BSI Regulatory Services for Medical Devices

Global Expertise

bsi.

...making excellence a habit.™

BSI Regulatory Services puts the patient at the heart of our work

We ensure patient safety while supporting timely market access for our clients' medical device products globally.

We provide our customers with thorough, responsive, predictable conformity assessments and certifications that are recognized and accepted worldwide.

Benefits of working with an industry leader

The challenges medical device manufacturers face in today's highly competitive marketplace make it essential to ensure that your products meet all regulatory and quality requirements. It is critical to work with a leader who understands the industry and has the experience to review and confirm the products' readiness for market – efficiently, reliably and robustly. BSI is a company that leads the way in working with manufacturers to navigate through the maze of regulatory requirements.

We are a trusted, world-class Notified Body dedicated to providing rigorous regulatory and quality management reviews and product certifications for medical device manufacturers — around the world. For more than 100 years, BSI's expertise has provided an assurance of safety and quality to manufacturers in over 180 countries.

A robust route for getting your products to market

As a client of BSI you will have confidence knowing that we conduct robust, comprehensive assessments that will stand up to scrutiny. We are well-known worldwide for our efficient and predictable service, meaning you will know what to expect with timely results. This creates the best route to market for you.

Appreciate our unique combination of advanced technological knowledge and accessibility. You will be assigned a dedicated Scheme Manager with product expertise relevant to your devices, and they will remain your point of contact through certification and beyond.

BSI works with a significant number of manufacturers, with a variety of products from novel to complex to high risk. We work with companies just starting out to large multinationals. We understand that each company and product are at different stages and have unique needs and priorities.

Five core reasons to choose BSI Medical Devices

We understand that obtaining certification and compliance can be a long and complicated journey. There are often "shortcuts" to market readiness, but BSI believes in excellence and that shows in our reviews.

When you work with BSI, you'll benefit from more than exceptional product and regulatory expertise: our team of dedicated professionals provides comprehensive support. Our solutions ensure cost-effective certification that stands up to scrutiny and supports your long-term goals.

When choosing BSI you can rely on our five core values:

1. **Product expertise** – our diverse and experienced team brings in-depth knowledge and understanding of complex medical device technologies.
2. **Global access** – we operate in over 180 countries with more than 100 years of experience and local offices around the world to serve you.
3. **Robust reviews** – providing flexible solutions for manufacturers needing efficient pathways to global markets.
4. **Confidence** – our stringent review process combines reliability with experience, integrity, independence and predictability.
5. **Experience** – our team has over 2,700 years' combined industry and regulatory experience, so we understand the challenges you face.

The preferred choice for **product expertise**

Over **95%*** of the top medical device companies work with BSI:
our extensive expertise enables us to support your market access needs.

BSI employs over 180 Quality Management System (QMS) assessors and over 130 medical device experts with experience in all aspects of the product life cycle including research and development, manufacturing, clinical and quality assurance. BSI is proud to cover all NBOG codes, ensuring that we can provide full service reviews.

We offer specialized in-house expertise in areas ranging from sterilization processes, and animal tissue utilization to combination medical device products.

Our core competencies and unique skills are calibrated to handle our customer's extensive portfolio of medical technologies including nanomaterials and software.

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

Regulatory and **quality management** programs and services

Product Certification

Our comprehensive approach offers you a wide range of proven regulatory and quality management programs that all work to move your medical devices to international markets promptly. These include:

CE marking

CE marking is the medical device manufacturer's claim that a product meets the Essential Requirements of all relevant European Directives or Regulations and is a legal requirement to place a device on the market in the European Union. The three medical devices directives are:

- Medical Devices Directive (MDD)
- Active Implantable Medical Devices Directive (AIMDD)
- In Vitro Diagnostic Directive (IVDD)

Following entry into force of the new Regulations on May 25th 2017, manufacturers have three years to transition to the new Medical Devices Regulation and five years to transition to the IVD Regulation. Until manufacturers have transitioned to the new Regulations, the requirements of the relevant Medical Devices Directive will apply. Make sure you're up to date with the latest requirements by using our comprehensive resources.

A BSI Readiness Review document can be used to start your transition planning, this document is also available via our revision webpages:

bsigroup.com/IVDR-Revision
bsigroup.com/MDR-Revision

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 a Registered Certification Body for certification of all Class II and designated Class III devices.

