

Our global expertise for your medical device

Passionate about patient safety

Our mission is to ensure patient safety whilst supporting timely market access to global medical device technology. We strive to set the global standard in thorough, responsive, robust conformity assessments, evaluations and certifications that are recognized and trusted worldwide.

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 new UKCA scheme.

Experience, product expertise and a focus on service

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 750; within that team are:

- our technical specialists with experience encompassing the full range of medical devices and management system standards
- our Quality Management System (QMS) auditors and client managers who maintain the latest credentials in their fields and have undergone intensive training to assess your QMS
- our microbiologists who provide complete confidence in the sterility of your medical device. Sterilization is a critical step in the process of manufacturing a medical device to ensure patient safety

Over 95%* of the top medical device manufacturers work with BSI because we understand the challenges manufacturers face in bringing compliant products to market efficiently and safely. 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.

BSI is a global network of over



Global market access

We are a global organization, trusted and recognized around the world.

We offer a wide range of proven regulatory and quality management services that work together for full international compliance and provide efficient pathways to bring your product to market. Our 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.

Seamless transfer to BSI

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

*95% of the top 20 manufacturers as listed by MedTech Insight, Pharma intelligence.



Full range of certification services for all medical devices

Our Medical Devices team has a broad range of industry, clinical and regulatory experience, including product design and development, manufacturing and clinical practice. We understand the specifics of these complex products through their full lifecycle and are able to offer CE certification services for medical devices and in vitro diagnostic (IVD) medical devices under the existing Active Implantable Medical Devices Directive (AIMDD), Medical Devices Directive (MDD) and In Vitro Diagnostic Medical Devices Directive (IVDD), and the new In Vitro Diagnostic Medical Devices Regulation (IVDR) and Medical Devices Regulation (MDR).

Examples of the medical devices we cover include:



Vascular



Dental



Orthopaedic



Ophthalmic



IVD



Woundcare



Animal Derivatives



Active



Drug/Device



Microbiology



Active Implantable

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

“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

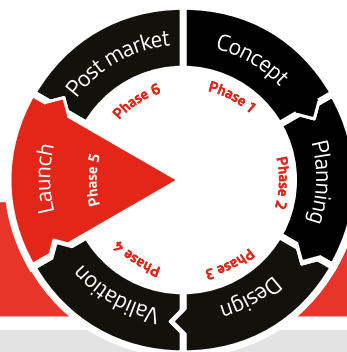
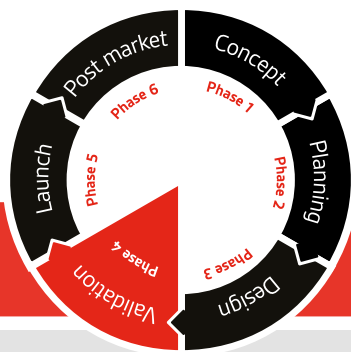
Manager, Quality and Regulatory, 3M Orthodontic Products

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.





Validation

Final validation of manufacturing process and preparation for product introduction

- Market plan/forecast
- Process validation
- Clinical validation
- Product claims
- Final labelling
- Regulatory submission
- Product reimbursement
- EU CE and UKCA marking
- Global market access certification

How BSI can support you

- EU CE and UKCA marking
- QMS ISO 13485
- MDSAP
- Global market access certification
- Training
- Business and technical standards
- Compliance Navigator

Launch

Product launch

- Regulatory approval
- Sales and clinician training
- Launch product to market
- Individual country reimbursement approval

How BSI can support you

- EU CE and UKCA marking
- QMS ISO 13485
- MDSAP
- Global market access certification
- Training
- Business and technical standards
- Compliance Navigator

Post market

Post market surveillance

- Post market surveillance
- Post market clinical follow-up
- Complaints and adverse events
- Product improvements
- Process improvements
- External body audits
- Market performance
- New market launches

How BSI can support you

- QMS ISO 13485
- Global market access
- Training
- Business and technical standards
- Compliance Navigator

Regulatory and quality management programs and services

Product certification

Our comprehensive approach offers you a wide range of proven regulatory and quality management programs to support you in bringing compliant products to market efficiently and safely. These include:

CE marking

CE marking is the medical device manufacturer's claim that a product meets the General Safety and Performance Requirements (GSPR) of all relevant European Medical Device Regulations and is a legal requirement to place a device on the market in the European Union.

