Turning our experience into your expertise

BSI Medical devices

bsi.

...making excellence a habit.™

Let BSI help you meet the world with confidence

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, predictable conformity assessments, evaluations, and certifications.

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 product meets all regulatory and quality requirements before launch. 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 promptly. BSI is a company that has been leading the way in assisting manufacturers to navigate through the maze of regulatory requirements.

We are a respected, 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 150 countries.

The best route to 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 fast, efficient and predictable service, meaning you will know what to expect with timely results and no surprises. This creates the best route to market for you.

You will appreciate our unique combination of advanced technological knowledge and accesibility. Our experts make themselves available to clients throughout the process, which will inspire a sense of connectivity and partnership**. You will have direct access to your named Scheme Manager.**

BSI works with every size of manufacturer, from novel to complex, from commodity to high risk, from new start-up to multinational BSI understands that different device manufacturers at different stages 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" – easier paths to market readiness – that arise, but your organization should never settle for a Notified Body whose focus is on short-term solutions.

When you partner with BSI, you'll benefit from more than exceptional product and regulatory expertise: Our team of dedicated professionals provides comprehensive support. Our solutions are tailored to your goals to 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 150 countries with more than 100 years of experience and offices around the world to serve you.
3. **Speed-to-market** – providing flexible solutions for manufacturers needing accelerated pathways to global markets.
4. **Confidence** – our stringent review process combines speed with experience, integrity, independence and predictability.
5. **Partnership** – we focus on establishing a partnership with each client so we can work together to meet their goals.

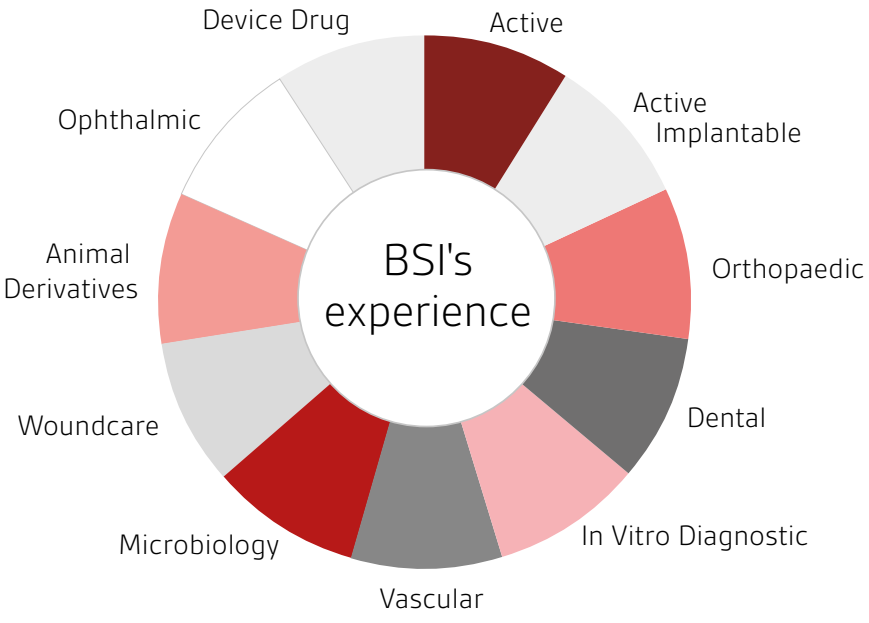
The preferred choice for **product expertise**

Over **70%** of the top medical device companies' partner with BSI, and our extensive expertise enables us to build long-term relationships with all our customers.

BSI employs over 150 Quality Management System (QMS) assessors and over 100 medical device experts with experience in all aspects of the product life cycle including research and development, manufacturing, and quality assurance.

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.



Regulatory and **quality management** programmes and services

Product Certification

Our comprehensive, one-stop shop approach offers you a wide range of proven regulatory and quality management programs and services that all work together 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 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 Diagnostics Directive (IVDD)

The EU is currently reviewing medical device regulations, BSI are involved heavily in the negotiations and are in a strong position to understand the implications for industry and patient safety.

