Flexible, robust solutions from BSI

A Woundcare Medical Device Notified Body

Expertise and experience

Aiding the healing process

Updated May 2017

bsi.

...making excellence a habit.™

Unrivalled expertise from the premier woundcare Notified Body

Woundcare is a diverse field with a wide range of treatments, utilizing a vast array of technologies. Devices can span the entire spectrum of classification. The diversity of intended uses and technologies means that an expert CE marking Notified Body is essential.

BSI is designated with a full scope which includes woundcare devices utilizing tissue of animal origin including TSE risk species.

For woundcare devices which incorporate ancillary medicinal substances, BSI has a proven track record of successful consultations with many competent authorities and the European Medicines Agency (EMA).

Our woundcare team has a wealth of experience gained from both the device and pharmaceutical industries, to understand the complete range of woundcare technologies.

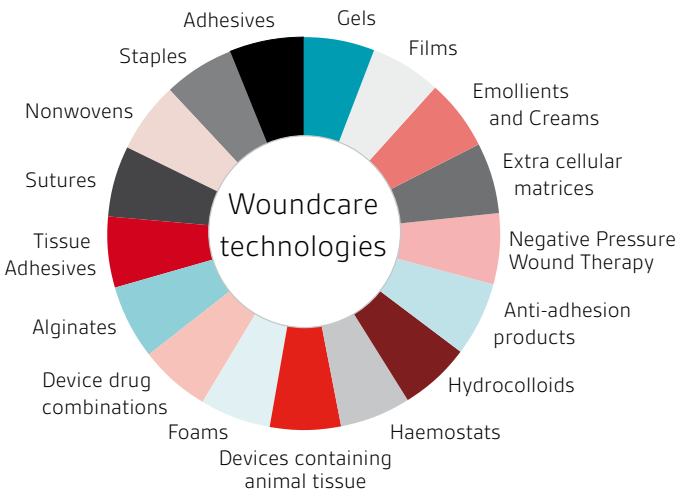
Three unique reasons to make BSI your woundcare Notified Body

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

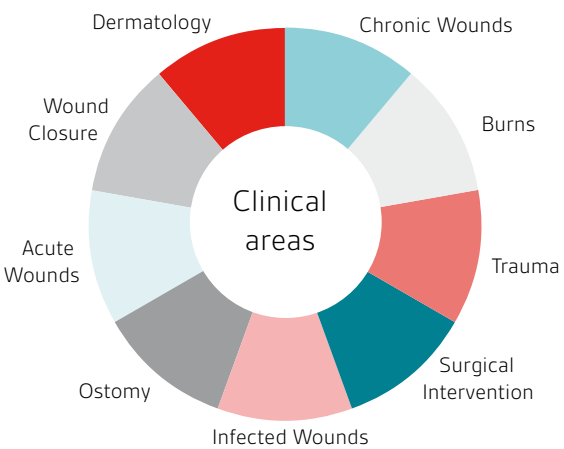
Focus on service:
BSI can offer a a range of review services, giving you a greater level of flexibility as well as predictability.

Market Access:
Our efficient review services means your product reviews won't slow down your launch plans, helping you to stay ahead of the competition.

BSI's woundcare technologies include:



Covering the following clinical areas...



Efficient routes into global markets with the guidance and experience of BSI.

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 technical 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 programmes 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:

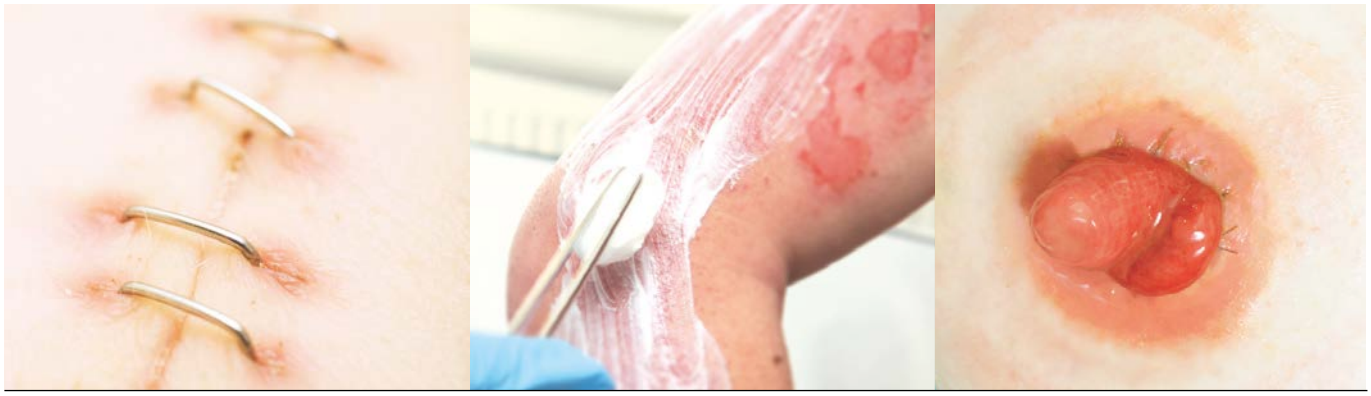
- Expert training courses:
  - In-house for your company
  - Public courses, see website for the latest schedule
- Regulatory Updates, helping you plan for the future
- Free webinars
- Access to relevant standards.

bsi.

...making excellence a habit.™

Please Note: our programmes do not guarantee CE marking certificate will be issued within a certain amount of working days, but are based on completing the review process with either a positive or negative recommendation.

BSI CE-Dedicated FastTrack and CE-Onsite FastTrack reviews are not available for devices utilizing animal tissue or containing human blood derivatives or medicinal substances.



Global expertise

Certification services

CE marking

ISO 13485 QMS Auditing

MDSAP Auditing – Australia, Brazil, Canada, Japan and USA

Japan PMD Act

Brazil INMETRO 60601 auditing and combined INMETRO, ISO 13485 and CE marking auditing

Hong Kong CAB

Malaysia CAB

Taiwan TCP

Training courses

CE marking for AIMD, MDD and IVD

ISO 13485 QMS

MDSAP: Fundamentals and Readiness

Creating and Maintaining Technical Files and Design Dossiers

Introduction to Risk Management for Medical Devices

CE marking Medical Devices with Software

Clinical Evaluation for Medical Devices

Device - Drug Combinations: Practical Guidance on Borderline Issues and the Consultation Process

Process Validation for the Medical Device industry

Post Market Surveillance and Vigilance

Medical Devices Utilizing Material of Animal Origin.

Global Market Access Courses

Your resource in worldwide compliance: Call BSI today on 0800 583 965 or visit bsigroup.com/en-nz – to start your journey

bsi.

BSI Group ANZ Pty Ltd
Level 10,
21 Queen Street,
Auckland 1010
New Zealand

T: 0800 583 965
E: info.nz@bsigroup.com

BSI/NZ/022/MD/0416/en/BLD

Visit us online at: bsigroup.com/en-nz