Malaysia CAB

The Malaysian Medical Device Act 2012 (Act 737) was fully enforced as of the 1 July 2013. BSI is accreditated to conduct product verification, Good Distribution Practices for Medical Devices (GDPMD), ISO13485 and full conformity assessment processes according to Medical Device Act 737/2012. Working with a CAB is essential for any medical device organization to apply for product lincense if you are either a distributor, a local authorized representative or a manufacturer based in Malaysia.

Brazil

BSI Brazil has extended their scope of INMETRO accreditation to include product certification to 60601 (safety of electro-medical, active, devices). INMETRO 60601 product certification is mandatory for electro-medical devices intended to be placed into Brazil before the manufacturer can receive ANVISA regulatory market clearance. As an INMETRO product Certification Body BSI Brazil can now receive applications from manufacturers outside Brazil.

Taiwan Technical Cooperation Programme (TCP)

The TCP allows exchange of Medical Device GMP and ISO 13485 Audit Reports between Accredited EU Notified Bodies and TFDA-authorized Auditing Organizations, replacing the requirement to submit QMS documentation.

Urkaine recognition programme

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

Quality Management

ISO 13485 Quality Management

ISO 13485 is an international standard recognized for medical device QMS registration. It helps manufacturers consistently manufacture devices that are safe and fit for their intended purpose, and meet regulatory requirements for manufacturing control. BSI is an accredited third party that conducts on-site assessments and makes recommendations for certification.
bsigroup.co.uk/ISO13485Revision

Pre-Assessment Service

An opportunity for a company to have an **optional** preliminary assessment to identify gaps in their QMS to prepare them for their assessment.

The Medical Device Single Audit Program (MDSAP)

MDSAP is an international initiative led by Regulatory Authorities (RA) to implement a program where Auditing Organizations (AO) can conduct a single audit of a medical device manufacturer that would be accepted by multiple regulators to address QMS/GMP requirements. The five RAs involved are: Australian TGA, Brazilian ANVISA, Health Canada, Japanese MHLW and US FDA. BSI is an approved AO for MDSAP. **bsigroup.co.uk/MDSAP**

Note: *As of 1st January 2019, Health Canada will only accept MDSAP certificates in place of CMDCAS certificates. Please speak to your Certification Body about your transition*

As the need arises additional services are added to our range.

Visit our website to learn more about our new services

BSI Transitions

Medical Devices Regulation

In Vitro Diagnostic Regulation

"Working with BSI gives our customers confidence in the products they're purchasing from us, because of BSI's reputation as a robust and trusted Certification Body."

Vanessa Mootoosamy,
Quality Manager at Opsens Inc.

Complementary BSI Services

BSI is a leading global independent business services organization that inspires confidence and delivers assurance to customers with standards-based solutions. Some of our additional services include:

ISO 9001 Quality Management

The worlds' 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 highly recognized in the United Kingdom, is a product and service certification mark, and is a symbol of trust, integrity and quality.

Product Testing

BSI has formed an alliance with the Canadian Standards Association, CSA Group. With more than 90 years of experience, CSA Group is a leading testing and certification organization in the USA and Canada. CSA Group is an accredited and accepted by ANSI, OSHA and SCC. CSA Group is also a member and national CB Scheme certification body of IECEE.

OHSAS 18001 Occupational Health & Safety Management

Ensuring employee safety is critical and this provides a framework that will help you identify and mitigate risk as well as defend and protect your workforce, reputation and brand. (Note OHSAS 18001 will be replaced by ISO 45001 in 2018).

ISO 14001 Environmental Management

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

Electrical and Electronics

Standards can help electrical engineers, electricians and product designers ensure safety, performance and compliance for a huge range of equipment. Standards can also help you achieve CE marking, needed for European market access.

Cybersecurity and Information Resilience

We can help organizations boost their cybersecurity and information resilience through solutions including technical solutions, research, and training.

