Active Implantable Medical Devices

By Royal Charter

EU Notified Body and UK Approved Body 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 (EU MDR) 2017/745

  Great Britain Medical Devices Regulations (UK MDR) 2002

- It is critical to work with an EU Notified Body or UK Approved Body 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 AIMD medical devices and can support you through the process of certifying your device.

- 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 that provides Conformity Assessments under the UKCA scheme.

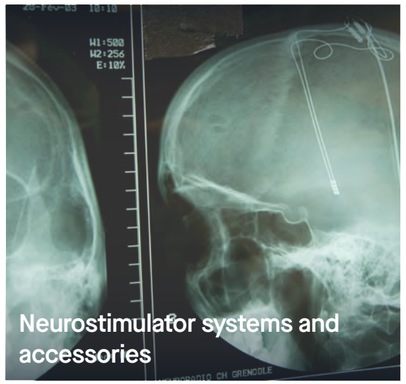
Defining Active Implantable Medical Devices

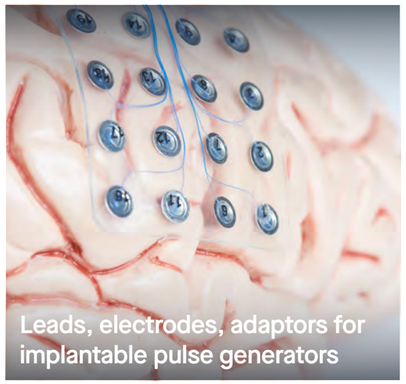
- Its functioning depends on an energy source other than that generated by the human body for that purpose or by gravity, and which acts by changing the density of or converting that energy
- It is to be totally introduced into the human body or used to replace an epithelial surface or the surface of 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

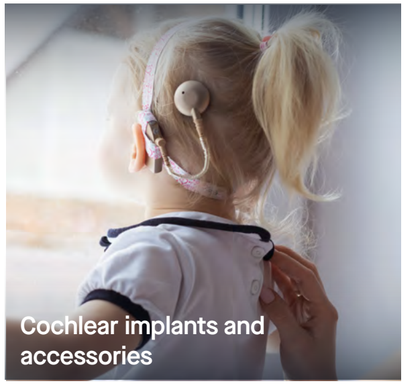

Pacemakers, defibrillators and accessories


Neurostimulator systems and accessories


Leads, electrodes, adaptors for implantable pulse generators

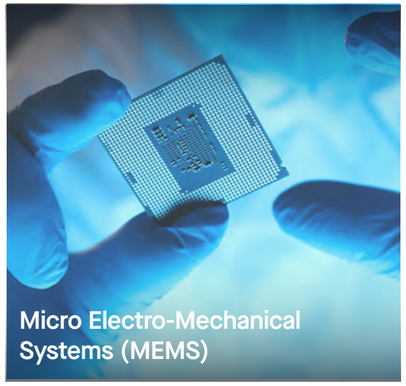

Brachytherapy systems and accessories


Ventricular Assist Devices (VADS) and accessories


Cochlear implants and accessories


Infusion pumps and accessories


Implantable glucose monitors and accessories

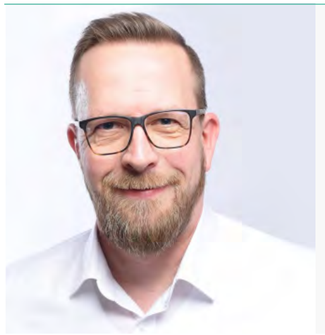

Micro Electro-Mechanical Systems (MEMS)

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"

