Your partner
in progress

Vascular Medical Devices

EU Notified Body, UK Approved Body and Auditing Organization Expertise

As a manufacturer of a vascular medical device, you must ensure that you meet the relevant regulatory requirements before placing your product onto the market.

Europe: Medical Device Regulation **(MDR)(EU) 2017/745** and In Vitro Diagnostic Regulation **(IVDR) (EU) 2017/746**

Great Britain: Medical Devices Regulations **(UK MDR 2002)**

Global: Medical Device Single Audit Program **(MDSAP)**

It is critical to work with a trusted EU Notified Body or UK Approved Body or Auditing Organization that understands the industry and has the experience to review and confirm your product's readiness for market - efficiently, promptly and robustly. Our Technical Specialists have extensive experience in vascular medical devices and can support you through the process of certifying your device.

BSI The Netherlands (2797) is a leading full-scope Notified Body; we review medical devices to ensure that they conform to the requirements of the European Directives and Regulations.

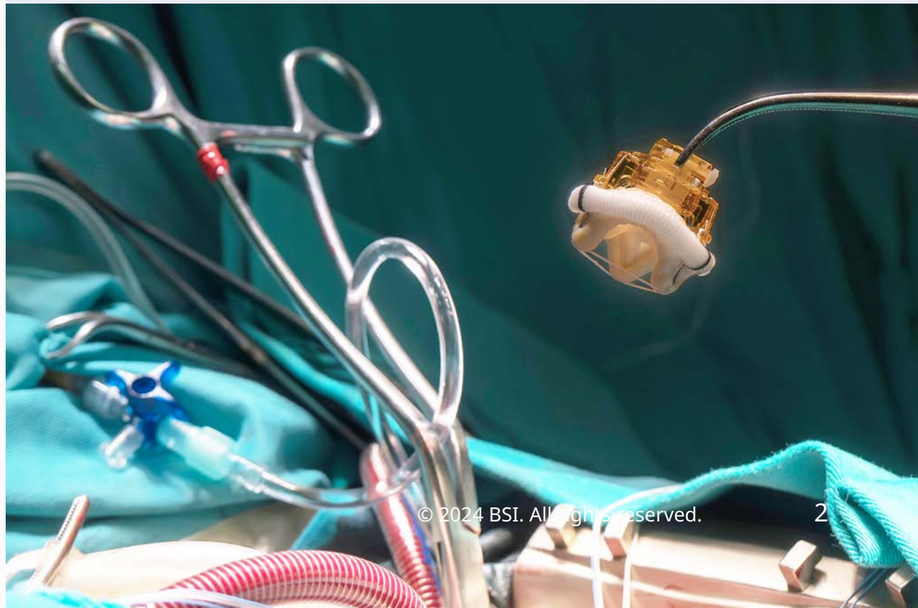
BSI UK (0086) is a full-scope UK Approved Body that provides Conformity Assessments under the UKCA scheme.

BSI Group America Inc. is a recognized MDSAP Auditing Organization.

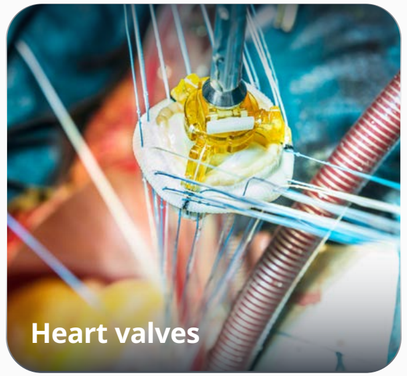
Defining Vascular Medical Devices

A vascular medical device can be defined as a device that is used in the arteries and veins or the heart itself, to control, diagnose, monitor, or correct disease, injury, or other conditions. This vasculature encompasses the cardiovascular, peripheral vascular, and neurovascular anatomy.

