Your partner
in progress

Active Implantable Medical Devices

EU Notified Body, UK Approved Body and Auditing Organization Expertise

As a manufacturer of an active implantable 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 active implantable medical devices and can support you through the process of certifying your device.

BSI Group The Netherlands B.V. (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 Group Assurance UK Ltd. (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.

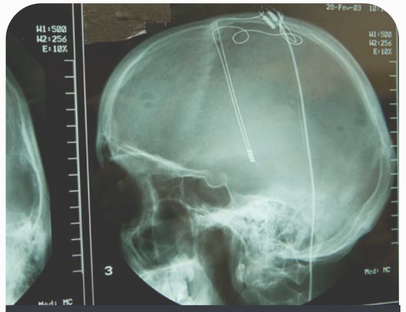
Defining Active Implantable Medical Devices

- Its functioning depends on an energy source other than that generated by the human body for that purpose or by gravity, and which acts by changing the density of or converting that energy
- It is to be totally introduced into the human body or used to replace an epithelial surface or the surface of the eye by clinical intervention and is intended to remain in place after the procedure
- It is intended to be partially introduced into the human body by clinical intervention and is intended to remain in place after the procedure for at least 30 days

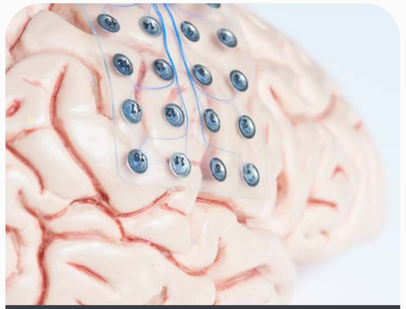
Active Implantable Medical Devices and their accessories are classified as Class III and therefore subject to the most rigorous regulatory controls. For further clarity and more detailed information on an AIMD, please reference the **MDR (EU) 2017/745** and the **Part III of The Medical Devices Regulations 2002 (as amended).**

Product range covered and more

Pacemakers, defibrillators and accessories



Neurostimulator systems and accessories



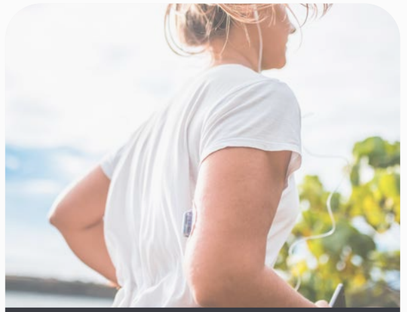
Leads, electrodes, adaptors for implantable pulse generators

Brachytherapy systems and accessories

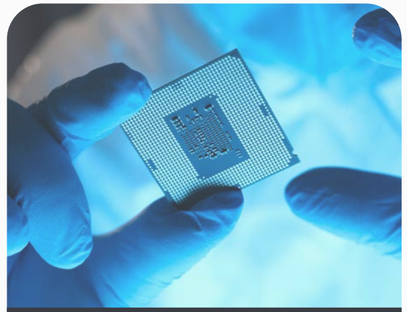
Ventricular Assist Devices (VADS) and accessories

Cochlear implants and accessories

Infusion pumps and accessories



Implantable glucose monitors and accessories



Micro Electro-Mechanical Systems (MEMS)