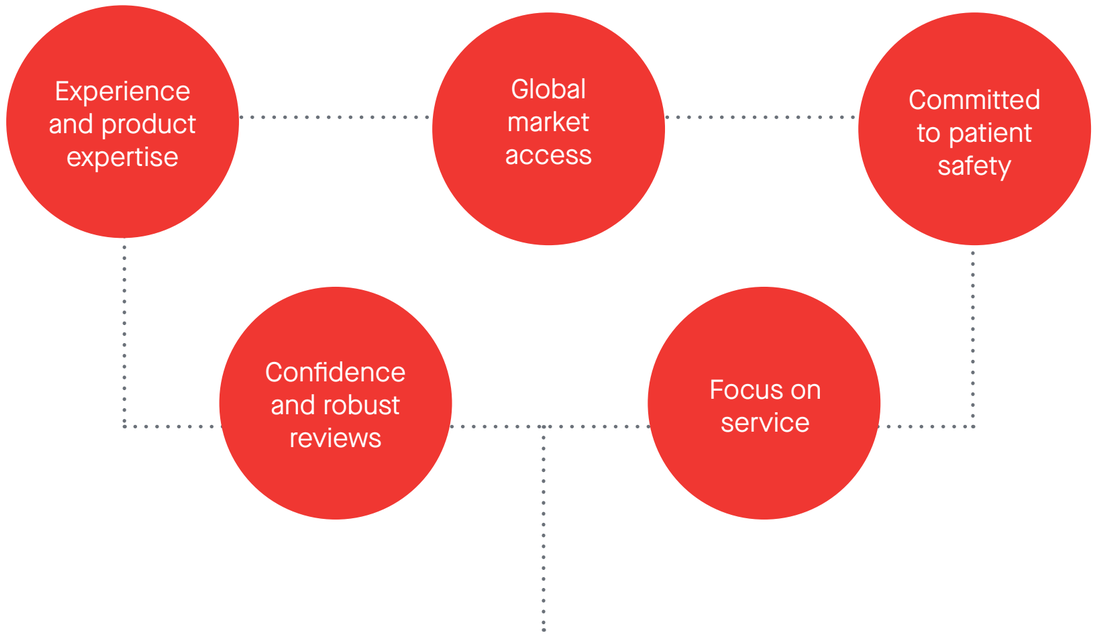
Thomas Doerge, Global Head of AIMD



+49 170 220 24 55
thomas.doerge@bsigroup.com
bsigroup.com/medical

BSI Group Deutschland GmbH
Hanauer Landstraße 115
60314 Frankfurt, Germany

Why choose BSI



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 900 professionals including technical experts competent 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.

Confidence 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.

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 to provide conformity assessments under the new UKCA scheme.

Focus on service

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

We offer a range of flexible product review services providing you with efficient pathways to bring your product to market.

Five steps from product-to-market

1

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.

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.

3

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.

4

Issue certificate

Upon successful certification, you will be issued with a certificate.

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

5

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.

How BSI supports your Medical Devices launch

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. Our Quality Management System (QMS) solutions include ISO 13485, ISO 9001, ISO 14001 and many more.

We are a recognized certification body in Japan, Malaysia, Singapore and Taiwan, and a recognized MDSAP auditing organization for all participating regulatory authorities.

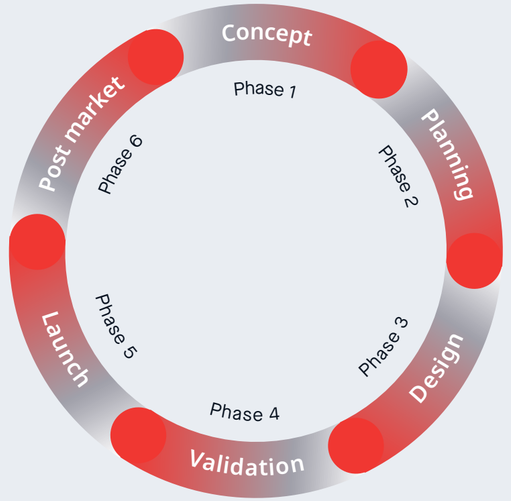
BSI Transfer

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

The MDR (EU 2017/745), which replaced the AIMDD (90/385/EEC) and MDD (93/42/EEC), applied on May 2021. Manufacturers have until May 2024 to ensure their Technical Documentation and processes meet the new requirements for placing medical devices on the EU market.

Manufacturers are invited to apply to a Notified Body for MDR as soon as possible and well in advance of the end of the transition period (at least 1 year before the expiry date of the MDD/AIMDD certificate) to ensure timely compliance with the Regulation by 26 May 2024.

Starting the certification process?

Transitioning to MDR?

Transferring your existing certification?

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

Technical Documentation guidance to meet MDR requirements

Continued support from our technical experts thorough your submission

CE/UKCA Excellence

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

Standard

Our standard service reviews are completed by experienced BSI Product Experts.

Dedicated

This service allows you to schedule your Technical Documentation review with a dedicated BSI Product Expert.

Talk to BSI today

1-800-862-4977

bsigroup.com/aimd

and start your journey

BSI UK Approved Body (0086)

Kitemark Court, Davy Avenue
Knowlhill
Milton Keynes MK5 8PP
United Kingdom

+44 345 080 9000
medicaldevices@bsigroup.com

BSI The Netherlands Notified Body (2797)

Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

+31 20 346 0780
medicaldevices@bsigroup.com

bsi.

Read more about our certification services on our website **bsigroup.com/medical**

Find us on LinkedIn