Regulatory Strategy Review

Regulatory Strategy Review helps to ensure that the device manufacturer's proposed Regulatory Strategy will be acceptable and sufficient to meet CE marking decision requirements needed by BSI.

Clinical Strategy Review

Clinical investigations are expensive and time-consuming. Therefore manufacturers may want to have to have their Clinical Strategy reviewed by their Notified Body before they start. This is to help ensure that once they are completed, they are acceptable and sufficient to meet CE marking decision requirements needed by BSI.

Australia – Conformity Assessment Body (CAB)

Importers of medical devices in Australia need to meet the requirements of the Therapeutic Goods Administration of Australia. BSI is designated as a Conformity Assessment Body under the Mutual Recognition Agreement (MRA) between EU and Australia.

Japan PAL

The revised Japan Pharmaceutical Affairs Law (PAL) expands regulation of medical devices sold in Japan. Quality Management System (QMS)system requirements have been established incorporating ISO 13485 and Global Harmonization Task Force (GHTF) principles. The 2005 revision allows BSI, as a Registered Certification Body (RCB), to certify lower risk Designated Controlled Medical Devices (Class II).

Taiwan, Technical Cooperation Programme (TCP)

The TCP allows exchange of Medical Device GMP and ISO 13485 Audit Reports between Republic of China, Department of Health Designated Medical Device GMP Auditing Organizations and EU AIMD/MDD/IVDD Notified Body Partners.

Hong Kong CAB

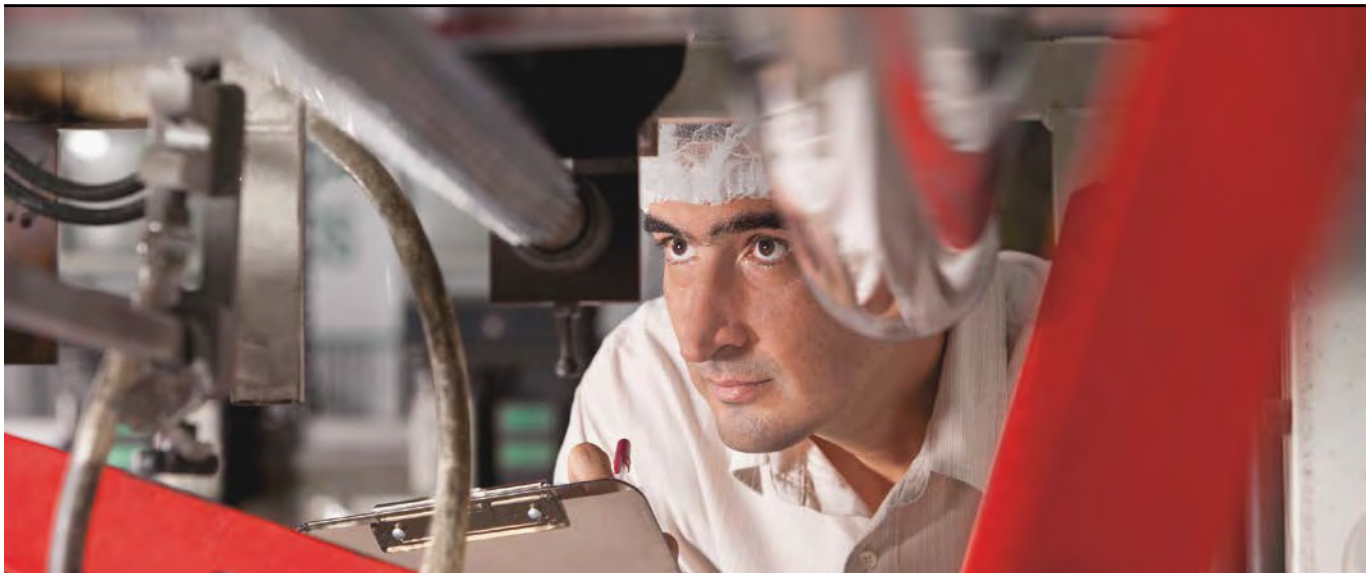
BSI was the first Hong Kong CAB under the Medical Device Administrative Control System. Using BSI as your HK CAB means BSI CE marking clients need only to submit a minimal amount of technical documentation and companies can get the CE marking and HK Registration with one assessment.

