations

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.



## 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 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.

[Request a quote](#)





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