

# Active Implantable Medical Devices

## Justifiably proud of our status as a full scope AIMD Notified Body

As one of the highest risk categories of device, Active Implantable Medical Devices (AIMDs) are subject to rigorous regulatory controls before they can reach global markets. [The Medical Device Regulation \(MDR\) \(EU\) 2017/745](#) defines the requirements of these medical devices.

The challenges AIMD manufacturers face in this highly competitive market make it essential that you ensure your product meets all regulatory and quality requirements before launch. It is critical to work with a notified body that understands the industry and has the experience to review and confirm your products' readiness for market – efficiently, promptly and robustly. BSI has been leading the way in providing product and system certification that inspires confidence and trust.

# Defining Active Implantable Medical Devices

An Active Implantable Medical Device 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](#).

## Meet our experienced AIMD team

Our AIMD technical and clinical specialists are not only experienced in the existing Active Implantable Medical Device Directive (AIMDD), 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.

"I am proud to be able to work with such a highly motivated and skilled group of technical specialists and clinical experts who fully understand the design, manufacture and application of Active Implantable Medical Devices and who put patients at the centre of all their thinking."

**Paul Risborough**

*Global Head of Active Implantable Medical Devices, BSI*



### 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

## 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 700; 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:**



## 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 has two Notified Bodies, one in the UK (0086) and one in the Netherlands (2797), both of which have full scope designations to the IVDR and MDR.

## Confidence and robust reviews

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

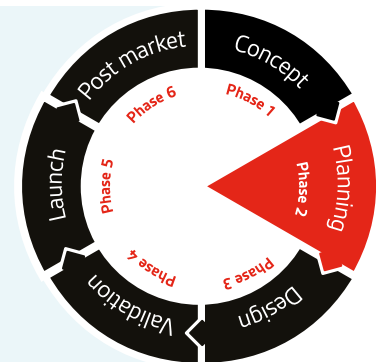
## Passion for patient safety

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 Hong Kong, 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, after which the Regulation will apply. 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 MDR brings 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](https://www.bsigroup.com/AIMD)**

and start your journey

**bsi.**

[bsigroup.com](https://www.bsigroup.com)

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