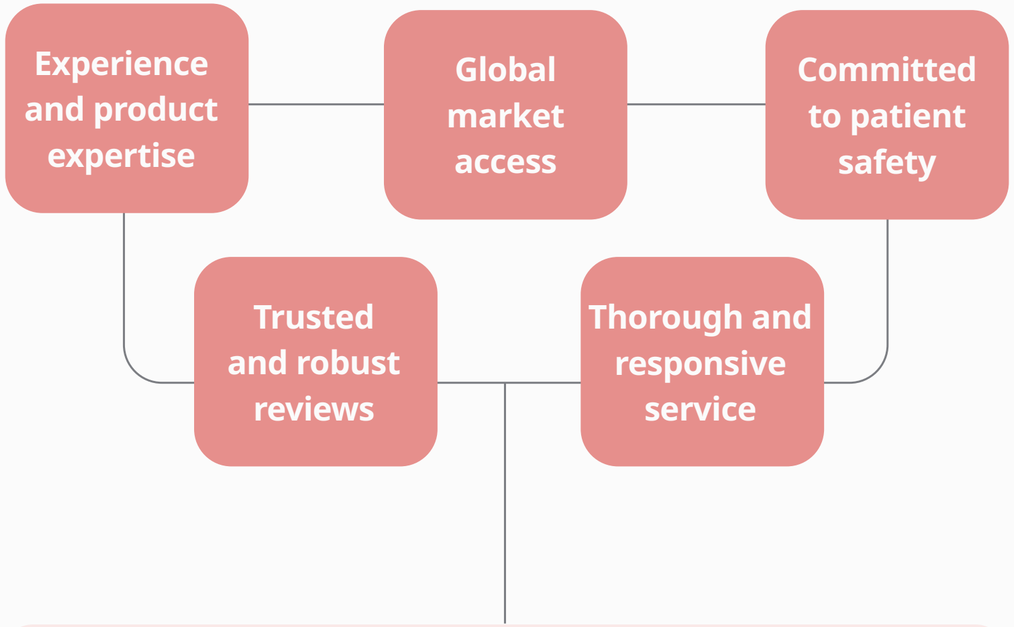
Meet our AIMD Team

Our AIMD technical and clinical specialists are experienced in the Active Implantable Medical Device Directive (AIMDD) and in Part III of The Medical Devices Regulations 2002 (as amended), as well as in the MDR. Our AIMD team has a broad range of industry, clinical and regulatory experience, including product design and development, manufacturing and clinical practice. We understand the specifics of these complex products through their full life cycle.

> “We understand that time to market is important for manufacturers, and transparency in review timelines is a key element of this. Our highly skilled clinical and technical experts perform thorough and timely conformity assessments to ensure AIMDs are safe for use. Knowing, after all, there is a patient benefitting from everything we do.

Thomas Doerge
Global Head of AIMD,
BSI

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 Medical Devices consists of a team of over 1000 professionals including technical experts and internal clinicians with expertise 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 Group The Netherlands B.V. (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 Group Assurance UK Ltd (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 continued 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.

BSI Group The Netherlands B.V. (2797) is a leading Notified Body achieving full-scope designation under MDR and IVDR.

We are a recognized certification body in Japan, Malaysia, Singapore. BSI Group The Netherlands B.V. (2797) is a recognized "Notified Body partner" in Taiwan's Technical Cooperation Programme (TCP), and a recognized MDSAP auditing organization for all participating regulatory authorities.

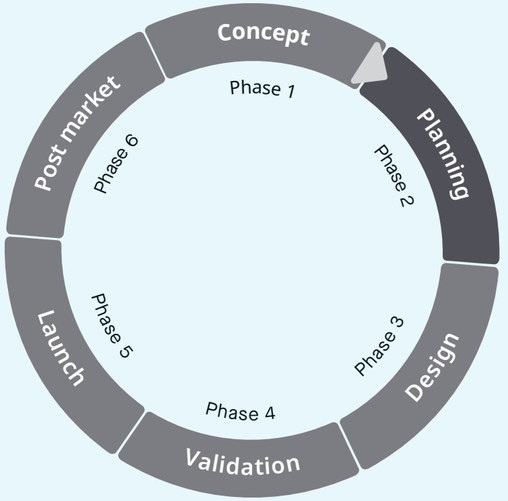
BSI Transfer

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.
- **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

Starting the certification process?

Transitioning to MDR?

Transferring to BSI your existing certification?

Manufacturers of medical devices and IVDs have to ensure their technical documentation and processes meet MDR and IVDR 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.

From the experts

Strong, statistically relevant clinical data demonstrating the safety and performance of your device is essential to ensuring a successful outcome of your MDR 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.

