Microbiology and Sterile Medical Devices

By Royal Charter

EU Notified Body, UK Approved Body and Auditing Organization expertise

- As a manufacturer of a sterile 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 microbiology technical specialists have extensive experience in sterile 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 Auditing Organization.

Defining microbiology and sterile medical devices

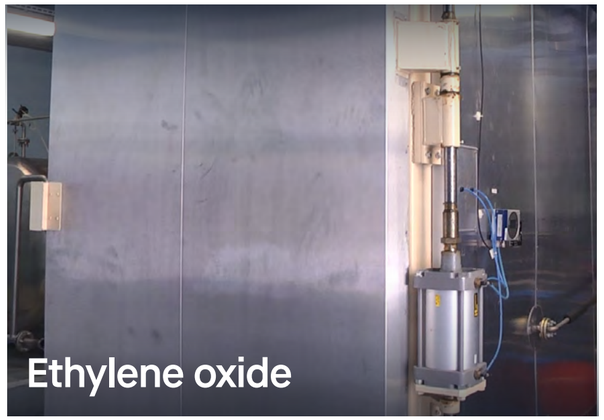
A sterile medical device is a device that must be free from viable bacteria or other microorganisms and their spores. Sterile medical device requirements are defined by national or regional standards and regulations, which detail the level of sterility assurance. Sterilization of a medical device may 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.

For more clarity on sterile medical devices and IVDs, please refer to MDR(EU)2017/745 and to IVDR(EU) 2017/746.

Sterilization Services and more

BSI maintains a full scope of sterilization modalities including non-standard methods. We are the preferred Certification Body for providers of sterilization and laboratory services under ISO 13485 and ISO 9001. Our management system expertise covers appropriate control of manufacturing processes and work environments, with a view to confirming end to end sterility assurance.



Preparing for a microbiology assessment

A microbiology assessment includes:

- Verification on the efficacy of controls in place for pre-sterilization bioburden, microbiological cleanliness and controls to assure your medical device sterility.
- Assessment of environmental monitoring and controlled environment.
- Verification of effective implementation of sterility assurance levels through sterilization and sterile barrier validations.
- Assessment of suitability and effectiveness of disinfectants and sterilizers.
- Assessment of suitability and effectiveness of instructions for end user cleaning, disinfection, sterilization and reprocessing.
- Assessment of product endotoxin testing including source.
- Verification of Sterile Release processes for all modalities.

Documentation Completeness Check

During a microbiology audit and assessment, the following documentation may be reviewed for technical content and completeness:

Controlled environment procedures and verification data, including:

- Air quality, including routine viable and non-viable monitoring
- Cleaning, disinfectant usage
- Gowning
- Disaster recovery planning
- Other facilities data as required (e.g., pest control logs/procedures, water system validation)

Routine sterilization procedures

Sterile load release records

Sterilization validation protocols, including any technical agreements and contracts

Sterilization validation data, including:

- Applicable load configurations/dosing maps and supporting data, as required
- Bioburden, bioburden recovery and endotoxin testing
- End-user sterilization instructions (if applicable)
- Sterility, including bacteriostasis/fungistasis
- Sterilant residual testing

Packaging equipment qualification and routine packaging procedures, including:

- Validation of sterile barrier including performance and stability testing

Training records as required for the activities previously listed

In addition to ISO 13485, reference to standards include:

- Controlled Environments: ISO 14644, ISO 14698, EN 17141, ISO 11737
- Sterile Device Packaging: ISO 11607 series
- Sterilization: ISO 11135, ISO 11137, ISO 17664, ISO 17665, ISO 14937, ISO 13408, ISO 10993, ISO 20857, ISO 22441

This is not a complete documentation list. Other documents may be identified during the audit.

Meet our Microbiology Team

We are the Certification Body of choice for over 90% of contract sterilization sites worldwide.

With an avarage of over 20 years of combined experience, 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 microbiology technical specialists fully understand the scientific aspects of the sterilization process and through their world-leading experience are able to provide expert assessment of controlled environments and medical devices sterility.

