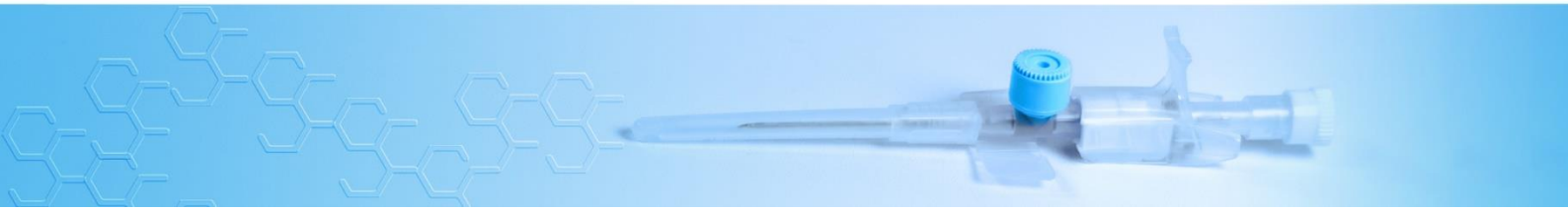
SAXOCON
Co-owned by Technical University of Denmark DTU



Ready-Set-Go Safe to Market

A CE Mark certificate is needed in order to market a medical device in the EU. This certificate verifies that the product is safe and performs as intended. The ISO 10993-1 standard prescribes a process for designing, testing, and documenting the biological safety of a medical device product. SAXOCON provides you with everything you need to plan, test, and document compliance with regulatory requirements, including:

- A Biological Evaluation Plan to describe and justify your test strategy
- The selection, screening, and characterisation of construction materials
- Assistance in scientific advisory meetings with regulatory bodies
- Selecting appropriate laboratories, reviewing protocols, and monitoring tests according to the requirements in the ISO 10993-series
- A toxicological risk assessment of results

Why choose us?

SAXOCON services for medical device manufacturers give you access to:

- A multidisciplinary team of highly skilled toxicologists, material scientists, and supply chain professionals
- Extensive experience with state-of-the-art safety evaluations according to international standards and regional regulatory guidelines
- Safety evaluations based on proprietary information obtained from our worldwide network of materials suppliers
- Smart, cost-effective test strategies that bring your products to market in a timely manner

Delivery

SAXOCON compiles all necessary documentation for the approval of your product in a Biological Evaluation Report.

hfm@saxocon.com +45 40 11 20 27 www.saxocon.com

bsi. ISO 13485:2016 Medical Device Quality Management