Malaysia CAB

As of the 1st of July 2013, the Malaysian Medical Devices Act 2012 (Act 737) will be fully enforced in the country, BSI has been approved as a CAB. Working with a conformity assessment body is essential for any medical device organization to register their medical device products, be certified to a medical device quality management system or to attain certification for their Good Distribution Practices for Medical Devices (GDPMD).

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 a INMETRO product certification body BSI Brazil can now receive applications from manufacturers outside Brazil.



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.

Health Canada CMDCAS

BSI is an accredited Registrar by the Standards Council of Canada (SCC) to conduct ISO 13485 registration and is recognized under the Health Canada CMDCAS sector program.

Pre-Assessment Service

An opportunity for a company to have an informal preliminary assessment that will not affect the outcome of the registration. This service will identify major flaws or gaps in the systems that the manufacturer can then correct.

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

Visit our website to learn more about our new services

Additional 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

A QMS gives you the framework to monitor and improve performance. ISO 9001 is the world's most established quality framework and sets the standard not only for quality management systems, but management systems in general.

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 recently formed an alliance with the 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 official testing and certification body, accredited and accepted by ANSI, OSHA and SCC. CSA Group is also a member and national CB Scheme certification body of IECEE.

Business Continuity Management

BS 25999 is the world's first British standard for business continuity management and was developed to assist companies to continue operations in the event of disruptions.

Occupational Health & Safety Management

An Occupational Health and Safety Management System promotes a safe and healthy working environment.

Environmental Management

An environmental management system provides a framework for managing environmental responsibilities efficiently.

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 marketing most electrical goods in the European Community.

