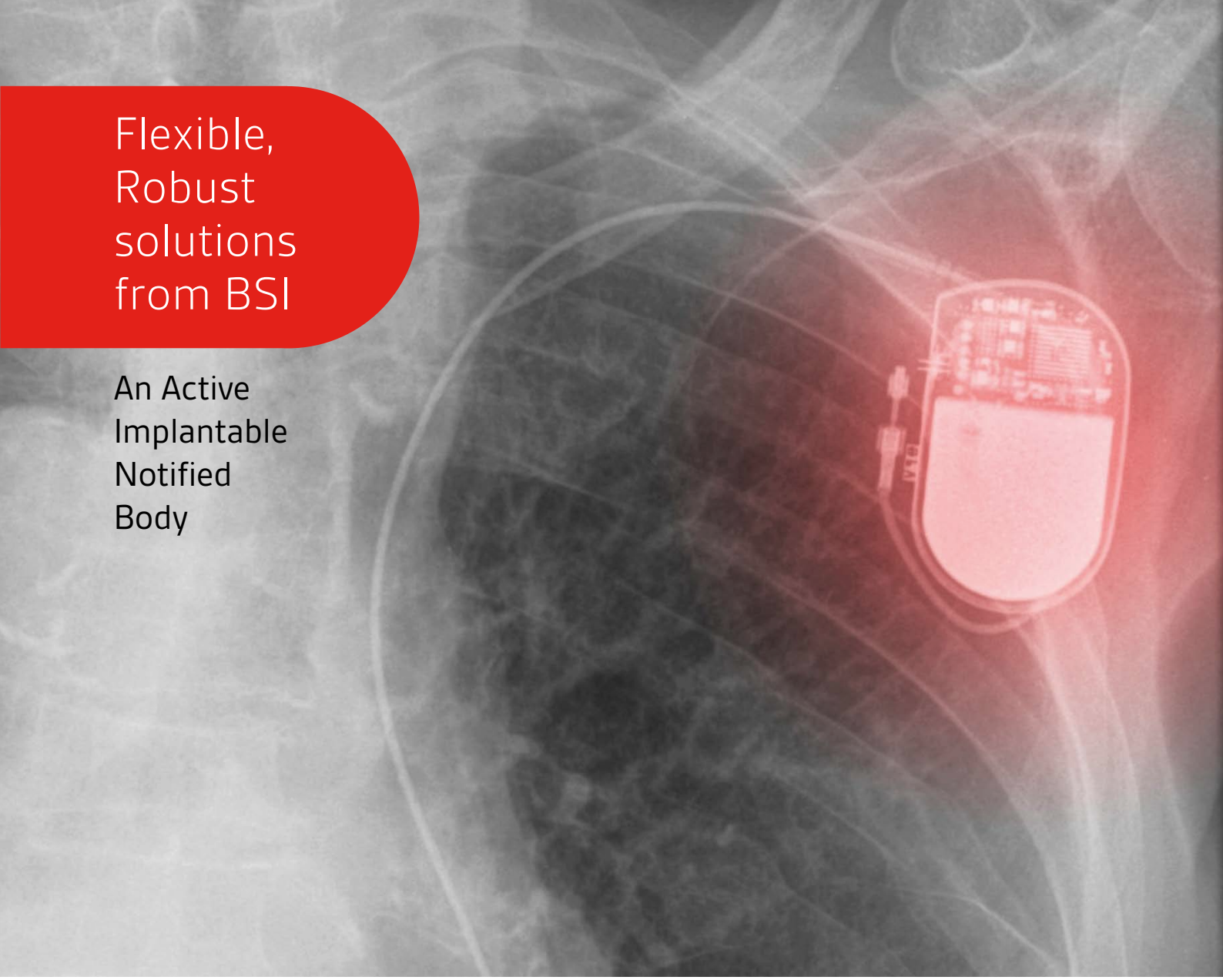


Flexible, Robust solutions from BSI

An Active Implantable Notified Body

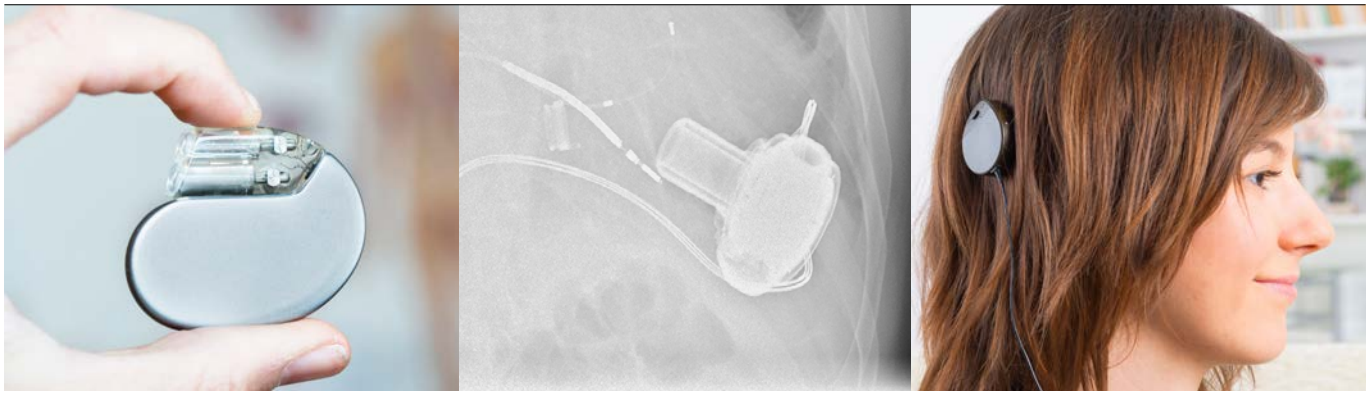
Expertise and experience

Supporting life, implanting excellence

Updated May 2017

bsi.

...making excellence a habit.™

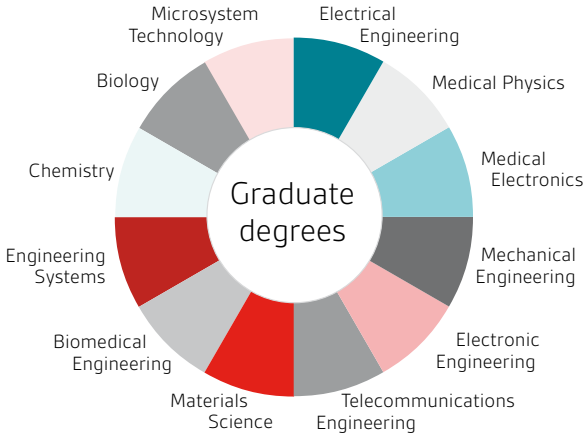


Unrivalled expertise from the premier Active Implantable Medical Device Notified Body

Used for a wide range of treatments in various specialized fields, Active Implantable Medical Devices (AIMDs) represent a significant and profitable segment of the healthcare industry. As a manufacturer of AIMDs, one of your biggest challenges in breaking into – or continuing success in – this market