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
- Selecting appropriate laboratories, reviewing protocols, and monitoring 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 with state-of-the-art safety evaluations according to international standards and regional regulatory guidelines
- Safety evaluations based on non-disclosed information obtained from our worldwide 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 the approval of your product in a Biological Evaluation Report.

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bsi. ISO 13485:2016 Medical Device Quality Management