A Notified Body for devices utilizing materials of animal origin

Unrivalled expertise from the premier Notified Body for devices utilizing materials of animal origin

Experience and expertise

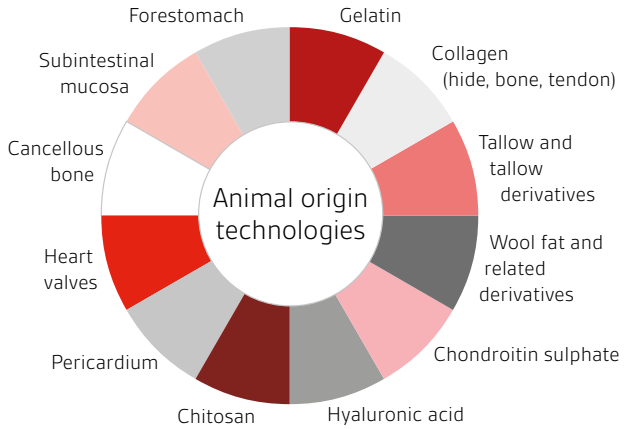
BSI recognises that the requirements for medical device manufacturers who utilize materials of animal origin can be burdensome. We have the expertise, knowledge and proven capability to guide you through this difficult process.

BSI is one of a few Notified Bodies designated to certify devices manufactured utilising materials of animal origin including those derived from Transmissible Spongiform Encephalopathy (TSE) susceptible species*. Our large in-house team of experts understands the challenges in gaining successful certification for your products.

Our auditors are qualified to conduct assessments at slaughterhouse facilities, tissue processors and all the way through the manufacturing chain to the finished product.

* TSE Susceptible Species are: bovine, caprine, deer, elk, feline, mink, ovine.

Experience of starting materials and derivatives



Our full scope covers the entire spectrum of devices in combination with:

- directive 2003/32/EC (shortly to be replaced by regulation 722/2012)
- EN ISO 22442 and all other aspects related to your certification needs across a wide range of device technologies
- sourcing and processing controls
- inactivation and elimination of viruses and TSE agents
- quality system assessments

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.

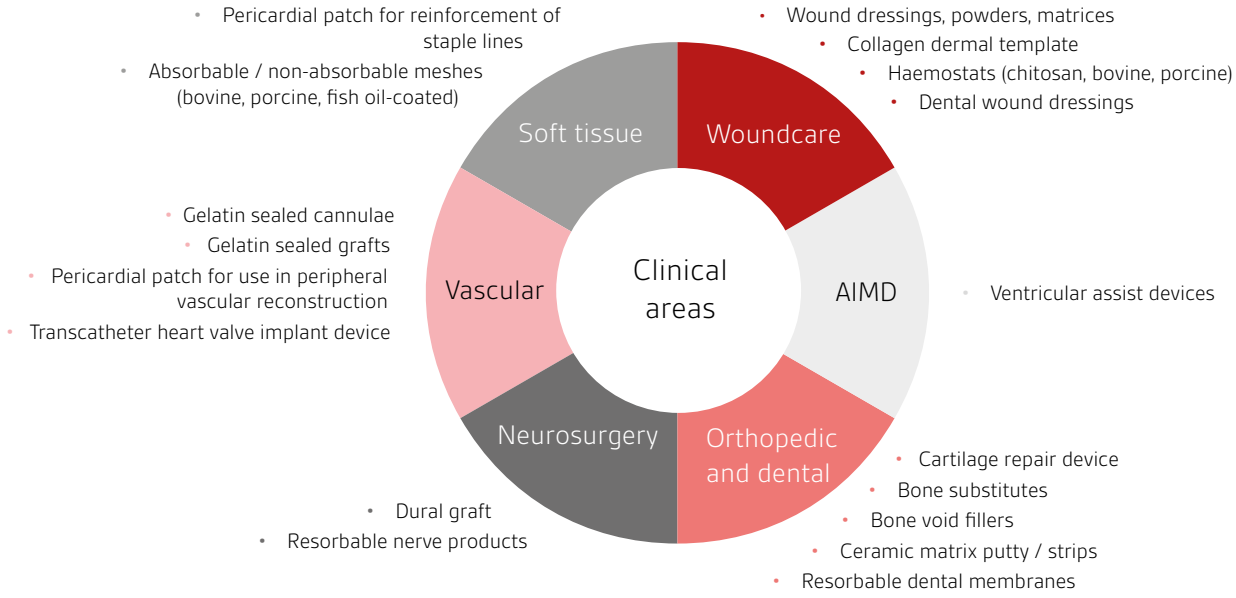
Bespoke service

Suppliers of materials of animal origin can also apply to BSI for EN ISO 13485 certification which may provide a competitive advantage when seeking to do business with device manufacturers. Certification will include a review against relevant requirements of EN ISO 22442 and may be taken in to consideration by Notified Bodies during conformity assessments.

bsi.

...making excellence a habit.™

Device technologies



Here to help

BSI is aware of the extra burden within this area of regulation and so will provide you with a timely, responsive, and informed approach to your certification needs. Come and talk to us about your individual circumstances.

BSI is a key player in groups responsible for related regulations and standards.

Your partner in worldwide compliance: Call BSI today on +44 845 080 9000 or visit medicaldevices.bsigroup.com – to start your partnership

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