



Flexible,  
Robust  
solutions  
from BSI

An Active  
Devices  
Notified  
Body

Expertise and experience

Actively supporting life

Updated May 2017

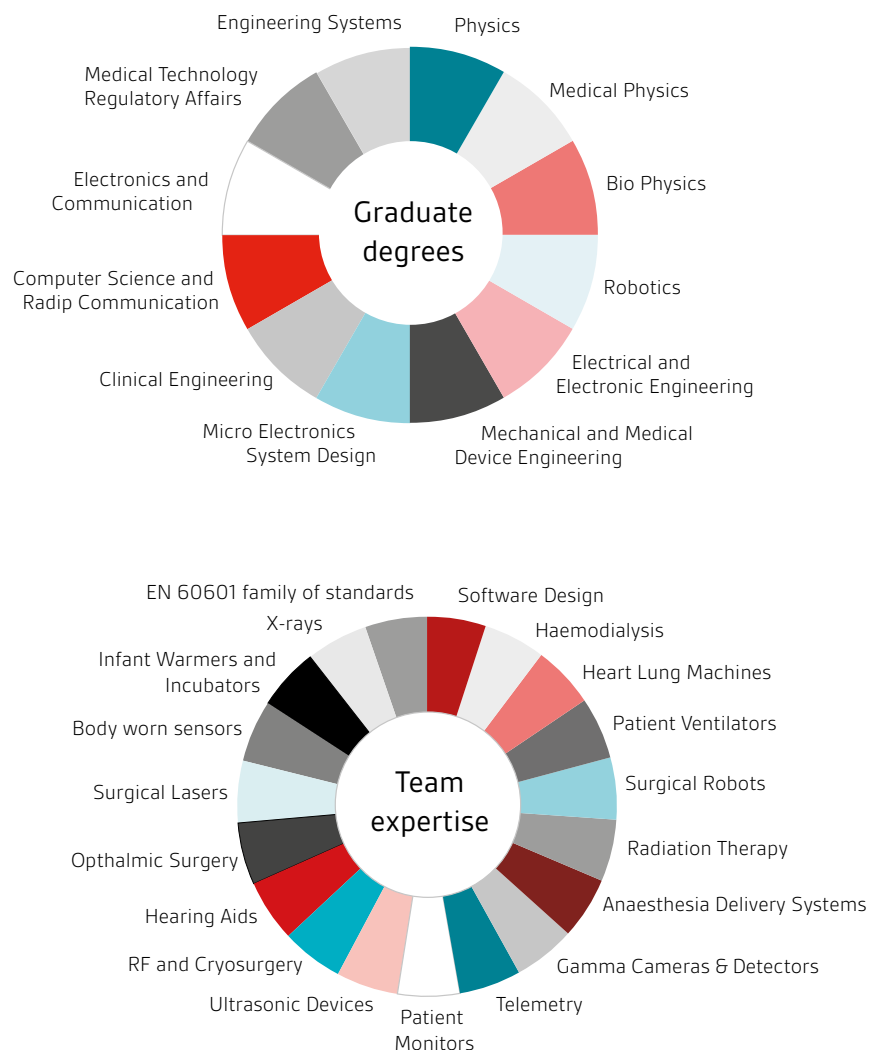
**bsi.**

...making excellence a habit.™



## Unrivalled expertise from BSI's Active Devices Team

BSI has been providing a service to Active Device manufacturers since 1979. The Active Devices Team includes 24 technical experts with a wide range of graduate degrees. They have a total of over 375 years of experience in the design, development, manufacture, certification and testing of active medical devices. Where products require additional expertise the BSI Notified Body has a number of teams covering all medical devices, including vascular, orthopaedic and dental, sterile products, IVD, medicinal substances, products utilizing animal tissue, active implantable devices, woundcare, ophthalmic and others. This strong in-house expertise, together with our efficient review services and wide range of global solutions means that the Notified Body service we provide our clients is best in class.



# Getting your products to market

Step  
1

## BSI prepares a quotation

A BSI company representative meets with your organization to discuss your services and the available solutions.

BSI has a full portfolio of global solutions and will provide the best services for your requirements.

Step  
2

## BSI performs a conformity assessment

A dedicated BSI Scheme Manager will be assigned to your company, supporting you throughout the process.

Quality Management System audit is performed.

Technical files reviewed by experienced experts thereby providing confidence.

Step  
3

## Certification decision

Successful Assessment leads to a Scheme Manager recommendation for certification.

BSI Certification Decision Team will review the recommendation and if satisfactory approve certification.

Step  
4

## Certificate issue

Upon successful certification a certificate will be issued to your company.

Step  
5

## Certification maintenance

On-going surveillance audits and reviews monitor for continued compliance.

Your BSI Scheme Manager is available to support you when you have questions.



# How can BSI support your Active 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

Throughout 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.

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**Your resource in worldwide compliance: Call BSI today on **1300 730 134** or visit **[bsigroup.com/en-au](https://www.bsigroup.com/en-au)** – to start your journey**

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