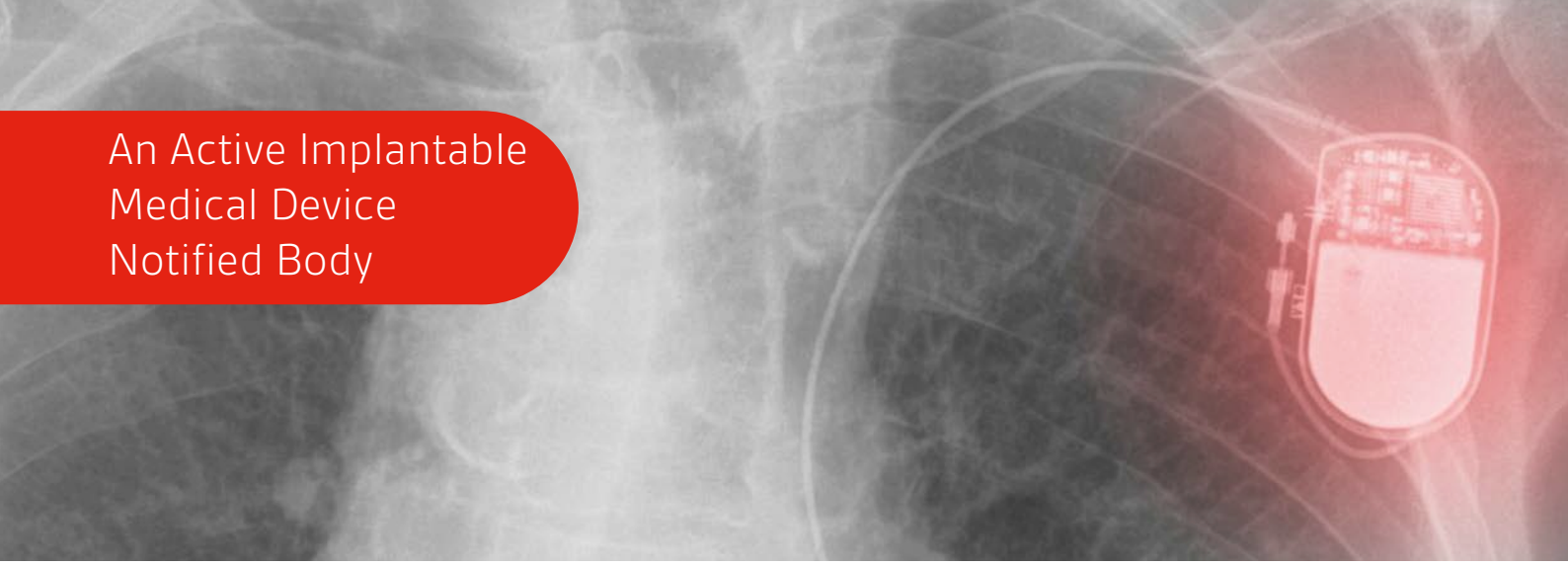


# Expertise and experience

## Supporting life, implanting excellence

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.

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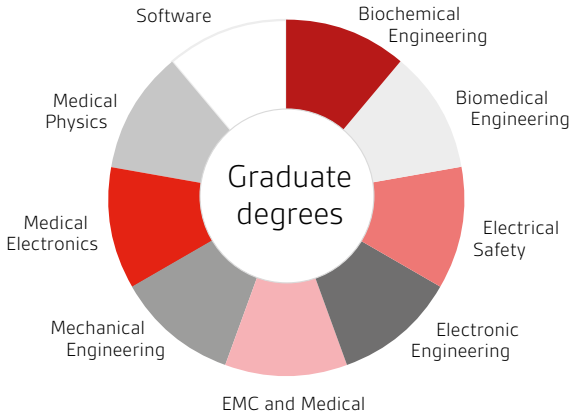
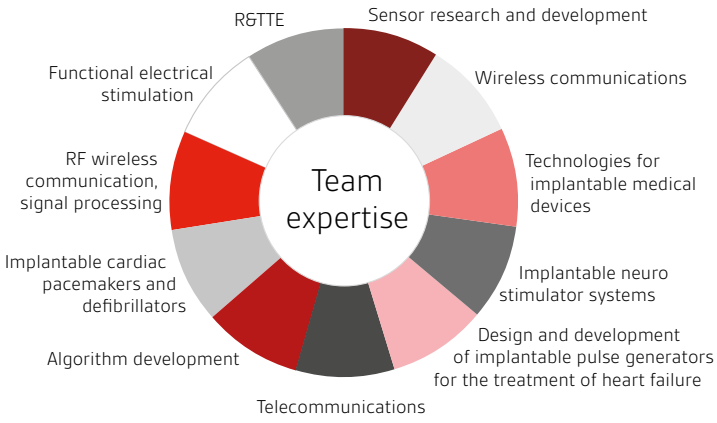
## Experience

BSI Medical Devices is justifiable proud of its status in the industry as an AIMD Notified Body. Nowhere is this more clearly seen that in our level of experience, our large specialist AIMD team has 9 technical experts, with 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.




bsi.

...making excellence a habit.™

## Defining AIMDs: Active Implantable Medical Devices Directive

AIMDs are typically high risk devices and are subject to rigorous standards and definitions before they can reach global markets. Directive 90/385/EEC regulates the market readiness and service parameters for active implantable medical devices (AIMDs). In order to meet regulations under 90/385/EEC, a product must meet the directive's definition of an AIMD: a medical device that is – at the same time – both "active" and "implantable."

Quote from the directive "Active implantable medical device' means 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."

This definition may apply to an entire system or to interchangeable parts intended to form a system (together along with other devices). In these cases, each part belonging to a system is covered under the Directive – regardless of whether such part on its own is "active", "active and implantable" or not.

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

**Experience and expertise –** You can be rest assured by increased patient safety, 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.

### Talk to BSI

We believe excellence should follow in everything we do, so if you would like to find out more about BSI, please **call or email us for an initial conversation**

**Your partner in worldwide compliance: Call BSI today on +91 11 2692 9000 or visit bsigroup.com/en-IN – to start your partnership**

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