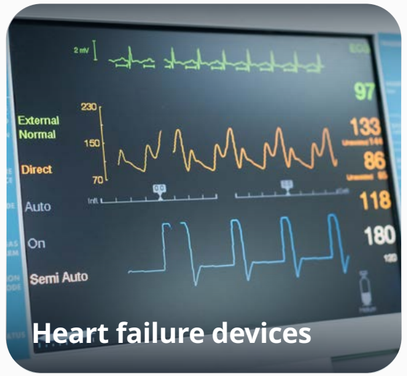
For more clarity on vascular and related medical devices, please refer to the **MDR (EU) 2017/745** and the **Part III of The Medical Devices Regulations 2002 (as amended).**



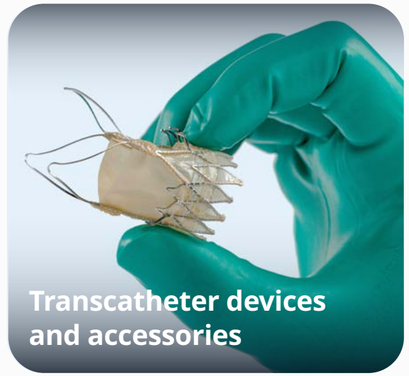
Product range covered

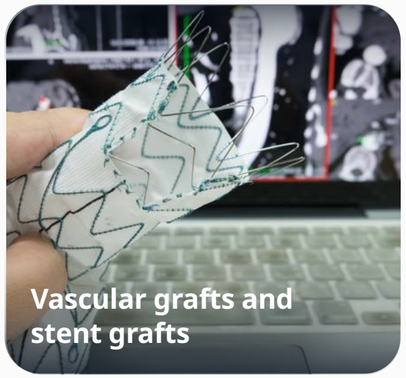

Heart valves


Cardiac electrophysiology and ablation catheters



Heart failure devices


Transcatheter devices and accessories


Vascular grafts and stent grafts


Structural heart occluders


Drug-eluting stents, bare metal stents, and bioresorbable stents


Valve repair devices


Introducers, catheters and guidewires

Meet our Vascular Team

Our vascular Technical Specialists are product experts highly trained in working with vascular medical device manufacturers and understand the specifics of these complex devices. The team has an average of 20 years' industry and regulatory experience.

We are experienced in working with manufacturers of apparatus, appliances, implants, instruments or other articles intended to be used in the arteries and veins that carry blood throughout the body.

We also provide conformity assessments for medical devices for the heart itself used in the diagnosis, prevention, monitoring, treatment and alleviation of disease or injury, as well as, in the investigation, replacement or modification of the anatomy in relation to the vasculature or the heart.

Where products require additional expertise, we collaborate with our in-house clinicians and technical teams in all areas from active implantable, dental and orthopaedic, to medicinal substances, devices utilizing animal tissue, and sterile medical devices.

"We understand that, as a manufacturer of a vascular medical device, completing your Technical Documentation for conformity assessment is a challenging and rigorous process. Our team of vascular technical specialists are passionate about ensuring that these complex, lifesaving medical devices perform as intended and, ultimately, are safe for use in patients."