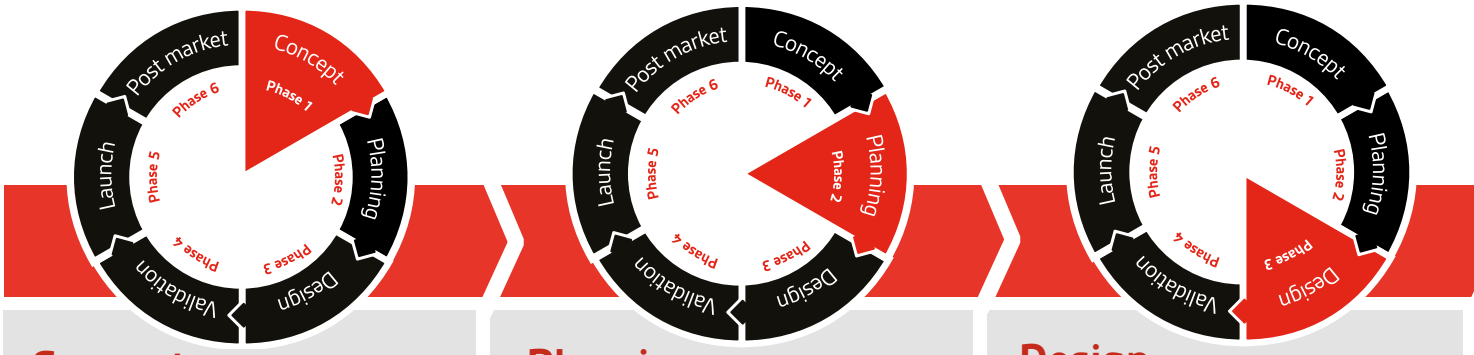
IEC/ISO 27001 Information Security Management

An excellent framework to help organizations manage and protect information assets so that they remain safe and secure.

ISO/IEC 27001 helps organizations continually review and refine how this is done, not only for today, but also for the future.

When should you consider **regulatory and quality requirements?**

In the competitive medical device market place, ensuring that product development meets all regulatory requirements is essential. Understanding and consideration of the complicated clinical and regulatory requirements early in the product lifecycle could ensure your company gains the competitive advantage needed to bring a product to market. Consolidated clinical and regulatory planning will assist your company to maximize resources and minimize time to market, and reduce the risk of costly development reworks.



Concept

Initial evaluation of possible development of commercial product

- Is it a medical device?
- Intended use
- Initial risk analysis
- Product definition and intellectual property
- Commercial plan
- Potential markets and routes
- Draft regulatory
- Personnel/resource requirements

How BSI can support you
Training
Business and technical standards
Compliance Navigator

Planning

Definition of design input based on customer needs and technical requirements

- Concept development
- Prototype analysis
- Initial testing
- Design file and risk analysis
- User feedback
- Commercial and market strategy
- Regulatory strategy
- Quality management system
- Project plan

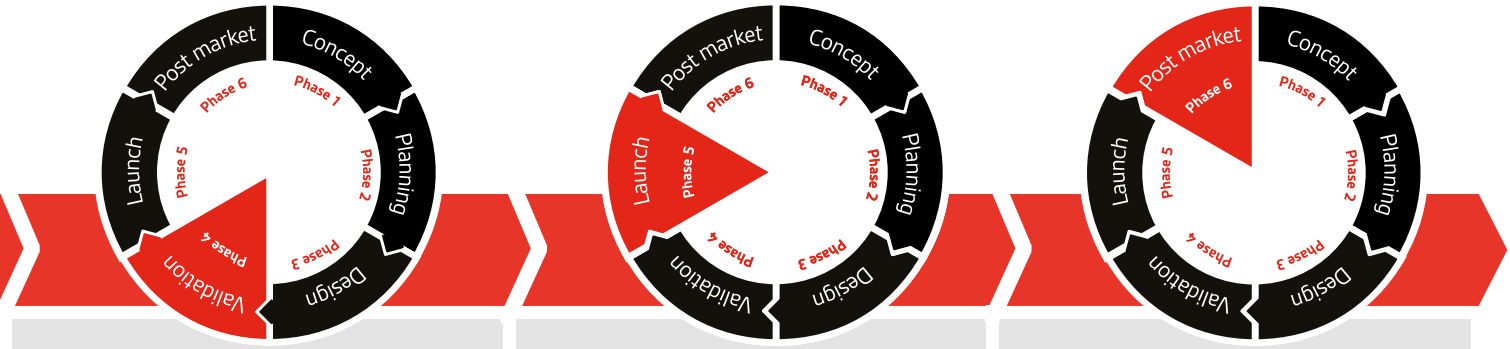
How BSI can support you
QMS ISO 13485
MDSAP
Training
Business and technical standards
Compliance Navigator
QMS ISO 13485 pre-assessment

