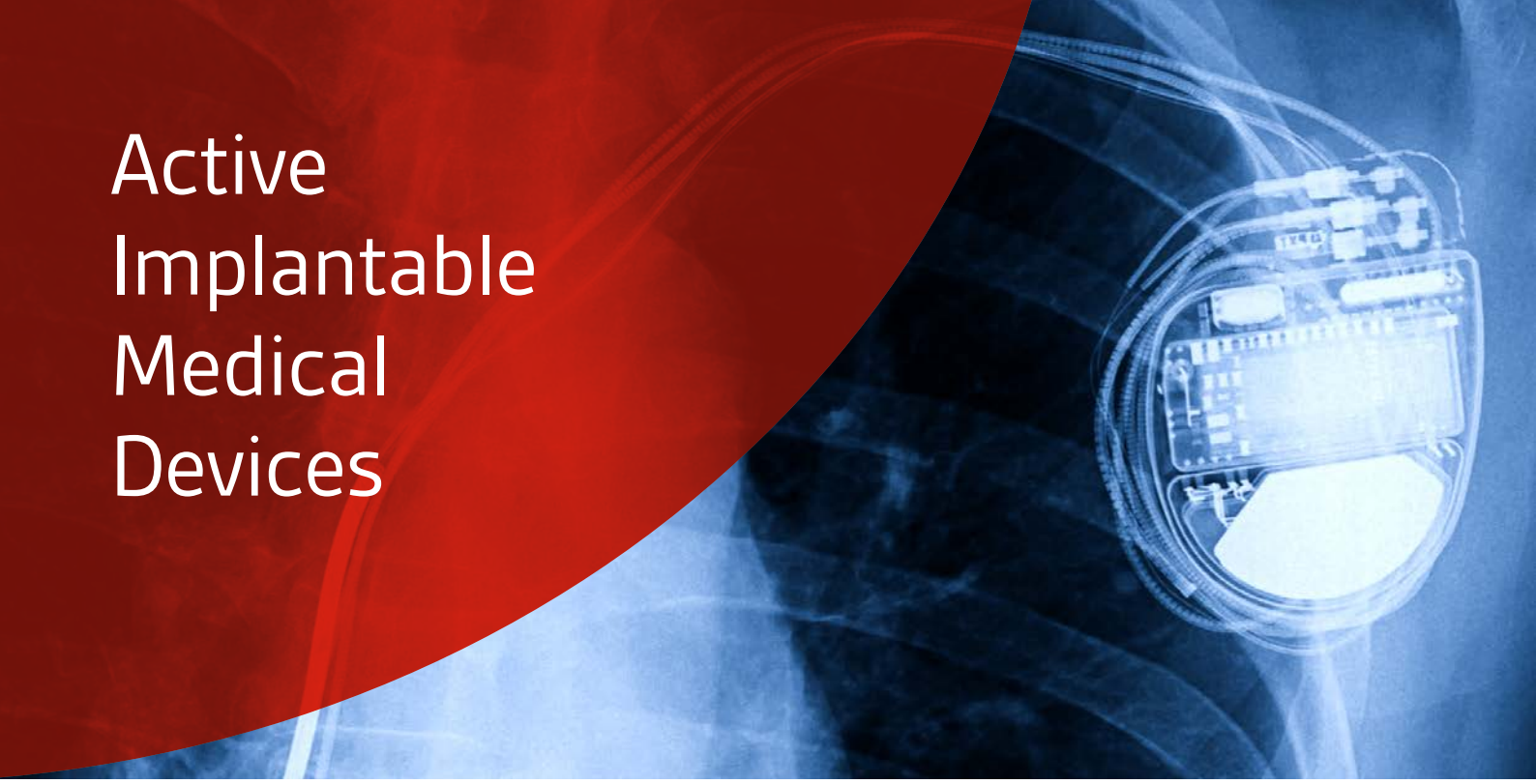
Active Implantable Medical Devices



Justifiably proud of our status as a full scope AIMD EU Notified Body and UK Approved Body

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; for the EU, these are outlined in the Medical Device Regulation (MDR) (EU) 2017/745 and for Great Britain, Part III of The Medical Devices Regulations 2002 (as amended).

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, reliably and promptly. 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 able to provide conformity assessments under the new UKCA scheme.

bsi.

...making excellence a habit.™

Defining Active Implantable Medical Devices

An Active Implantable Medical Device in the MDR is defined as:

- a device the operation of which 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,
- which 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,
- which is intended to remain in place after the procedure
- and includes any active device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days

All 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).