Maritza Carballo, Global Head of Vascular Medical Devices

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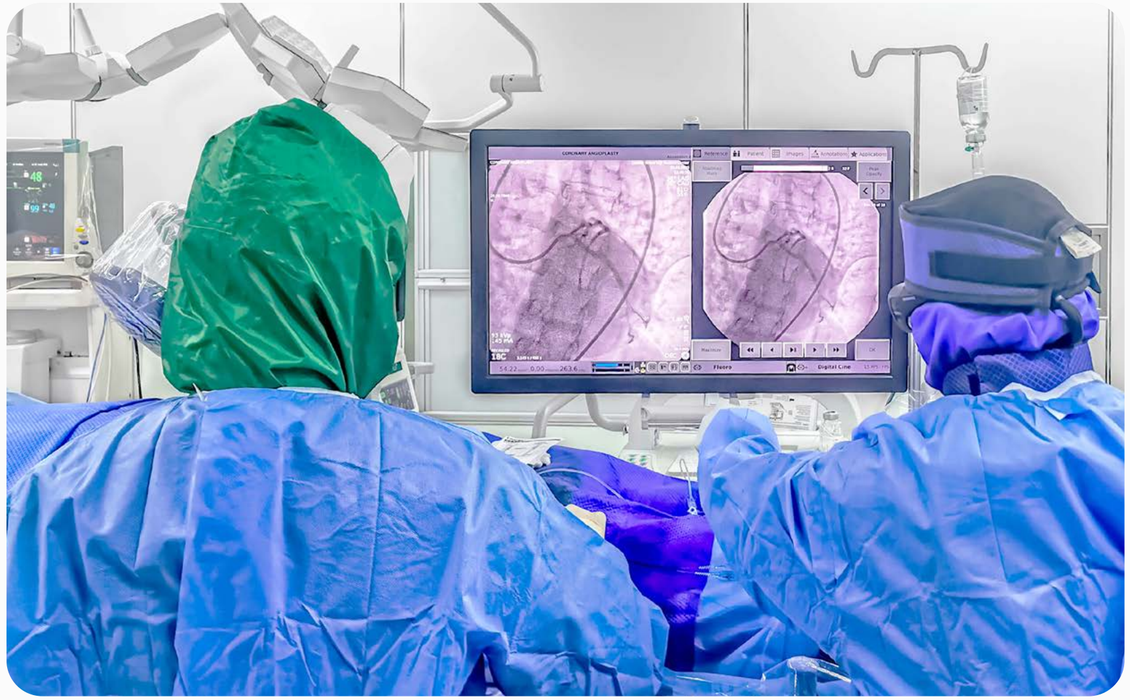
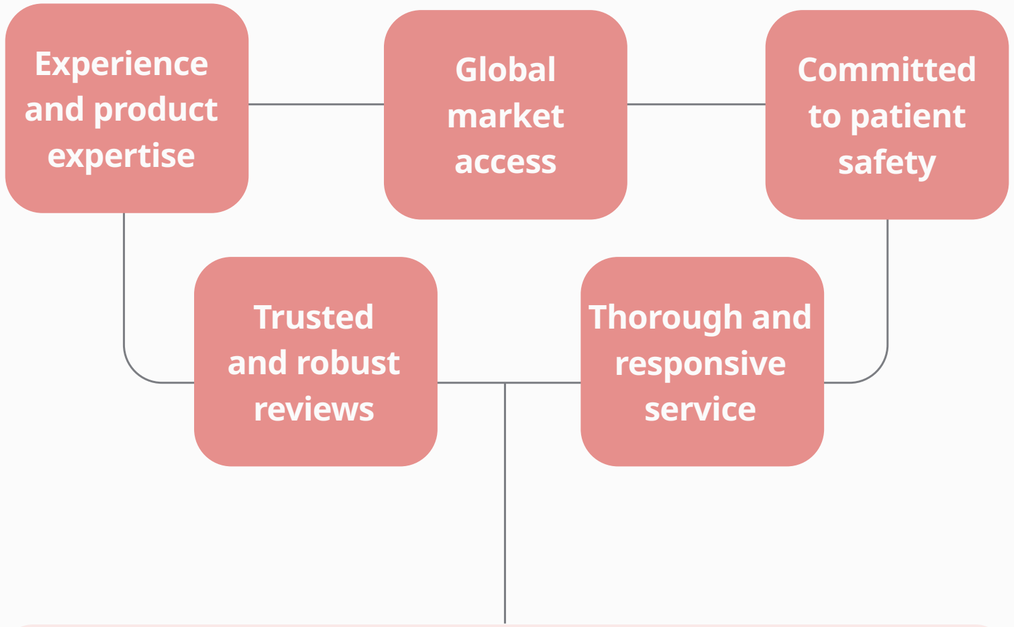


Why choose BSI



Over **5,000** people
supported by **12,000** industry experts
in more than **193** countries

Experience and product expertise

In the complex and ever-changing medical device industry, support from experienced, professional and well qualified technical specialists is critical.

BSI's medical devices consists of a team of over 1000 professionals including technical experts and internal clinicians expert in encompassing the full range of medical devices and management system standards.

Committed to patient safety

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 and robust conformity assessments, evaluations and certifications.

Thorough and responsive service

We truly understand the challenges medical devices manufacturers face in bringing compliant products to market efficiently and safely.

We offer standard and dedicated review services providing you with the efficient pathways to bring your device to market.

Global market access

We are a global organization, trusted and recognized around the world.

BSI The Netherlands (2797) is a leading Notified Body. We review medical devices to ensure that they conform to the requirements of the European Directives and Regulations.

BSI UK (0086) is a UK Approved Body able toprovide conformity assessments under the UKCA scheme.

BSI is a recognized Auditing Organization, providing Quality Management System certification through Medical Device Single Audit Program (MDSAP).