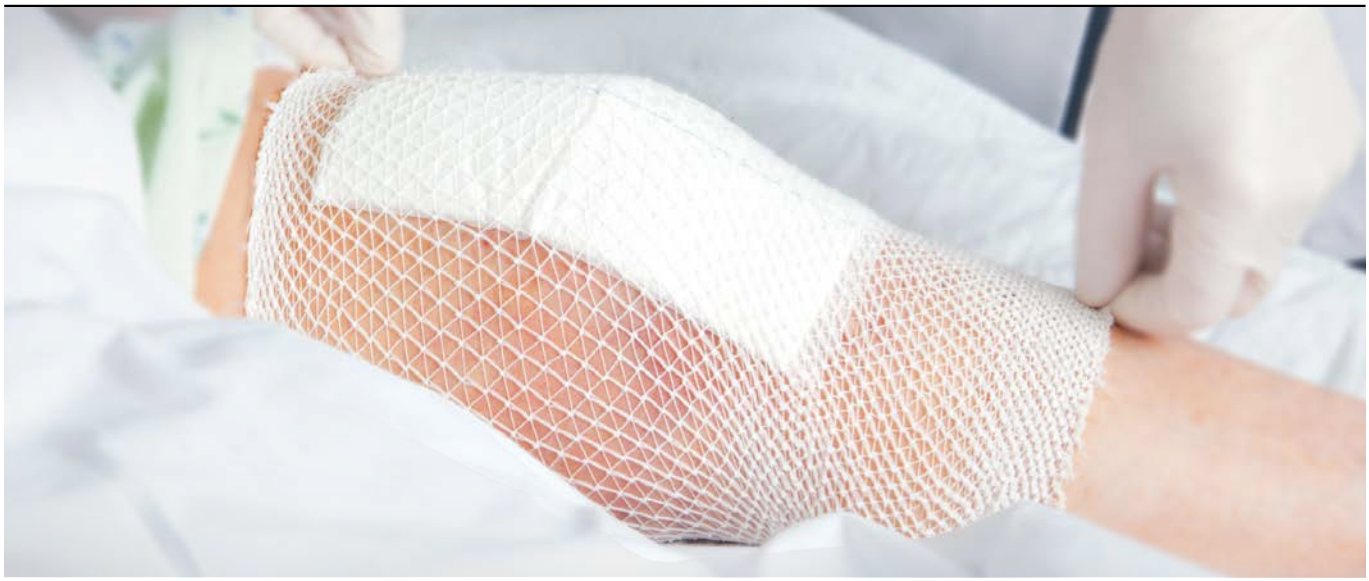
R&TTE

The R&TTE Directive (1999/5/EC) covers all radio equipment and all equipment intended to be connected to public telecommunications networks. It establishes a regulatory framework for the placing on the market, free movement and putting into service. Medical Devices containing Radio or Telecommincation components must comply with this directive.

When should you consider regulatory 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 maximise resources and minimise time to market, and reduce the risk of costly development reworks.

Concept	Planning	Design
Phase 1 Initial evaluation of possible development of commercial product	**Phase 2** Definition of design input based on customer needs and technical requirements	**Phase 3** Development of product design and of manufacturing process, verification and validation
Is it a Medical Device? Intended Use Initial Risk Analysis Product Definition & Intellectual Property Commercial Plan Potential Markets & Routes Draft Regulatory & Clinical Strategy Personnel / Resource Requirements	Concept Development Prototype Analysis Initial Testing Design File & Risk Analysis User Feedback Commercial & Market Strategy Regulatory Strategy Quality Management System Project Plan	User Feedback Manufacturing Process Design Verification & Validation Risk Management Draft Technical Documentation Clinical Strategy Product Claims & Branding Regulatory Requirements
BSI Products Regulatory Strategy Review Clinical Strategy Review Training Business and Technical Standards	**BSI Products** Regulatory Strategy Review QMS ISO 13485 Training Business and Technical Standards	**BSI Products** Clinical Strategy Review QMS ISO 13485 Training Business and Technical Standards