Meet our experienced AIMD team

Our AIMD technical and clinical specialists are not only experienced in the Part III of The Medical Devices Regulations 2002 (as amended), they are fully trained on the MDR. This replaces the AIMDD as the legislation detailing the requirements manufacturers must meet to place their medical devices on the market in the European Union as of 26 May 2021. 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*

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.

Examples of products we cover

- Implantable cardiac pacemakers and accessories
- Implantable defibrillators and accessories
- Implantable neurostimulator systems and accessories
- Leads, electrodes and adaptors for implantable pulse generators
- Brachytherapy systems and accessories
- Ventricular Assist Devices (VADs) and accessories
- Cochlear implants and accessories
- Implantable infusion pumps and accessories
- Implantable glucose monitors and accessories
- Micro Electro-Mechanical Systems (MEMS)

Reasons to make BSI your AIMD Notified Body and UK Approved Body

Experience and product expertise

The benefits of having experienced, professional and well-qualified technical specialists cannot be overstated in the complex and ever-changing medical device industry. BSI Medical Devices has a team of over 900; within that team are our technical experts with experience encompassing the full range of medical devices and management system standards.

BSI Group is a global network of over:

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

Focus on service

Clients work with us because we understand the challenges medical device 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.

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.

Confidence and robust reviews

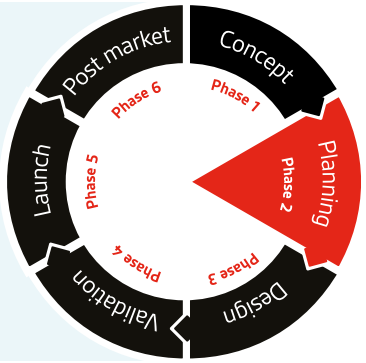
Our comprehensive review process combined with our world-leading experience as a Notified Body and UK Approved Body will ensure that your conformity assessment process is both efficient and robust.

Passion for 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, robust conformity assessments, evaluations and certifications.

The Product Lifecycle: when to consider 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. Consolidated clinical and regulatory planning will assist 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.



How can BSI support your AIMD launch?

Be prepared

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

Worldwide access

We offer a wide range of proven regulatory and quality management programs that work together for full 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.

Seamless transfer to BSI

We can offer a seamless service with comprehensive support and the absolute minimum level of disruption.

Certification support and additional services

We offer continual support throughout the certification process and beyond; we also offer:

- **access to more than 34,000 standards** and related products, as well as online guidance documents
- **expert training** delivered online or face-to-face, either in-house or through our public training courses
- **regulatory updates** and a newsletter service focusing on industry changes, helping you to plan for the future
- **webinars** delivered by our experts on complex regulatory issues
- **comprehensive whitepapers** providing the latest insights on key industry topics

Navigating your transition to the MDR

The Medical Devices Regulation (EU 2017/745), which replaces the Active Implantable Medical Devices Directive (90/385/EEC) and Medical Devices Directive (93/42/EEC), has a transition period of four years starting from May 2017 Manufacturers have the duration of the transition period to update their Technical Documentation and processes to meet the new requirements if they want to place medical devices on the market in the European Union.

The EU MDR and the GB Part III of The Medical Devices Regulations 2002 (as amended), bring with it more scrutiny of Technical Documentation; addresses concerns over the assessment of product safety and performance by placing stricter requirements on clinical evaluation and post-market clinical follow-up; and requires better traceability of devices through the supply chain.

Whether you're starting the certification process, looking to transfer, or just need to discuss options for your organization, we have a range of materials to support you through this regulatory change. Our MDR Best Practices Guidelines (BPG) provide guidance on preparing and structuring your Technical Documentation. Following these will ensure your submission to BSI is complete and thorough.

CE-Excellence: Technical Documentation Review

Our CE-Excellence: Technical Documentation Review services deliver the efficiency you need to be both competitive in the market and maintain confidence through our robust technical reviews.

CE-Standard

Our standard service reviews are completed by experienced BSI Product Experts, giving you confidence in the review.

CE-Dedicated

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

Five steps to getting your product to market

Step 1

BSI prepares a 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.

Step 2

BSI performs a conformity assessment

A dedicated BSI scheme manager will be assigned to you, supporting your organization throughout the process. A QMS audit will then be performed and all Technical Documentation reviewed by one of our experienced technical experts.

Step 3

Certification 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.

Step 4

Issue certificate

Upon successful certification, you will be issued with a certificate. You will then be able to CE mark your product and launch to market.

Step 5

Certification maintenance

On-going surveillance audits and reviews are required to monitor for continued compliance. Your BSI scheme manager will be able to support you with any queries you might have.

Talk to BSI today

Call: **+44 345 080 9000**

Visit: **bsigroup.com/AIMD**

and start your journey

bsigroup.com

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