Design

Development of product design and of manufacturing process, verification and validation

- User feedback
- Manufacturing process
- Design verification and validation
- Risk management
- Draft technical documentation
- Regulatory strategy
- Product claims and branding
- Regulatory requirements

How BSI can support you
QMS ISO 13485
MDSAP
Training
Business and technical standards
Compliance Navigator
QMS ISO 13485 pre-assessment



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 marking
- Global market access certification

How BSI can support you

EU CE 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 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

CE Excellence: Meeting requirements without compromise

BSI has a strong commitment to providing the most experienced and efficient routes to global markets.

Our trusted review services combine efficiency with the integrity, independence and robustness you have come to expect from BSI.

BSI CE-Excellence services are designed for medical device manufacturers wanting to get their products to European markets efficiently and safely.

CE-Standard

The CE-Standard review service allows you to work closely with your assigned BSI Technical Specialist on your product certification. These reviews are conducted remotely, with communication between you and your BSI Technical Specialist via phone and email, as required.

CE-Dedicated FastTrack

The CE-Dedicated FastTrack review service allows you to book your technical documentation review in advance. The service is conducted remotely with your BSI Technical Specialist, who uses the time allocated to your company to conduct a focused review of your technical documentation. This allows you to interact with your BSI expert, providing them information during the review. The CE-Dedicated FastTrack service improves the efficiency of the process, and provides predictability in your planning of the review.

CE-Onsite FastTrack

The CE-Onsite FastTrack review service is conducted at your premises; a BSI Technical Specialist visits the facility for a period of time. CE-Onsite FastTrack reviews allow for dynamic communications and opportunities for immediate responses to questions raised by the reviewer. Planning a CE-Onsite FastTrack review in advance provides you with more predictability and the reassurance of knowing when your BSI Technical Specialist will be at your premises.

Note: Our services do not guarantee a CE marking certificate will be issued within a certain amount of working days, but are based on completing the review process with either a positive or negative recommendation. CE-Dedicated FastTrack and CE-Onsite FastTrack are not available for devices utilizing animal tissue, blood derivatives or medicinal substances.

Technical Specialist and more. **Why BSI?**

The benefits of having professional, experienced and well-qualified Technical Specialists cannot be overstated when it comes to meeting customer needs and handling the ever-changing, complex medical device industry. BSI's Medical Devices Team has a combination of regulatory as well as industry expertise to meet these challenges.

Technical Specialists

Strong, robust technical documentation is the heart of the manufacturer's claim of compliance and thorough review by a Technical Specialist provides the manufacturer confidence for signing defendable Declarations of Conformity. At BSI we use Technical Specialists to conduct the technical visits. Our highly trained Technical Specialists have the knowledge, background and skill to handle technical documentation evaluations, which are substantially different than quality management audits.

Project Management Team

A Project Management Team is assigned, based on the needs of each customer. The team's responsibility is to manage the account, organize the necessary steps, oversee the proper flow of all documentation and coordinate the scheduling. The Team may include a Team Leader, BSI Scheme Manager, Client Manager, Technical Specialist, QMS Assessor (Auditor), and Microbiologist, along with the Sales Representative and Client Services Coordinator.

Microbiologists

BSI requires the use of trained Microbiologists because sterility is critically important to many medical devices. Anything less than complete confidence in a manufacturer's level of sterilization control could place patient safety in significant jeopardy. As a key step in the manufacturing process, sterilization must be closely reviewed. Whether products are sold as sterile or ultimately consumed as sterile, the sterility process requires 100% confidence as the ramifications of failure in this area are enormous.

After experiencing a BSI Microbiologist assessment, many manufacturers have reported implementing positive changes from the feedback they received.

Quality Assessors

BSI Client Managers are our Assessors, or Auditors. They are experienced in the medical device industry, which gives them a greater understanding of the customers' challenges. In addition, BSI Client Managers have undergone extensive training programs and maintain strong credentials in their fields of expertise.

BSI will always ensure that your Client Manager has the appropriate expertise and qualifications to assess your QMS.

BSI is known for its fair but robust audits.

