Microbiology and Sterile Medical Devices

Setting the standard with our expert Microbiology team

As a manufacturer of a sterile medical device, meeting the necessary ISO 13485 regional and global regulations can be a challenging and complex process. It is critical to work with a notified body that understands the industry and has the experience to review and confirm your products' readiness for market – efficiently, promptly and robustly.

BSI has two Notified Bodies, one in the UK (0086) and one in the Netherlands (2797), both of which have full scope designations to the IVDR and MDR. We are the Notified Body of choice for over 90% of contract sterilization registrations worldwide.

bsi.

...making excellence a habit.™

What is microbiology and what are sterile medical devices?

A sterile medical device is a device that must be free from live bacteria or other microorganisms and their spores. Sterile medical device requirements are defined by national or regional standards and regulations, which detail the sterility requirements. Sterilization of a medical device may include exposure to ethylene oxide, gamma irradiation, steam, dry heat, or chemical sterilization under defined conditions, and any necessary post-treatment required for the removal of by-products.

Sterilization of medical devices is a specialized process and requires specific knowledge and expertise. We are passionate about patient safety and reducing patient risk through microbiology assessments, carried out by our qualified microbiologists.

A typical microbiology assessment from BSI would include:

- verifying effective controls are in place to assure the sterility and product bioburden of your medical device
- assessing your environmental monitoring and controlled environment room or cleanroom areas
- verifying effective implementation of sterility assurance levels through sterilization and sterile barrier validations
- assessing the suitability and effectiveness of disinfectants and sterilizers
- assessing the suitability and effectiveness of instructions for end user sterilization and reprocessing

Meet our experienced Microbiology team

Our Microbiology team has a broad range of medical, pharmaceutical, industry and regulatory experience, including product design and development, manufacturing, sterilization and product testing.

Our technical specialists have an average of 20 years' experience in the industry and understand the scientific aspects of the sterilization process. This world-leading experience supports you as a manufacturer by providing expert feedback on controlled environments and the sterility of your medical device.

"I am honoured to lead a team specializing in sterile medical devices. We ensure that manufacturing and sterilization processes are appropriately controlled and suitable work environments are consistently maintained. These critical processes are independently assessed by our expert microbiology technical specialist."

Lou Stinson

Global Head of Microbiology, BSI Medical Devices

From the experts

The implementation of the appropriate sterilization technique can be the difference between a medical device not receiving certification and one which is approved for use on the market to enhance and save patients' lives. Contact us early in the planning process for your sterile medical device submissions and certifications.

Reasons to make BSI your Sterile Medical Devices Notified Body

Experience and product expertise

The benefits of having experienced, professional and well-qualified technical specialists cannot be overstated in the complex and ever-changing medical device industry. BSI Medical Devices has a team of over 700; within that team are our technical experts with experience encompassing the full range of medical devices and management system standards.

BSI Group is a global network of over:

5,000 people supported by 12,000 industry experts in more than 193 countries

Focus on service

Clients work with us because we understand the challenges medical device 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.

Global market access

We are a global organization, trusted and recognized around the world. BSI has two Notified Bodies, one in the UK (0086) and one in the Netherlands (2797), both of which have full scope designations to the IVDR and MDR.

Confidence and robust reviews

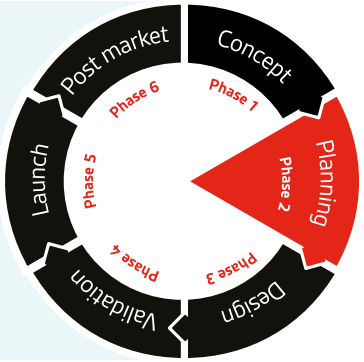
Our comprehensive review process combined with our world-leading experience as a Notified Body will ensure that your conformity assessment process is both efficient and robust.

Passion for 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, robust conformity assessments, evaluations and certifications.

The Product Lifecycle: when to consider 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. Consolidated clinical and regulatory planning will assist 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.



How can BSI support your medical device launch?

Be prepared

In the competitive medical device marketplace, ensuring that product development meets all regulatory requirements is essential. We provide guidance and training to support you through the application process.

Worldwide access

We offer a wide range of proven regulatory and quality management programs that work together for full 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 Hong Kong, Japan, Malaysia, Singapore and Taiwan, and a recognized MDSAP Auditing Organization for all participating Regulatory Authorities.

Seamless transfer to BSI

We can offer a seamless service with comprehensive support and the absolute minimum level of disruption.

Certification support and additional services

We offer continual support throughout the certification process and beyond; we also offer:

- **access to more than 34,000 standards** and related products, as well as online guidance documents
- **expert training** delivered online or face-to-face, either in-house or through our public training courses
- **regulatory updates** and a newsletter service focusing on industry changes, helping you to plan for the future
- **webinars** delivered by our experts on complex regulatory issues
- **comprehensive whitepapers** providing the latest insights on key industry topics

Navigating your transition to the IVDR and MDR

The Medical Devices Regulation (MDR) (EU) 2017/745 has a transition period of four years starting from May 2017, after which the Regulation will apply. The In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746 entered into force on the 25 May 2017 marking the start of a five-year transition period.

Manufacturers have the duration of the transition periods to update their Technical Documentation and processes to meet the new requirements if they want to place medical devices and in vitro diagnostic medical devices on the market in the European Union.

The MDR brings with it more scrutiny of Technical Documentation, addressing concerns over the assessment of product safety and performance by placing stricter requirements on clinical evaluation and post-market clinical follow-up. The IVDR brings with it significant changes to the regulatory requirements for IVD medical device manufacturers and introduces a new rule-based classification system with stricter notified body oversight, as well as significant changes to the depth and requirements of the associated Technical Documentation.

Visit our website for more information: bsigroup.com/medical

CE-Excellence: Technical Documentation Review

Our CE-Excellence: Technical Documentation Review services deliver the efficiency you need to be both competitive in the market and maintain confidence through our robust technical reviews.

CE-Standard

Our standard service reviews are completed by experienced BSI Product Experts, giving you confidence in the review.

CE-Dedicated

This service allows you to schedule your Technical Documentation review with a dedicated BSI Product Expert.

Five steps to getting your product to market

Step 1

BSI prepares a 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.

Step 2

BSI performs a conformity assessment

A dedicated BSI scheme manager will be assigned to you, supporting your organization throughout the process. A QMS audit will then be performed and all Technical Documentation reviewed by one of our experienced technical experts.

Step 3

Certification decision

Successful assessment leads to your BSI scheme manager recommending certification of your product. The BSI Certificate Decision Maker will then review the recommendation and, if satisfactory, approve certification.

Step 4

Issue certificate

Upon successful certification, you will be issued with a certificate. You will then be able to CE mark your product and launch to market.

Step 5

Certification maintenance

On-going surveillance audits and reviews are required to monitor for continued compliance. Your BSI scheme manager will be able to support you with any queries you might have.

Talk to BSI today

Call: **+91 11 2692 9000**

Visit: **bsigroup.com/microbiology-uk/** and start your journey

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