Flexible, FastTrack solutions from BSI

An Active Implantable Notified Body

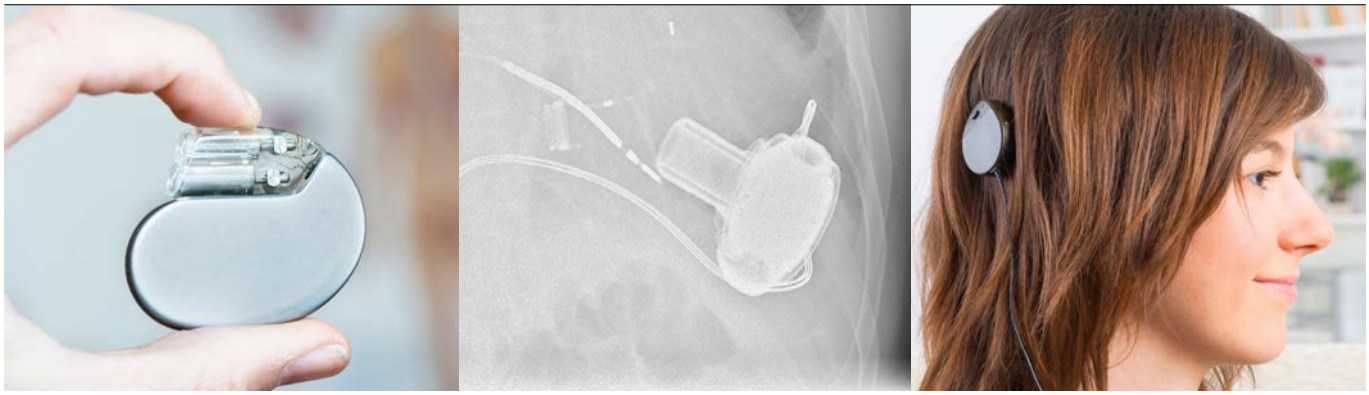
Expertise and experience

Supporting life, implanting excellence

Updated February 2016

bsi.

...making excellence a habit.™

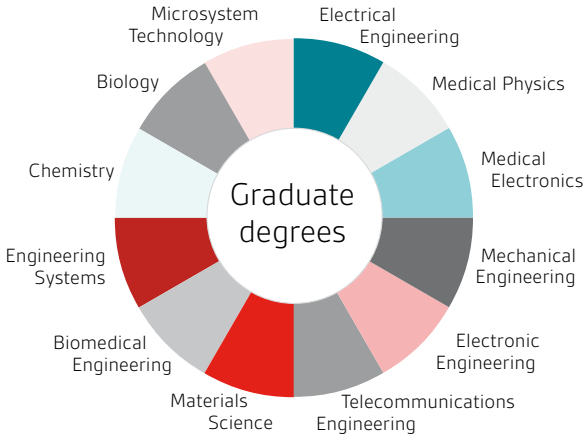


Unrivalled expertise from the premier Active Implantable Medical Device Notified Body

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.

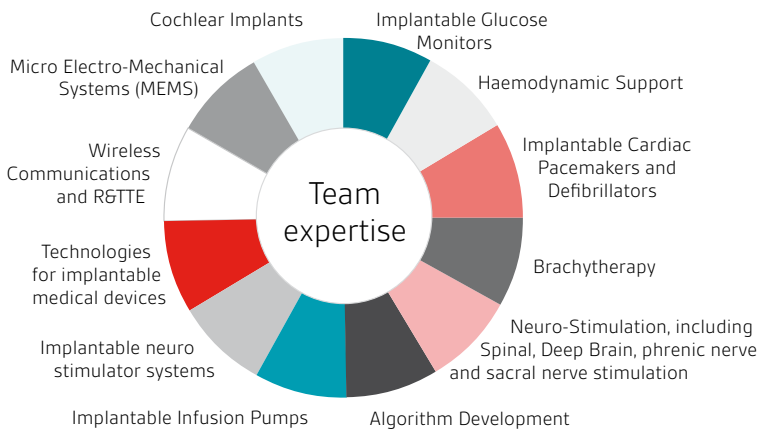
Experience

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 11 technical experts, with over 12 graduate degrees between them:



Market access

Our in-house expertise and speed-to-market 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 radio telecommunications (R&TTE) and 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 marking: Speed-to-market

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

CE-90 Standard: Our standard service reviews are completed within 90 days from submission, giving you predictability for better planning.

CE- FastTrack: Our FastTrack programmes deliver the speed-to-market you need to be competitive and move ahead of the competition. The aim is review completion in 45 days from submission with a choice of options:

- CE-45: Standard 45 day service
- CE-Onsite: The review service is conducted at your premises, allowing for a faster timeline and dynamic communication.
- CE-Dedicated: Your review will be conducted remotely, your Product Expert will be able to arrange flexible schedules with you.

Worldwide access

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

BSI works with international regulators to ensure we understand what is required to get products approved in the USA, Canada, Japan, Australia, Brazil, Hong Kong, Malaysia and Taiwan.

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. With 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.

A resource for excellence

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

Experience and expertise – You can rest assured by BSI's focus on excellence, thereby reducing your corporate risk.

Focus on service – BSI offers a premium customized service, giving you a greater level of flexibility as well as predictability.

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

Additional services

Medical device e-update 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.

Informational webinars – We offer a wide variety of interactive multimedia presentations allowing convenient participation via a web-based interface.

Guidance documents – Our online Guidance Documents provide assistance in understanding the requirements of the medical devices directives.

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 partner in worldwide compliance: Call BSI today on 1 800 862 6752 or visit bsigroup.ca/medical – to start your partnership

bsi.

Toronto Office
6205B Airport Road, Suite 414
Mississauga, ON L4V 1E3
T: 416 620 9991
TF: 1 800 862 6752
F: 416 620 9911

Ottawa Office
515 Legget Drive, Suite 110
Ottawa, ON K2K 3G4
T: 613 271 7007 TF: 1 800 862 6752 F: 613 271 9007

Montréal
1, Place Ville Marie, Suite 2901
Montréal, QC H3B 2C4
T: 514 940 1778
TF: 1 800 862 6752
F: 514 866 2115

Visit us online at: bsigroup.ca/medical