

A Notified Body for  
devices utilizing materials  
of animal origin

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

## Experience and expertise

BSI recognizes 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 provide you with the excellence you need through this difficult process.

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

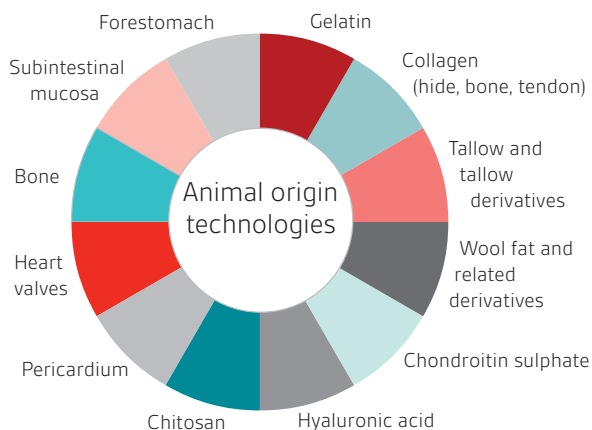
\* TSE Susceptible Species are: bovine, caprine, deer, elk, feline, mink, ovine.

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

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

- EU 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

## Experience of starting materials and derivatives



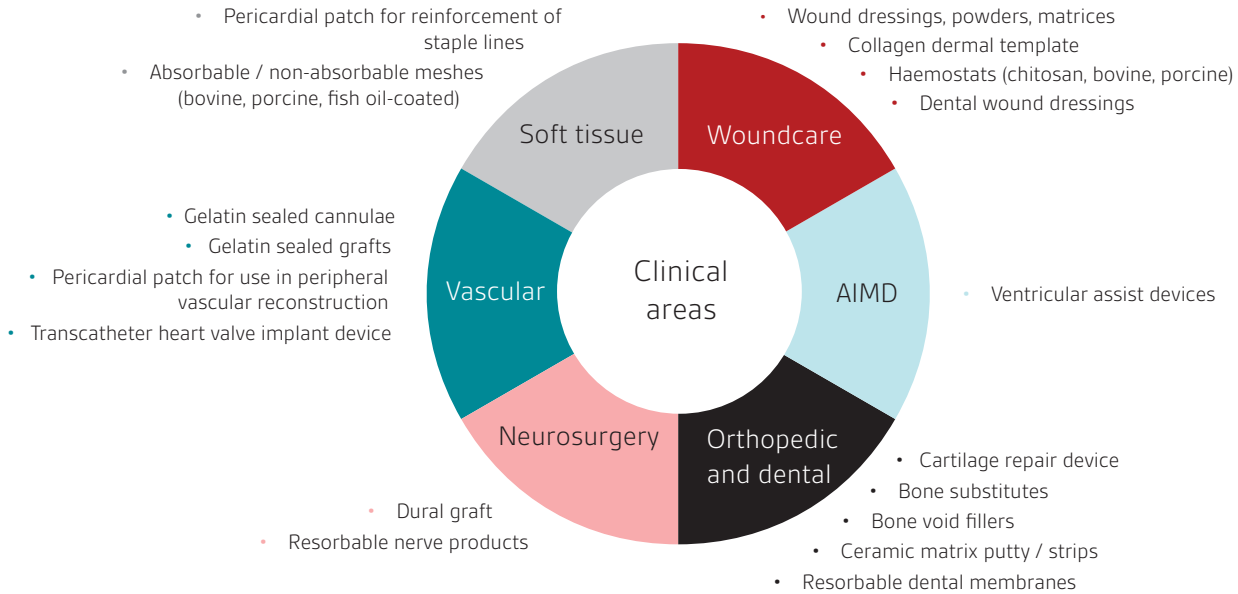
## Market access

Our in-house expertise and efficient review services 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.

## Device technologies



## Specialized training

BSI offers a specialized one-day course covering the use of animal tissue in medical devices: Utilizing Tissue of Animal Origin. The course provides expertise from our product specialists to allow you to better understand the requirements for these products.

For more information, or to book a course with us, visit our website: [bsigroup.com/medical-training](https://bsigroup.com/medical-training) or call **1 800 862 4977**

**Your resource in worldwide compliance: Call BSI today on 1 800 862 4977 or visit [bsigroup.com/medical](https://bsigroup.com/medical) – to start your journey**



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