



Flexible,  
FastTrack  
solutions  
from BSI

An Active  
Devices  
Notified  
Body

Expertise and experience

Actively supporting life

Updated February 2016

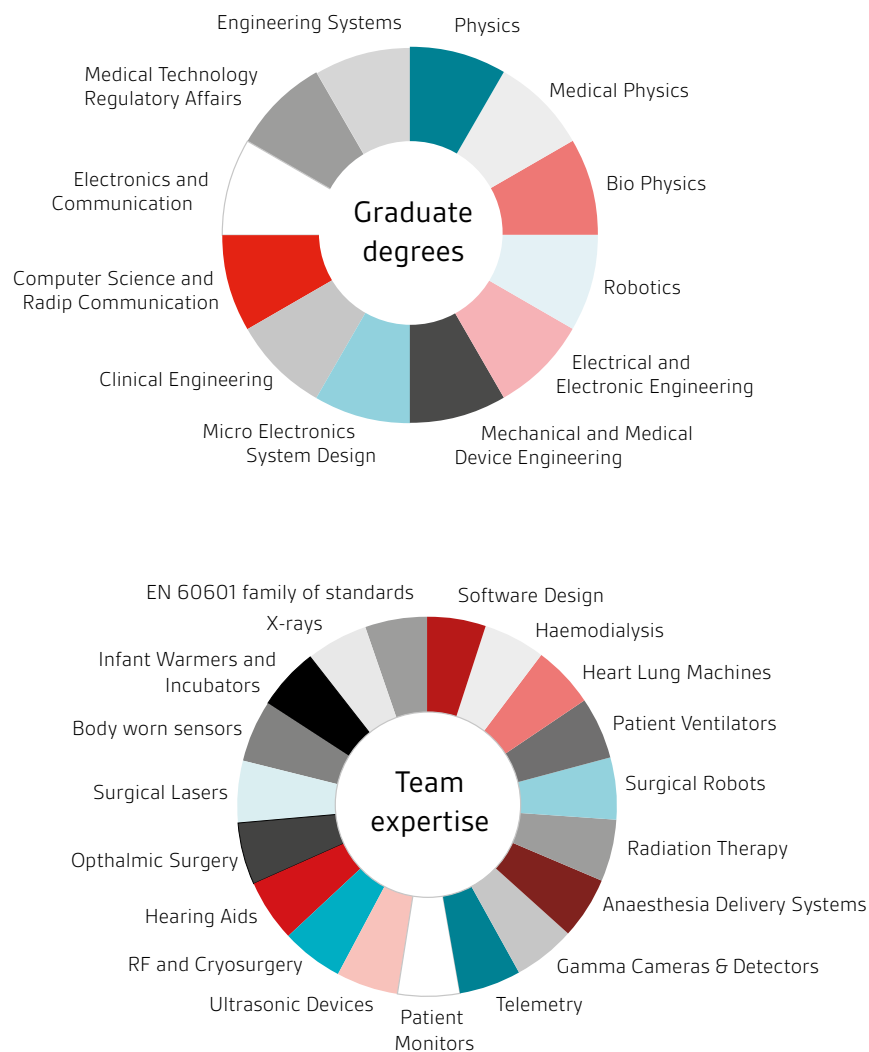
**bsi.**

...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 23 technical experts with a wide range of graduate degrees. They have a total of over 300 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 speed to market programmes 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 requirements and the available solutions.

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

Step  
2

## BSI performs a conformity assessment

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

Quality Management System audit is performed.

Technical files reviewed by experienced experts within agreed timescales thereby providing predictability.

Step  
3

## Certification decision

Successful Assessment leads to a Project Manager recommendation for certification.

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

Step  
4

## Certificate issue

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

Step  
5

## Certification maintenance

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

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



# How can BSI help 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 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

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 partner in worldwide compliance: Call BSI today on +44 345 080 9000 or visit [bsigroup.com/medical-devices](https://bsigroup.com/medical-devices) – to start your partnership**

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