is navigating the regulatory process efficiently. Our AIMD specialists are not just experienced in the regulatory process, but they are product experts who understand the specifics of active implantable products.

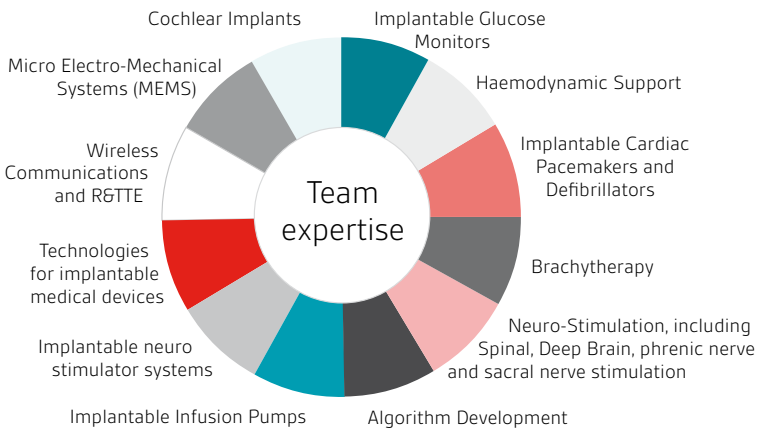
Experience

BSI Medical Devices is justifiably proud of its status in the industry as an AIMD Notified Body. Nowhere is this more clearly seen than in our level of experience, our large specialist AIMD team has over 12 technical experts, with over 14 graduate degrees between them:



Market access

Our in-house expertise and efficient service means your product reviews won't slow down your launch plans, helping you stay ahead of the competition.



