

# A Vascular Notified Body

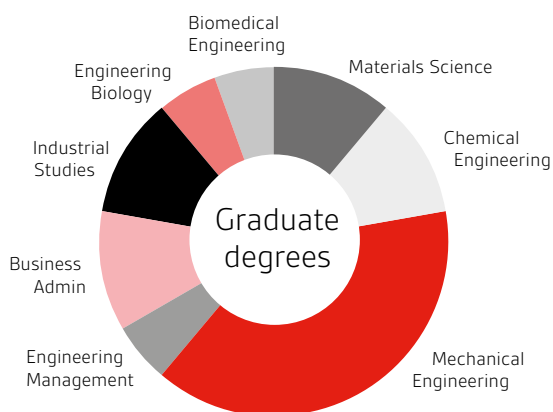
## Expertise and experience

### At the heart of your business

As an experienced vascular 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 170 years design and development experience

The BSI vascular team has over 170 years combined medical device design, development and manufacturing experience, as well as over 40+ 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 11 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 help you achieve compliance and better understand the challenges of the marketplace. 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's and coils
- 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

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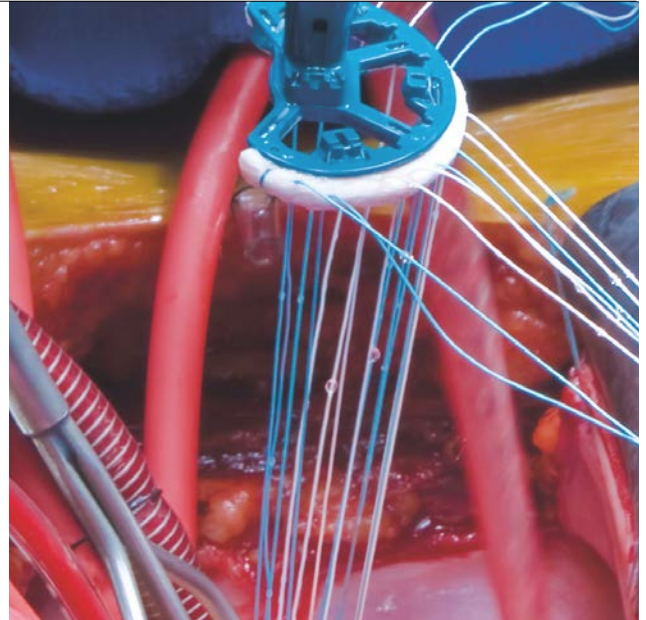
...making excellence a habit.™

## 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.

## Talk to BSI

We believe excellence should follow in everything we do, so if you would like to find out more about BSI, please **call or email us for an initial conversation**

**Your partner in worldwide compliance: Call BSI today on +44 845 080 9000 or visit [medicaldevices.bsigroup.com](http://medicaldevices.bsigroup.com) – to start your partnership**



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