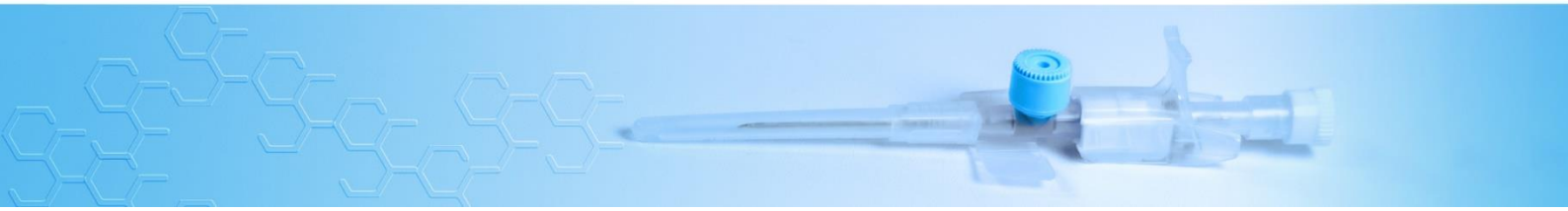
SAXOCON
Co-owned by Technical University of Denmark DTU



Assure Safe In-Vitro Diagnostics

A CE Mark certificate is needed in order to market an in vitro diagnostic medical device in the EU. This certificate verifies that the product is safe and performs as intended. Regulation (EU) 2017/746 (IVDR) Annex I prescribes general safety and performance requirements for designing and verifying in-vitro diagnostic medical device products.

SAXOCON provides you with everything you need to plan, test, and document compliance with regulatory requirements, including:

- The selection, screening, and characterisation of construction materials and reagents in order assure compatibility with body fluid, cell or tissue samples intended to be tested
- Evaluation for compliance with *Regulation (EU) 1272/2008 on Classification and Labelling of Hazardous Substances*
- The selection of appropriate laboratories, review of protocols, and monitoring of required tests
- 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