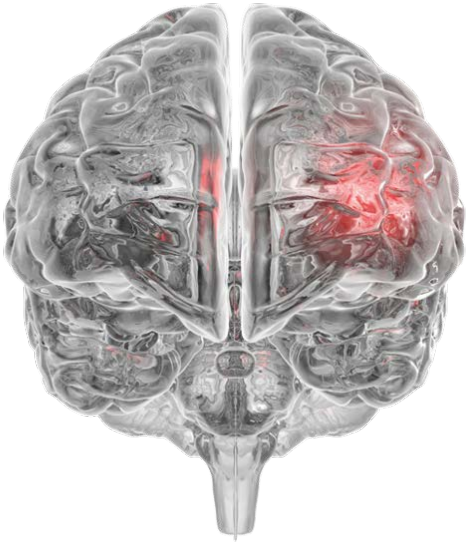
Direct access to the right person **to support you**

"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, Ph.D. , Manager, Quality & Regulatory 3M Orthodontic Products

BSI medical device training

Turning our experience into your expertise



More than 5,500
delegates trained

Medical device training courses

- **CE marking**
  - Introduction to CE marking
  - Medical Device CE marking
  - Application of the IVD Directive.
  - MDD to MDR Transition
  - IVDD to IVDR Transition
- **ISO 13485**
  - ISO 13485:2016 Transition
  - ISO 13485:2016 Auditor Refresher
  - ISO 13485:2016 Transition & 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): Fundamentals and readiness
- **Specialist Training Courses**
  - Introduction to risk management for Medical Devices
  - Creating and Maintaining Technical Files and Design Dossiers
  - Clinical Evaluation for Medical Devices
  - Technical Files and design dossiers for In Vitro Diagnostics
  - Performance evaluation and clinical evidence for In Vitro Diagnostics
  - Microbiological Validation and Control of Sterile Medical Devices Training

Why choose BSI for your training?

- **World-leading industry subject matter experts**, over 200 BSI Medical Device product and regulatory experts.
- **State-of-the-art courses**, representing up-to-date thinking on the current and possible future interpretations of the directives, standards and guidance.
- **Accelerated learning philosophy** – you don't just sit and listen, you experience the subject. You 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** – its your choice. We schedule public courses for you to book onto or if you prefer to have a group of employees attend a course together, choose in-house.
- **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.

Getting your products to market

Step 1

BSI prepares a quotation

A BSI company representative meets with your organization to discuss your requirements and the available solutions.

BSI has a full portfolio of global solutions and will provide the best services for your requirements.

Step 2

BSI performs a conformity assessment

A dedicated BSI Contact will be assigned to your company, supporting you throughout the process.

A Quality Management System audit is performed.

Technical files are reviewed by experienced experts thereby providing confidence.

Step 3

Certification decision

Successful assessment leads to your Scheme Manager recommending your certification.

BSI Certification Panel will review the recommendation and, if satisfied, approve certification.

Step 4

Certificate issue

Upon successful certification a certificate will be issued to your company.

Step 5

Certification maintenance

On-going surveillance audits and reviews monitor for continued compliance.

Your BSI Scheme Manager is available to support you when you have questions.

Start your journey to business excellence,
Visit **bsigroup.com/en-au**
or call **1300 730 134**

bsi.

Your resource for excellence

Talk to BSI

- We have 4,000 colleagues globally
- Offices in 30 countries around the world
- Over 86,000 clients operating in 193 countries
- Together our clients account for 49% of the FTSE 100, 75% of the Fortune 500 and 77% of the Nikkei 225 listed companies
- We are one of the world's largest independent certification bodies for management systems, with over 121,000 registered sites across the globe.

Additional services

Medical device newsletter service – Keep updated on what's happening in the industry and changes in regulatory and quality requirements. You can take advantage of this free service by signing up on our website.

Informative webinars – Hear regular updates from our experts on key topics; listen live or listen back.

Comprehensive white papers – Our Technical Specialists collaborate with external experts to bring you the latest views and understanding on complex regulatory issues. Download your complimentary copies now.

Medical device guidance documents – Our online guidance documents provide assistance in understanding the regulatory requirements for medical devices.

Standards – BSI British Standards delivers leading-edge best practice solutions through the development and publication of more than 59,000 standards and related products.

Your resource in worldwide compliance: Call BSI today on 0800 583 965 or visit bsigroup.com/en-nz – to start your journey.

bsi.

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