"I am honored to lead a highly experienced team of technical specialists. We are a truly international team with a deep knowledge of device sterilization processes. BSI's specialist assessment of the critical sterility processes to ensure device safety leads us to believe that this represents the most responsible approach that will enable us move forward together as we continue to support our customers, society and each other."

Lou Stinson, Global Head of Microbiology

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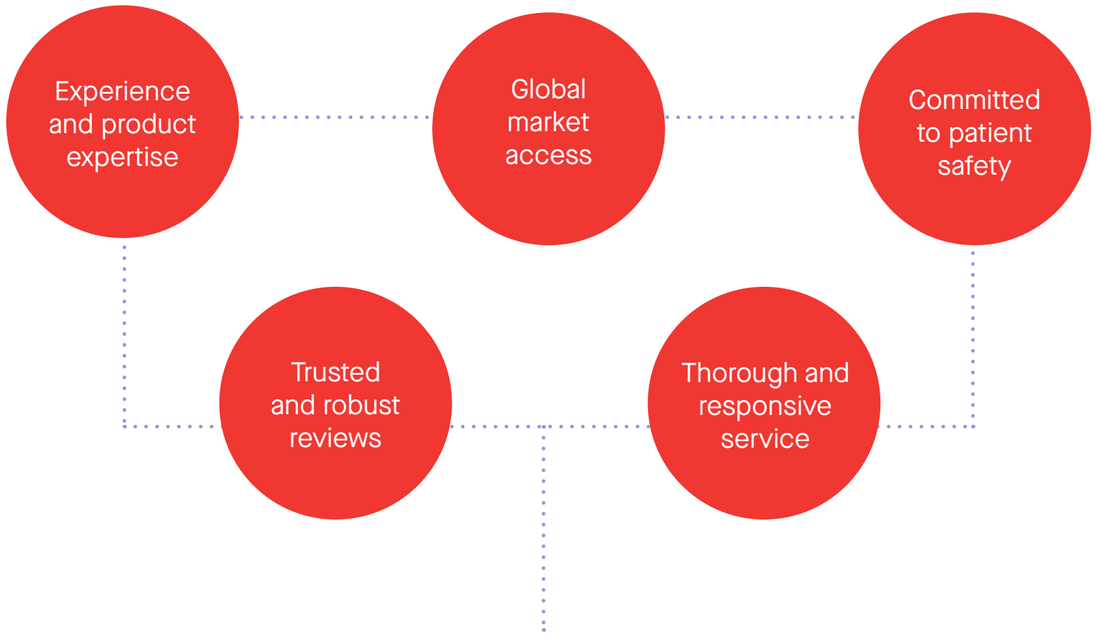
Why choose BSI



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).

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 one of our experienced 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 certification, 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 persistent 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. Our Quality Management System (QMS) solutions include ISO 13485, ISO 9001, ISO 14001 and many more.

We are a recognized certification body in Japan, Malaysia, Singapore and Taiwan, and a recognized MDSAP auditing organization for all participating regulatory authorities.

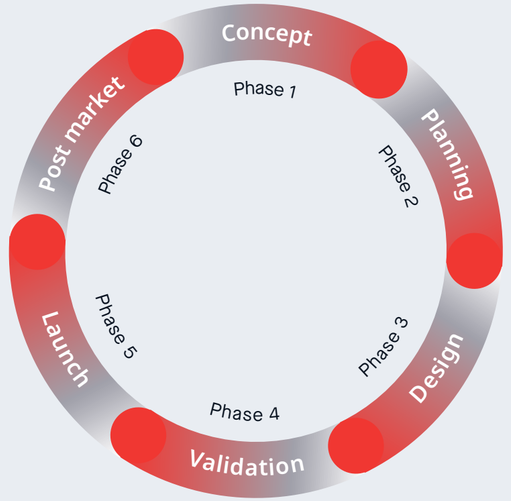
BSI Transfer

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 for 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 sterile medical devices can be challenging. The implementation of the appropriate sterilization technique is essential for 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/microbiology

and start your journey

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Read more about our certification services on our website **bsigroup.com/medical**

Find us on **LinkedIn**