

**bsi.**

● Medical Device  
Quality Management  
System Certification



# Introduction

Medical device manufacturing is one of the most regulated sectors in which significant quality system and product requirements must be satisfied.

Regulatory requirements are intended to ensure that manufacturers consistently design, produce and place onto the market, medical devices that are safe, and operate in accordance with their intended purpose.

A medical device manufacturer's quality management system (QMS) represents a solid foundation to maintain manufacturing and operational high-quality standards, while complying with regulatory requirements.

A compliant QMS drives improvement and effectiveness, whilst promoting trust in the manufacturer and in the devices placed on the market, as well as on other processes involved in the medical device life-cycle, such as design, development, production, storage and distribution.



## Understanding Medical Device Quality Management System Certification

EN ISO 13485 is an effective solution to meet the comprehensive requirements for a QMS. Adopting EN ISO 13485 provides a practical foundation for manufacturers to address the regulations and responsibilities, as well as demonstrating a commitment to the safety and quality of medical devices.

EN ISO 13485 supports medical device manufacturers in designing a QMS that establishes and maintains the effectiveness of their processes. EN ISO 13485 covers several aspects of medical device manufacturing processes and related services, including design, development, production, installation, and delivery through to disposal.

### BSI's approach

BSI selects and recruits professionals to conduct EN ISO 13485 audits based on their qualifications, experience, and expert knowledge of medical device design, development, functioning and manufacturing. Our auditors come to BSI with exceptional first-hand industry experience, which is maintained and enhanced through BSI internal training and qualification processes. This includes best practice quality system auditing techniques, understanding of critical manufacturing processes and interpretation of regulatory compliance expectations.

BSI auditors are experts in current state-of-the-art and are constantly trained on new requirements and future changes. BSI is always looking ahead to ensure that our clients are informed of future changes to compliance and the regulatory landscape.

“As I look over the 20 years that 3M Unitek and BSI have worked together, it has been a very satisfying part of my career. The professional and collegial atmosphere BSI brings to these audits strongly encourages us to want to continually improve our quality management system. Please convey my great appreciation to you and your colleagues for this.”

**Jerry Horn, PhD**

Manager, Quality and Regulatory,  
3M Orthodontic Products



# EN ISO 13485 and CE marking

EN ISO 13485 is the harmonised standard that medical device organisations can implement to demonstrate the ability to provide medical devices and related services that meet both patient needs and regulatory requirements.

EN ISO 13485 represents the most recognised quality management system standard to fulfil European Regulations requirements for CE marking.

Although adopting EN ISO 13485 is not a mandatory requirement for CE marking, the standard is harmonised, and thus applies for the purposes of presumption of conformity with the relevant requirements of EU Regulations (MDR, IVDR).

## Find out more

We have developed a range of additional resources, including webinars, whitepapers, and training courses to help increase your knowledge on EN ISO 13485

**[www.bsigroup.com/ISO-13485](http://www.bsigroup.com/ISO-13485)**

When it comes to medical device manufacturing, patient safety greatly depends on the quality and consistency of medical products.



# The importance of EN ISO 13485

EN ISO 13485 is critical to manufacturers but also to importers, suppliers and distributors to enhance their organisation's trust and marketability, particularly as more and more manufacturers require EN ISO 13485 certification when outsourcing certain medical device related services.

When it comes to medical device manufacturing, patient safety greatly depends on the quality and consistency of the QMS in which medical devices are manufactured. Ensuring effectiveness, control and maintenance of your QMS is critical to customers, stakeholders, patients, users and Competent

Authorities. The value of EN ISO 13485 is not just in its implementation, but also in providing practical guidance on organisational internal processes for the assessment of your QMS effectiveness.





“Successfully certified organisations can demonstrate the effective interconnectivity of their processes. It is essential to be able to demonstrate how outputs from complaints, for example, feed into management review, improvement processes, technical documentation, and risk management updates, to name a few”

Bill Enos, PhD  
Global Assessment Delivery Director, BSI

# Why choose BSI?

## Readiness

In the competitive medical device sector, ensuring that product manufacturing processes and related services meet the relevant regulatory requirements are essential. We will support you through the application and certification process

## Worldwide Access

We offer a wide range of regulatory and quality management certification services that work cohesively for international compliance.

BSI The Netherlands (2797) is a leading, full scope Notified Body; we review your medical device to assess conformity against European Regulations.

BSI UK (0086) is a full-scope UK Approved Body; we review your medical device to assess conformity against UK Regulation.

BSI is also an accredited EN ISO 13485 Certification Body and a recognized Auditing Organization under the Medical Device Single Audit Program (MDSAP).

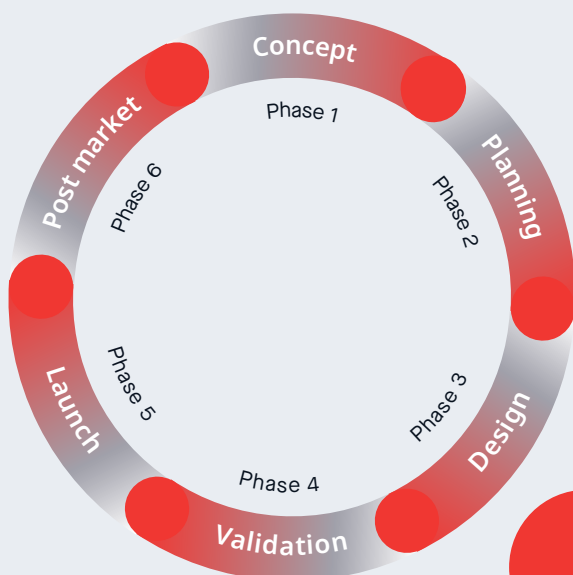
## BSI Transfer

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 will 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, <https://bsigroup.com/en-GB/medical-devices/our-services/product-lifecycle/> for more information about the product lifecycle

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