BSI is a Conformity Assessment Body for EN ISO 17021-1 (EN-ISO 9001, ISO 14001, ISO 13485) as accredited by the Dutch Accreditation Council (RvA) and the UK Accreditation Service (UKAS).

Trusted and robust reviews

Our comprehensive review process combined with our world-leading experience as a Notified Body and UK Approved Body will ensure that your conformity assessment path is efficient and robust.

Five steps from product-to-market

Quotation

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

We will also discuss the best service for your requirements.

1

2

Conformity assessment

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

A QMS Audit will then be performed and all Technical Documentation reviewed by one of our experienced technical specialists.

Certificate decision

Successful assessment leads to your BSI scheme manager recommending certification of your product.

The BSI Certification Decision Team will then review the recommendation and, if satisfactory, approve certification.

3

4

Issue certificate

Upon successful conformity assessment you will be issued with a certificate.

You will then be able to CE/UKCA mark your product and launch to market.

Certificate maintenance

On-going surveillance audits and reviews are required to monitor for persistent compliance.

Your BSI scheme manager will support you with any queries you might have.

5

How BSI supports your market readiness

Readiness

In the competitive medical device marketplace, ensuring that product development meets all regulatory requirements is essential. We support you through the application and certification process.

Worldwide Access

We offer a wide range of regulatory and quality management programs that work cohesively for international compliance. BSI is an accredited Conformity Assessment Body for Quality Management Systems against ISO 17021-1with ISO 13485, ISO 9001 and ISO 14001 in its scope.

We are a recognized certification body in Japan, Malaysia, Singapore. BSI NL (NB2797) a recognised "Notified Body partner" in Taiwan's Technical Cooperation Programme (TCP), and a recognized MDSAP auditing organization for all participating regulatory authorities.

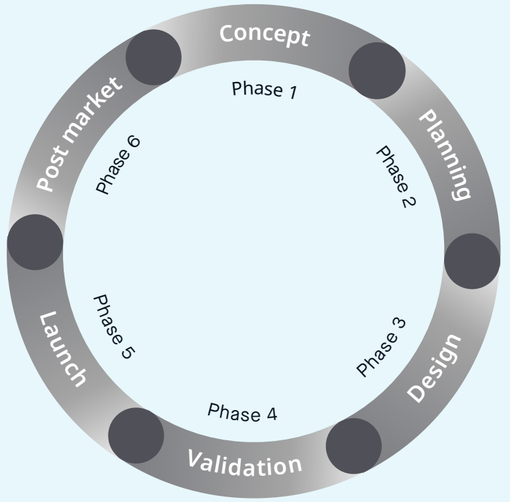
BSI Transfer

We offer a seamless transfer to our services providing comprehensive support to ensure minimal disruption to your company.

Additional Services

- **Access to more than 34,000 standards** and related products, as well as online guidance documents
- **Expert training** online or face-to-face through our public training courses and read our **Excellence Pathways brochure**
- **Regulatory updates and newsletters** focusing on industry changes, helping you to plan for the future
- **Webinars** delivered by our experts on regulatory issues
- **Comprehensive whitepapers** providing the latest insights on key industry topics

The product lifecycle



Considering clinical and regulatory requirements

An understanding of the complex clinical and regulatory requirements early in the product lifecycle could ensure you gain the competitive advantage needed to bring your product to market.

Our consolidated clinical and regulatory planning will support you in maximizing resources and reducing the risk of costly redevelopments later in the lifecycle.

Visit our **website** for more information about the product lifecycle

Navigating your compliance to the MDR

Manufacturers of medical devices have to ensure their technical documentation and processes meet MDR requirements before placing their products on the EU Market.

Manufacturers are invited to apply to a Notified Body as soon as possible to ensure compliance with the Regulations.

Starting the certification process?

Transitioning to MDR?

Transferring your existing certification?

From the experts

Vascular medical devices are complex and the process of CE or UKCA marking for these devices can be challenging. Strong and statistically relevant clinical evidence, demonstrating the safety and performance of your device, is essential to ensure a successful outcome of your MDR/UKCA application.

MDR Best Practices Guidelines to support you

Conformity Assessment guidance to meet MDR requirements

Continued access to our technical experts throughout your submission

CE/UKCA Excellence

Technical Documentation Review Services deliver the efficiency you need to be competitive in the market and maintain trust.

