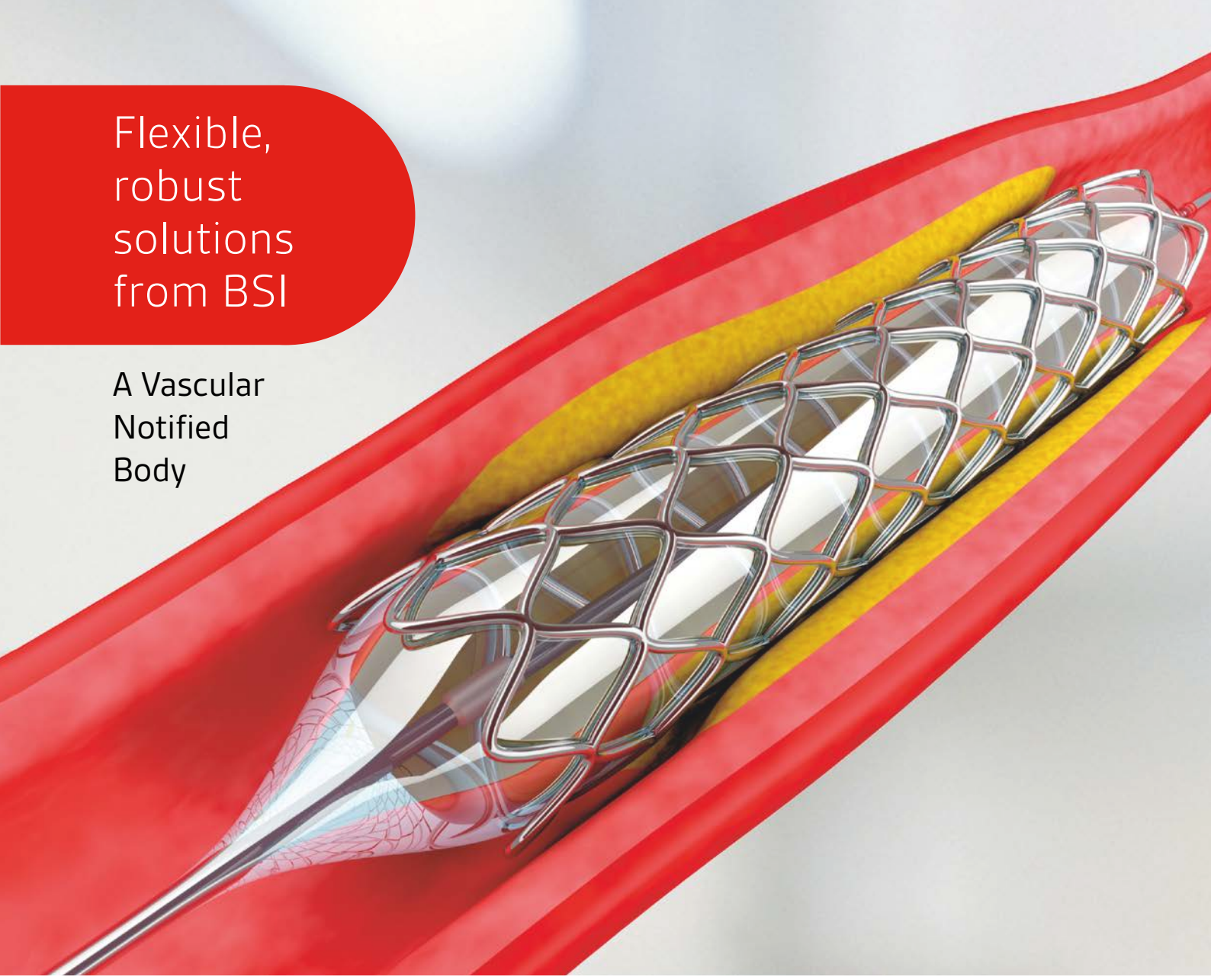


Flexible, robust solutions from BSI

A Vascular Notified Body

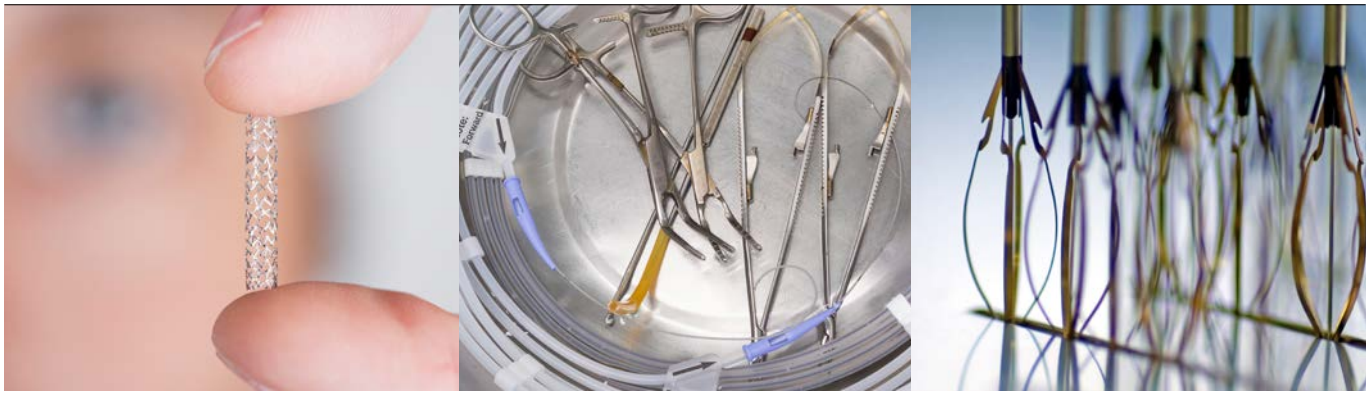
Expertise and experience

At the heart of your business

Updated April 2017

bsi.

...making excellence a habit.™

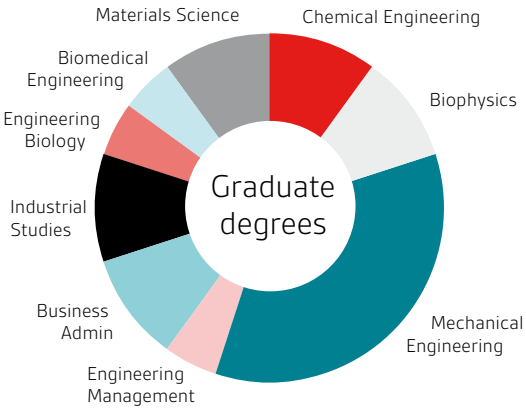


Unrivalled expertise from the premier vascular Notified Body

As an experienced vascular Notified Body, BSI has a unique skillset to support your global market access goals. Our focus is efficient service, so product reviews from BSI will support timely global market access - without compromise.

The value of over 290 years design and development experience

The BSI vascular team has over 290 years combined academic and medical device design, development and manufacturing experience, as well as over over 85 years of combined regulatory experience. The members of the team collectively hold more than 80 US patents for a number of devices, including stents, ablation systems, thrombectomy devices, mitral repair devices, and vena cava filters. We have over 20 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:

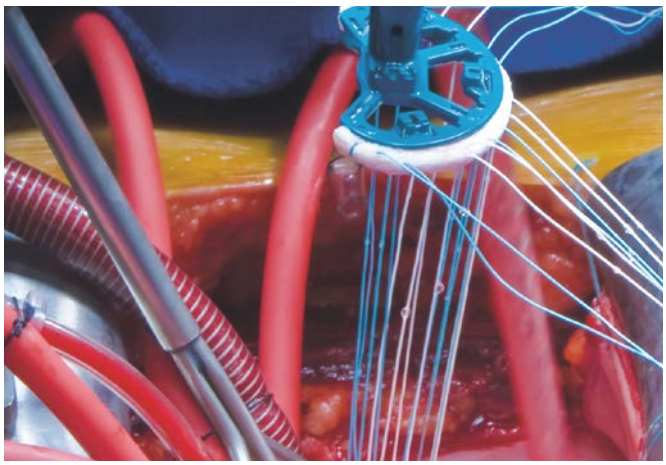
- Bare metal stents (coronary and peripheral)
- Drug eluting stents
- Bioresorbable stents
- Various coronary and peripheral catheters, balloon dilatation and introducers, PICCs, CVC
- Guidewires
- Intra-aortic balloon catheters
- Devices for the treatment of neurovascular diseases including catheters, 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 – BSI focuses on excellence, thereby reducing your corporate risk.

Focus on service – BSI offers a range of review services, giving you a greater level of flexibility as well as predictability.

Market access – Our efficient review services means your product reviews won't slow down your launch plans, helping you to stay ahead of the competition.



Certification

The BSI vascular team 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-Excellence

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

Our CE-Excellence review services deliver the efficiency you need to be competitive while maintaining confidence through a robust review. Explore the options below:

- CE-Standard: Our standard service reviews are completed by experienced BSI Product Experts, giving you confidence in the review.
- CE-Dedicated FastTrack: This service allows you to schedule your technical documentation review with a dedicated BSI Product Expert.
- CE-Onsite FastTrack: This review is conducted at your premises; a BSI Product Expert visits the facility for a period of time. This allows dynamic communications and opportunities for immediate responses.

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 is a recognized Certification Body in Australia, Brazil, Canada, Hong Kong, Japan, Malaysia and Taiwan, and is a recognized MDSAP Auditing Organization for all participating Regulatory Authorities.

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. We have 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 4,000 colleagues globally
- Offices in 30 countries around the world
- Over 81,000 clients operating in 180 countries
- Together our clients account for 75% of the FTSE 100, 51% of the Fortune 500 and 68% 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 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 37,000 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

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