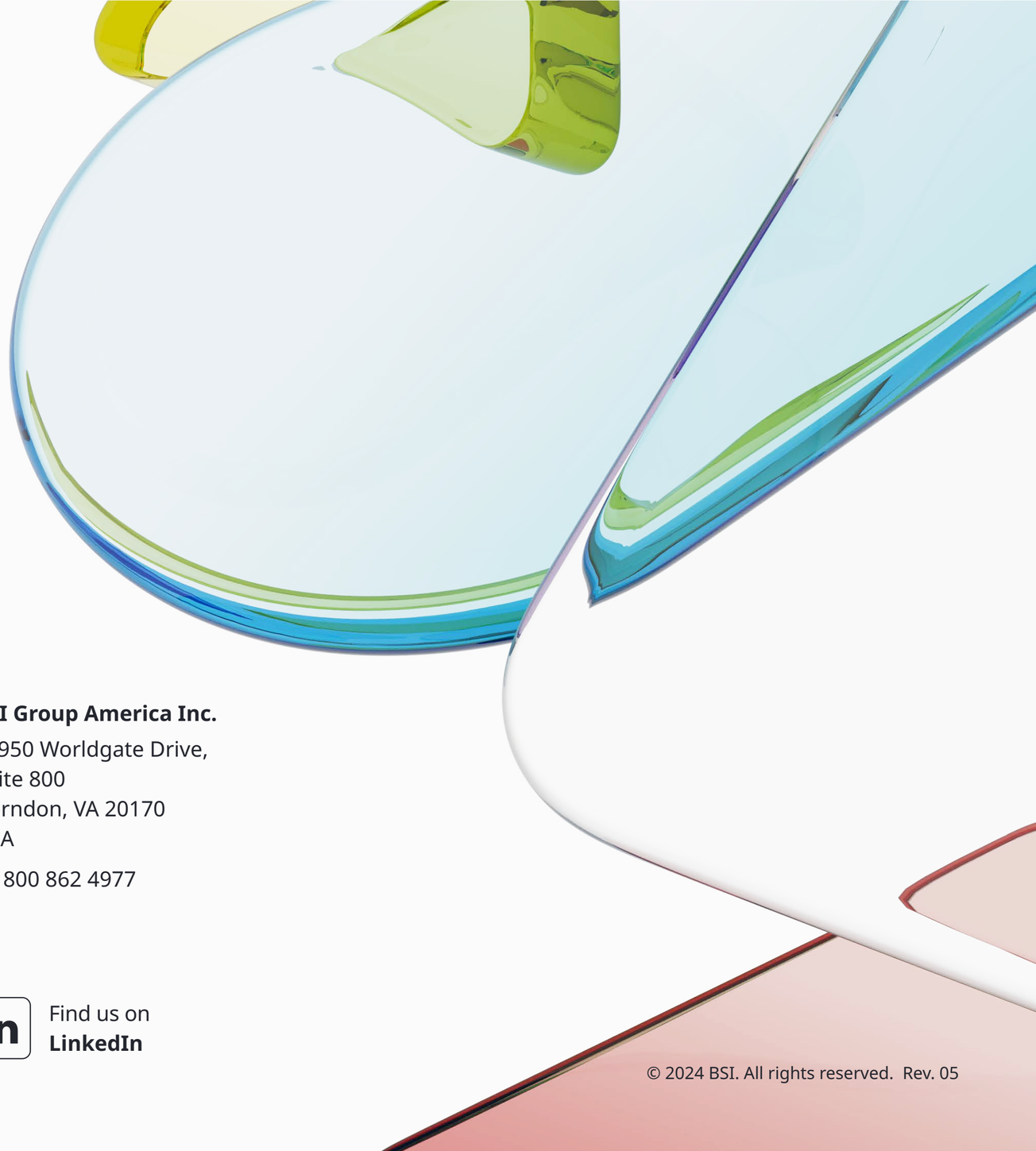
Talk to BSI today and start your journey

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Request a quote

Your partner in progress



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