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 IVD medical devices on the market in the European Union.

Our [IVDR Best Practices Guidelines](#) and [MDR Best Practices Guidelines](#) provide guidance on preparing and structuring your Technical Documentation.

UKCA marking

UKCA marking came into force in Great Britain in January 2021 when the UK left the European Union. UKCA Certification is available from UK appointed Approved Bodies, such as BSI (0086). There will be a transition period to 30 June 2023 to allow existing CE certifications to be replaced by the new UKCA mark. From 1 January 2021, medical devices must be registered with the MHRA before being placed on the UK market irrespective of whether UKCA marked or CE marked. Please refer to the MHRA timelines for the risk class of your medical device.

For Northern Ireland, the EU MDR and IVDR will apply from 26 May 2021 and 26 May 2022 respectively. Even after 1 July 2023, a CE mark will continue to be required for medical devices placed on the Northern Ireland market and manufacturers will need to meet EU regulations.

Brazil ANVISA

All medical devices in Brazil are regulated by the Brazilian Health Surveillance Agency (ANVISA). ANVISA requires that all devices must complete a device registration process. Non-Brazilian

manufacturers need a local Brazilian Registration Holder (BRH) based in Brazil to submit technical files to ANVISA. BSI is an accredited MDSAP Auditing Organization in Brazil.

Japan PMD Act

The revised Japan Pharmaceutical and Medical Device (PMD) Act expands regulation of medical devices sold in Japan. The Act includes requirements for both product and system certification to allow Japanese market access. BSI is one of four Registered Certification Bodies (RCB) that is authorized to conduct certifications by the Ministry of Health, Labour and Welfare (MHLW) for all types of Class II Designate Controlled Medical Devices and In Vitro Diagnostic Reagents.

Malaysia CAB

The Malaysian Medical Device Act 2012 (Act 737) was fully enforced on 1 July 2013. BSI is accredited to conduct product verification, Good Distribution Practices for Medical Devices (GDPMD), ISO 13485 and full conformity assessment processes according to Medical Device Act 737/2012. Working with a CAB is essential for any medical device organization applying for product license if you are either a distributor, a local authorized representative or a manufacturer based in Malaysia.

Taiwan TCP

Manufacturers wishing to sell their products in Taiwan must comply with registration requirements of the Taiwan Food and Drug Administration (TFDA). BSI is a partner in the Technical Cooperation Programme (TCP) on exchange of medical device GMP and ISO 13485 Audit Reports between EU Notified Body Partners and TFDA Authorized Medical Device GMP Auditing Organizations.

Ukraine recognition programme

BSI has signed an agreement with major Ukraine Conformity Assessment Bodies in order to offer manufacturers the possibility to submit BSI CE and QMS conformity assessment documentation to their Ukrainian Conformity Assessment Body to support local approval.



Quality Management System (QMS) certification

The ISO 13485 standard is an effective solution to meet the comprehensive requirements for a QMS. Adopting 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.

Visit our website: bsigroup.com/13485

Pre-assessment service

An opportunity for a manufacturer to have an optional preliminary assessment to identify gaps in their QMS and prepare them for their assessment. This is only available for ISO 13485 certification as a standalone service.

The Medical Device Single Audit Program (MDSAP)

MDSAP allows a single audit of a medical device manufacturer's QMS, which satisfies the requirements of multiple regulatory jurisdictions. Audits are conducted by Auditing Organizations, such as BSI, which are authorized by the participating Regulatory Authorities to audit under MDSAP requirements.

MDSAP is a way that medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets:

- **Australia** – Therapeutic Goods Administration (TGA)
- **Brazil** – Brazilian National Health Surveillance Agency (ANVISA)
- **Canada** – Health Canada (HC)
- **United States** – US Food and Drug Administration's Center for Devices and Radiological Health
- **Japan** – Ministry of Health, Labour and Welfare (MHLW) and Pharmaceutical and Medical Devices Agency (PMDA)

A BSI MDSAP audit can also be combined with assessment for CE, UKCA and ISO 13485.

Visit our website: bsigroup.com/MDSAP

As the need arises, additional services are added to our range. Visit our [website](https://bsigroup.com) for the full range of services we offer

Complementary BSI services

ISO 9001 Quality Management

The world's most widely adopted QMS standard and used by organizations of all sizes. This powerful business improvement tool can help organizations improve customer satisfaction, boost resilience and build for the long term.

