SAXOCON
Co-owned by Technical University of Denmark DTU

Gas pathways of medical devices

In order to market a medical device in the EU, a CE Mark certificate is needed. This certificate verifies that the product is safe and performs as intended. The *ISO 18562-1* standard prescribes a process for testing and documenting the biological safety of the gas pathway of a medical device product intended to provide respiratory care or supply substances via the respiratory tract.

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

- A Biological Evaluation Plan to layout and justify your test strategy
- The selection, screening, and characterisation of construction materials suitable for respiratory use
- Assistance in scientific advisory meetings with regulatory bodies
- The selection of appropriate laboratories, review of protocols, and monitoring of tests according to requirements in the ISO 18562-series
- 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
- High-level experience in state-of-the-art safety evaluations according to international standards and regional regulatory guidelines
- Safety evaluations based on non-disclosed information obtained from our world-wide network of material suppliers
- Smart, cost-effective test strategies for bringing your products to market in a timely manner
- A well-established test set-up with leading CRO

Delivery

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

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