Validation

Phase 4

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

BSI Products

EU CE marking

Global Market Access Certification

QMS ISO 13485

Training

Business and Technical Standards

Launch

Phase 5

Product Launch

Regulatory Approval

Sales & Clinician Training

Launch Product to Market

BSI Products

EU CE marking

Global Market Access Certification

QMS ISO 13485

Training

Business and Technical Standards

Post market

Phase 6

Post Market Surveillance

Post Market Surveillance

Post Market Clinical Follow-up

Complaints & Adverse Events

Product Improvements

Process Improvements

External Body Audits

Market Performance

New Market Launches

BSI Products

Global Market Access

QMS ISO 13485

Training

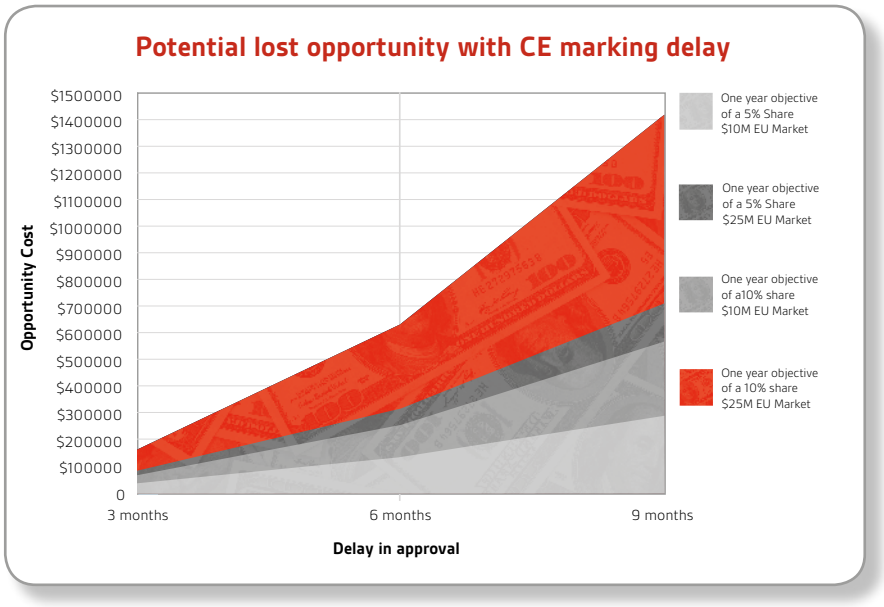
Business and Technical Standards

Risk managed approach to clearing the regulatory hurdles

With a new product launch in sight, it is important that when it comes to CE marking the product for the European Union market, the process doesn't get stalled at this final hurdle causing a failure to launch on time. Such a delay even of a few months, can have far reaching effects for the company.

A late to market launch means:

- Market expectation is missed
- Shareholder expectation is missed
- Missed benefits to patients, clinicians, healthcare providers and payers
- The market opportunity is missed
- The market share is missed
- First to market advantage is missed
- Missed or declining revenues
- Plans and forecasts are missed
- Boardroom dissatisfaction



Assumptions: Market share Growth linear from Launch, Graph Represents Cumulative sales to Date expected if Launch date Hit. Therefore any given point of the line reflects the cumulative lost sales opportunity at that delayed launch point. e.g. 6 months Delay in $25M market and a 10% objective year end equates to a 5% share at six months in the half year market of $12.5M or Lost sales of $600K

BSI has a strong commitment to providing the most experienced and efficient routes to global markets. This delivers the speed-to-market you need if you want to stay competitive, or more importantly, move ahead of the competition.

CE-45 FastTrack

We make getting your product to global markets as important to us as it is to you. BSI knows every day can have an impact on the bottom line, so we created the CE-45 FastTrack Programme.

The CE-45 is an expedited Design Dossier service where most reviews are completed within 45 working days from submission. Our goal is to assist you in getting your products to market faster, realizing a faster return on your investment.

CE-Onsite FastTrack

BSI's CE-Onsite FastTrack Review Service is aimed at medical device manufacturers needing to get their products to European markets quickly and safely. The review service is conducted at the customer's premises, in which BSI Product Experts visit the facility for a dedicated period of time.

This premium service works toward a CE marking target of 45 working days from submission. CE-Onsite Reviews usually allow for a much faster timeline with dynamic communications and opportunities for immediate response to questions.
Real time for real results.

CE-Dedicated FastTrack

BSI CE-Dedicated FastTrack Programme is designed for medical device manufacturers needing to get their products to European markets quickly and safely. This premium CE marking Programme is for high risk medical devices requiring design dossier reviews. We provide you the same high quality reviews just at an accelerated rate, usually within 45 working days or less.

CE-Dedicated is conducted via teleconferencing, as a result it does not require Product Experts to travel to the customer's site. This means scheduling times can be more flexible and adjusted if needed.

Note: *Programmes do not guarantee a CE marking certificate in a certain amount of working days but commits to completing the review process with either a positive or negative recommendation. Programmes exclude reviews outside BSI's control (e.g., products containing medicines, animal or blood derivatives).*

Product Experts and more. **Why BSI?**

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

Product Experts

Strong, robust technical documentation is the heart of the manufacturer's claim of compliance and thorough review by product experts provides the manufacturer confidence for signing defendable declarations of conformity. At BSI we use product experts to conduct the technical visits. Our highly trained product experts 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 need, to handle each customer's account. 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, Project Manager, Product Expert, Client Manager or Auditor, and Microbiologist, along with the Sales Representative and Client Services Coordinator.

Direct access to the right person **to support you,** not a nameless email.

Microbiologists

BSI requires the use of trained Microbiologists because sterility is critically important to many medical devices and 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.