BSI Kitemark™

The Kitemark, which is widely recognized in the United Kingdom, is a product and service certification mark. The Kitemark is a symbol of integrity, quality and trust.

ISO 45001 Occupational Health and Safety Management

Ensuring employee safety is critical and provides a framework that will help you identify and mitigate risk as well as defend and protect your workforce, reputation and brand.

ISO 14001 Environmental Management

The most established international environmental management system will help you to reduce environmental risk, improve environmental performance and show stakeholders that regulatory requirements have been met.

EN 60601 Electrical and Electronics

The standard provides assurance to electrical engineers, electricians and product designers on safety, performance and compliance for an extensive range of equipment. The standard can support in the assessment of your product for CE marking, which is required to place a product on the market in the European Union.

Cybersecurity and information

BSI can support organizations with their cybersecurity and information resilience through world-leading technical solutions, research and training.

IEC/ISO 27001 Information Security Management

An excellent framework to support organizations in managing and protecting their information assets so that they remain safe and secure.

ISO/IEC 27001 also provides a tool to review and refine your information security management systems for your organization in the future.



BSI training for Medical Devices

Turning our experience into your expertise

Medical device training courses

CE marking

- IVDD to IVDR Transition
- MDD to MDR Transition
- Requirements and Implementation of the IVDR
- Requirements and Implementation of the MDR

ISO 13485

- ISO 13485:2016 Transition
- ISO 13485:2016 Auditor Refresher
- ISO 13485:2016 Transition and Auditor Refresher Combined
- ISO 13485:2016 Senior Management Briefing
- Introduction to ISO 13485:2016
- ISO 13485:2016 Clause by Clause
- Implementing ISO 13485:2016
- Internal Auditor ISO 13485:2016
- Lead Auditor ISO 13485:2016 (BSI certified, TPECS)

Global Market Access

- Medical Device Single Audit Program (MDSAP)

Specialist Training Courses

- Clinical Evaluation for Medical Devices
- Introduction to Medical Device Software
- Introduction to Risk Management for Medical Devices
- Manufacturing Process Validation for Medical Devices
- Performance Evaluation and Clinical Evidence for IVDS
- Post Market Surveillance and Vigilance under the IVDR and MDR
- Technical Documentation for IVDS
- Technical Documentation for the MDR

ISO 13485 Auditor Qualifications

Our auditor qualifications for ISO 13485 Quality Management Systems provide the knowledge and skills you need. First you'll become an auditor practitioner, and then you'll learn techniques in process improvement to become a professional auditor. Once you've achieved your professional qualification, you can apply to become certified – a three-year rolling programme to validate the practical application of your continuing professional development and learning within your industry.

Why choose BSI for your training?

- **World-leading industry subject matter experts** with over 200 BSI Medical Device product and regulatory training experts
- **State-of-the-art courses** representing up-to-date thinking on the current and possible future interpretations of EU directives and regulations, standards and guidance
- **Accelerated learning technique** – actively participate in hands-on exercises, case studies, group work, mock real-life situations and learning aids including photos, charts, games and quizzes
- **In-house, online or public** – it's your choice. We regularly schedule public courses or, if you prefer to have a group of employees attend a course together, choose in-house. For complete flexibility, you can also join a live classroom-style course online, led by the same expert tutors
- **Cost efficient** – a BSI training course can provide you with the knowledge to save significant time and money in bringing your product to market
- **Make excellence a habit** – BSI training will prepare you to take the excellence habit back to your business

More than 5,500
delegates trained

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

Technical Documentation Review

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

Standard

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

Dedicated

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

Five steps to CE or UKCA marking your product

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 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 or UKCA 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: **+34 91 400 86 20**

Visit: bsigroup.com/medical
and start your journey



BSI UK Approved Body (0086)

Kitemark Court, Davy Avenue
Knowlhill
Milton Keynes MK5 8PP
United Kingdom

T: +44 345 080 9000

E: medicaldevices@bsigroup.com

BSI The Netherlands Notified Body (2797)

Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780

E: eu.medicaldevices@bsigroup.com

The trademarks in this material (for example the BSI logo or the word "KITEMARK") are registered and unregistered trademarks owned by the British Standards Institution in United Kingdom and certain other countries throughout the world.

bsigroup.com