Flexible, FastTrack solutions from BSI

A Vascular Notified Body

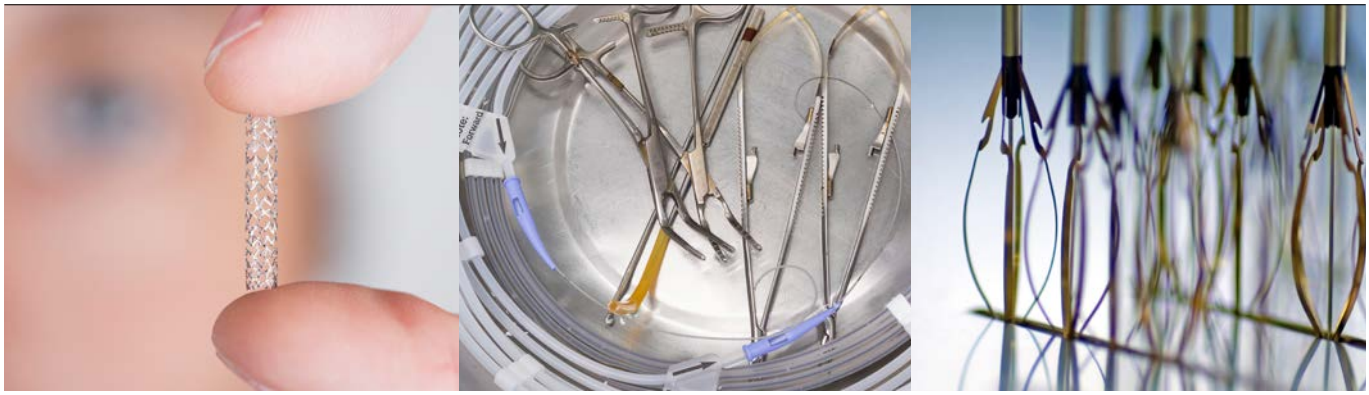
Expertise and experience

At the heart of your business

Updated February 2016

bsi.

...making excellence a habit.™

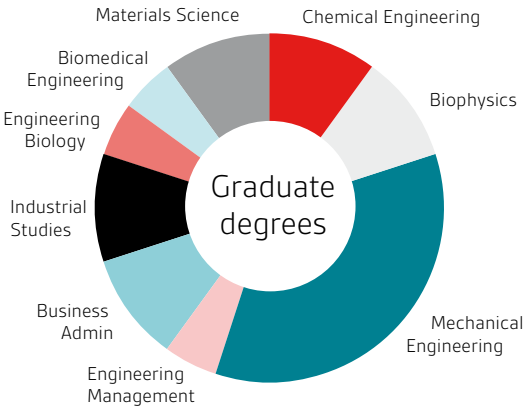


Unrivalled expertise from the premier vascular Notified Body

As an experienced vasular Notified Body, BSI has a unique skillset to help you reach global markets faster. Our focus is speed-to-market service, so product reviews from BSI will help you succeed in global markets faster – not delay your timelines.

The value of 348 years design and development experience

The BSI vascular team has over 275 years combined academic and medical device design, development and manufacturing experience, as well as over over 65 years of combined regulatory experience. The members of the team collectively hold more than 20 US patents for stents, drug eluting stents, vascular and endovascular grafts, related technologies and processing. We have over 17 technical experts, with degrees in:



Whether you're aiming to achieve MDD Requirements for Class I sterile, Class II or Class III Vascular Medical Devices, BSI has the knowledge and expertise to ensure robust and timely support of your regulatory activities. Our team's command of the complex design, development and manufacturing processes of vascular medical devices is marked by worldwide industry success with products that include:

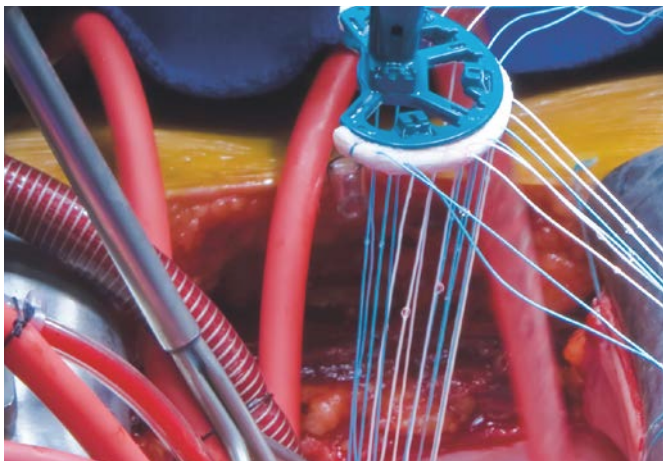
- Bare metal stents (coronary and peripheral)
- Drug eluting stents
- Bioresorbable stents
- Various coronary and peripheral catheters, balloon dilatation and introducers, PICCs, CVC
- Guidewires
- Intra-aortic balloon catheters
- Devices for the treatment of neurovascular diseases including catheters, wires, embolic coils and stents
- Flexible and rigid heart valves and related accessories
- Transcatheter heart valves
- Embolic filters
- Vena Cava filters
- Vascular grafts (textile and ePTFE)
- Devices for the treatment of Abdominal Aortic Aneurysms (AAA)
- Cardiac electrophysiology and ablation catheters
- Renal artery denervation devices

Three unique reasons to make BSI your Vascular Notified Body

Experience and expertise – You can be rest assured by BSI focus on excellence, thereby reducing your corporate risk.

Focus on service – BSI offers a premium customized service, giving you a greater level of flexibility as well as predictability.

Market access – Our speed-to-market service means your product reviews won't slow down your launch plans, helping you to stay ahead of the competition.



Certification

The BSI vascular team also brings a high level of expertise to the design examination of Class III devices and technical file audits. Our success is achieved through a working knowledge of the development process and an intimate involvement in the manufacturing process. In addition, our vascular team has experience in performing risk analysis, process validations and animal studies, ensuring your BSI reviewer will be able to engage in a meaningful dialogue with the you on important design and manufacturing elements.

How can BSI support your vascular device launch?

Be prepared

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. Consolidated clinical and regulatory planning will assist your company to maximise resources and minimise time to market.

CE marking: Speed-to-market

Clients work with us because we understand the challenges medical device manufacturers face in getting compliant products to market quickly.

CE-90 Standard: Our standard service reviews are completed within 90 days from submission, giving you predictability for better planning.

CE- FastTrack: Our FastTrack programmes deliver the speed-to-market you need to be competitive and move ahead of the competition. The aim is review completion in 45 days from submission with a choice of options:

- CE-45: Standard 45 day service
- CE-Onsite: The review service is conducted at your premises, allowing for a faster timeline and dynamic communication.
- CE-Dedicated: Your review will be conducted remotely, your Product Expert will be able to arrange flexible schedules with you.

Worldwide access

Our expertise offers a wide range of proven regulatory and quality management programmes that work together for full international compliance. Our QMS solutions include: ISO 13485, ISO 9001, ISO 14001 and many more.

BSI works with international regulators to ensure we understand what is required to get products approved in the USA, Canada, Japan, Australia, Brazil, Hong Kong, Malaysia and Taiwan.

Seamless transfer to BSI

If you decide to transfer your certification to BSI, we can offer a seamless exercise with comprehensive support and the absolute minimum level of disruption. With expertise encompassing the full range of industry sectors and management system standards.

Certification support

Thoughout the certification process and beyond we can continually support you. We can provide:

- Expert training courses:
  - In-house for your company
  - Public courses, see website for the latest schedule
- Regulatory Updates, helping you plan for the future
- Free webinars
- Access to relevant standards.

A resource for excellence

Talk to BSI

- We have over 3,000 members of staff
- 76 BSI offices around the world
- 80,000 clients operating in 182 countries
- Together our clients account for 77% of the FTSE 100, 45% of the Fortune 500 and 65% of the Nikkei 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 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.

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 1 800 862 6752 or visit bsigroup.ca/medical – to start your partnership

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