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

Quality Assessors

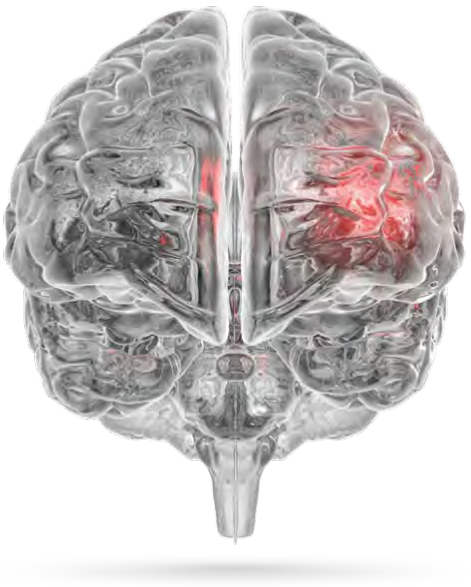
BSI Client Managers, who are our Assessors possess experience in the medical device industry, which gives them a greater understanding of the customers' challenges. They have empathy with our clients as they know what it means to be on the other side of an assessment and to submit a quality system to scrutiny. In addition, BSI Client Managers have undergone extensive training programs and maintain strong credentials in their fields of expertise.

BSI also has a unique matching system that matches the manufacturer's product type to the appropriate auditor's credentials and background.

BSI is known for its fair but thorough audits.

BSI medical device training

Helping to make regulatory compliance excellent



99% of course attendees would strongly recommend BSI Training

Medical device training courses

- **CE marking**
  - Introduction to CE marking
  - Medical Device CE marking
  - Introduction to CE marking for the In Vitro Diagnostics Directive
  - Application of the In Vitro Diagnostics Directive.
- **ISO 13485**
  - Introduction to ISO 13485
  - Implementing ISO 13485
  - Internal Auditor ISO 13485
  - Lead Auditor ISO 13485 (BSI-certified, IRCA, TPECS).
- **Specialisms**
  - Introduction to Risk Management – Key concepts and requirements
  - CE marking Medical Devices with Software
  - Compiling and Maintaining Technical Files and Design Dossiers
  - Clinical Evaluation for Medical Devices
  - Device - Drug Combinations: Practical Guidance on Borderline Issues and the Consultation Process
  - Process Validation for the Medical Device industry
  - Post Market Surveillance and Vigilance
  - Medical Devices Utilizing Material of Animal Origin.

Why choose BSI for your training?

- **World-leading industry subject matter experts**, over 200 BSI Medical Device product and regulation experts.
- **Course instructors are active practitioners in their subjects**, ensuring the latest developments are fully understood.
- **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.
- **On-line, Public or In-house Course** – 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. Courses can be customised to your requirements.
- **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.

Visit: medicaldevices.bsigroup.com/training or call +27 12 004 0279

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 recommendation for your requirements.

Step 2

BSI performs a conformity assessment

A dedicated BSI Project Manager 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 within agreed timescales thereby providing predictability.

Step 3

Certification decision

Successful Assessment leads to a Project Manager recommendation for certification.

Certification Decision Team will review the recommendation file and if satisfactory approve certification.

Step 4

Certificate issue

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

Step 5

Certification maintenance

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

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

Please note: *Additional steps may be required for products that require consultation outside BSI's control (e.g., products containing medicines, animal or blood derivatives).*

Start your journey to business excellence,
Visit medicaldevices.bsigroup.com
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A resource for excellence

Here to help you:

- We have 2,900 members of staff
- 65 BSI offices around the world
- 70,000 clients operating in 150 countries
- Together our clients account for 54% of the FTSE 100, 40% of the Fortune 500 and 24% of the Nikkei listed companies
- We are one of the world's largest independent certification bodies for management systems, with over 90,000 registered sites across the globe.

Additional services

Medical device e-update 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 at our website.

Informational webinars – We offer a wide variety of interactive multimedia presentations allowing convenient participation via a web-based interface.

Medical device guidance documents – Our online Guidance Documents provide assistance in understanding the requirements of the medical devices directives.

Standards – BSI British Standards delivers leading-edge best practice solutions through the development and publication of more than 34,000 standards and related products.

Your partner in worldwide compliance: Call BSI today on +27 12 004 0279 or visit bsigroup.com/en-ZA/ISO-13485-Medical-Devices/ – to start your partnership

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