



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 design and verification of an in vitro diagnostic medical device product. 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 in state-of-the-art safety evaluations according to international standards and regional regulatory guidelines
- Safety evaluations based on proprietary information obtained from our world-wide 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.