Defining AIMDs: The Active Implantable Medical Devices Directive

The Active Implantable Medical Devices (AIMD) Directive 90/385/EEC defines an active implantable medical device as 'any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure'. As one of the highest risk categories of device, they are subject to rigorous regulatory controls both pre- and post-market. The regulatory controls set out in the AIMD Directive also apply to any accessories that are used to enable the device to operate as intended, for example leads, programmers, controllers, battery packs, software applications, implant kits and refill kits.

As a full scope Notified Body, BSI offers CE certification services to the AIMD Directive. Our AIMD team has a broad range of industry and regulatory experience, including product design and development, manufacture and regulatory expertise. The AIMD team also has specific expertise in software development.

How can BSI support your Active Implantable Medical Device launch?

Be prepared

In the competitive medical device market place, ensuring that product development meets all regulatory requirements is essential. Understanding and consideration of the complicated clinical and regulatory requirements early in the product lifecycle could ensure your company gains the competitive advantage. Consolidated clinical and regulatory planning will assist your company to maximise resources and minimise time to market.

CE-Excellence

Clients work with us because we understand the challenges medical device manufacturers face in getting compliant products to market efficiently and safely.

Our CE-Excellence review services deliver the efficiency you need to be competitive while maintaining confidence through a robust review. Explore the options below:

- **CE-Standard:** Our standard service reviews are completed by experienced BSI Product Experts, giving you confidence in the review.
- **CE-Dedicated FastTrack**: This service allows you to schedule your technical documentation review with a dedicated BSI Product Expert.
- **CE-Onsite FastTrack:** This review is conducted at your premises; a BSI Product Expert visits the facility for a period of time. This allows dynamic communications and opportunities for immediate responses.

Worldwide access

Our expertise offers a wide range of proven regulatory and quality management programs that work together for full international compliance. Our QMS solutions include: ISO 13485, ISO 9001, ISO 14001 and many more.

BSI is a recognized Certification Body in Australia, Brazil, Canada, Hong Kong, Japan, Malaysia and Taiwan, and is a recognized MDSAP Auditing Organization for all participating Regulatory Authorities.

Seamless transfer to BSI

If you decide to transfer your certification to BSI, we can offer a seamless exercise with comprehensive support and the absolute minimum level of disruption. We have expertise encompassing the full range of industry sectors and management system standards.

Certification support

Thoughout the certification process and beyond we can continually support you. We can provide:

- Expert training courses:
  - In-house for your company
  - Public courses, see website for the latest schedule
- Regulatory Updates, helping you plan for the future
- Free webinars
- Access to relevant standards.

Your resource for excellence

Three unique reasons to make BSI your Active Implantable Medical Device Notified Body

Experience and expertise – BSI focuses on excellence, thereby reducing your corporate risk.

Focus on service – BSI offers a range of review services, giving you a greater level of flexibility as well as predictability.

Market access – Our efficient service means your product reviews won't slow down your launch plans, helping you to stay ahead of the competition.

Additional services

Medical device newsletter service – Keep updated on what's happening in the industry and changes in regulatory and quality requirements. You can take advantage of this free service by signing up at our website.

Informative webinars – Hear regular updates from our experts on key topics; listen live or listen back.

Comprehensive white papers – Our technical specialists collaborate with external experts to bring you the latest views and understanding on complex regulatory issues. Download your complimentary copies now.

Guidance documents – Our online guidance documents provide assistance in understanding the regulatory requirements for medical devices.

Standards – BSI British Standards delivers leading-edge best practice solutions through the development and publication of more than 34,000 standards and related products.

Your resource in worldwide compliance: Call BSI today on 1300 730 134 or visit bsigroup.com/en-au – to start your journey

bsi.

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