Standard

Access to technical review timeline after Technical Documentation submission.

Dedicated

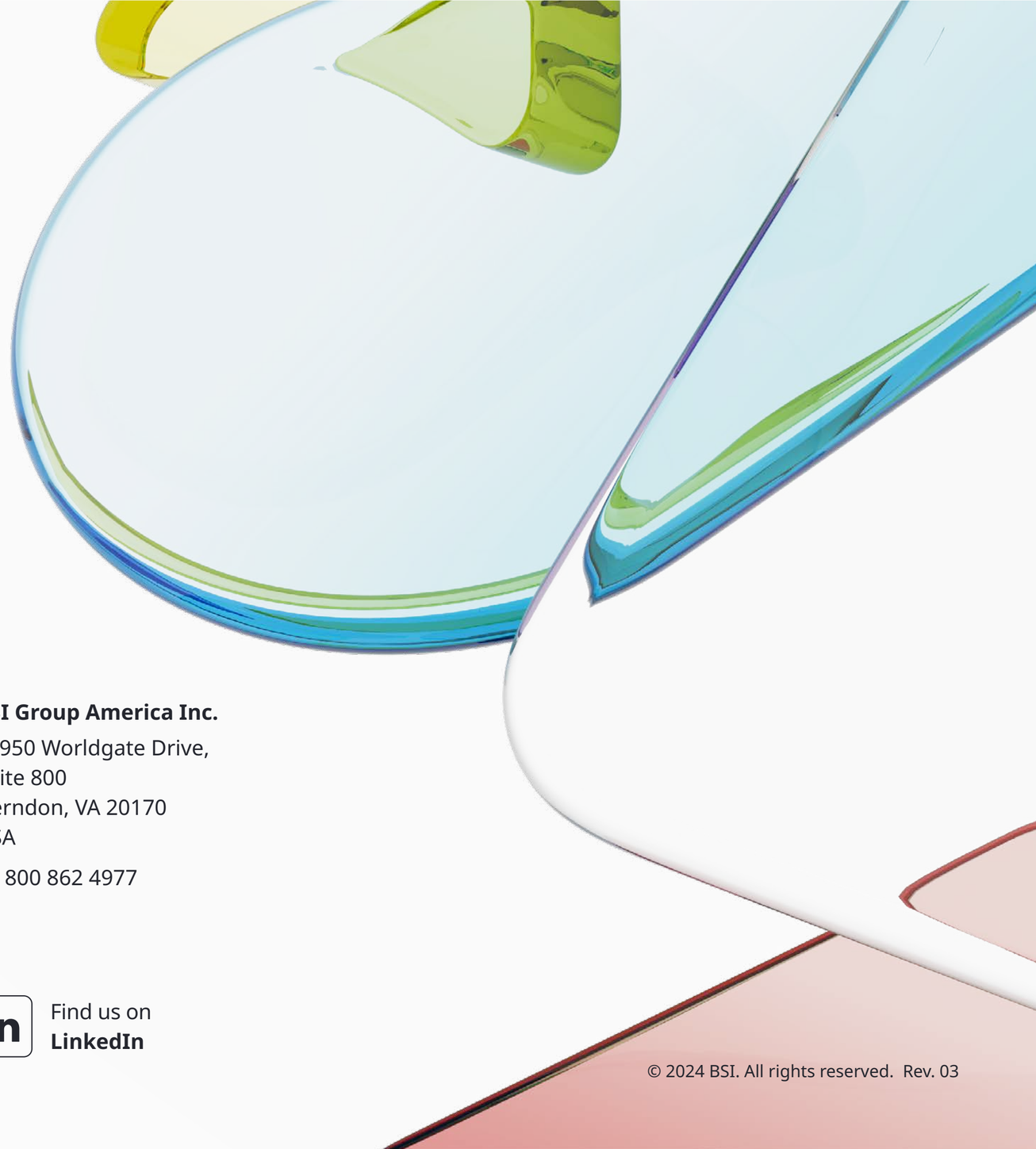
Technical review planned up-front to Technical Documentation submission.

Talk to BSI today and start your journey

call: +44 345 080 9000

visit: bsigroup.com/vascular

Your partner in progress



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