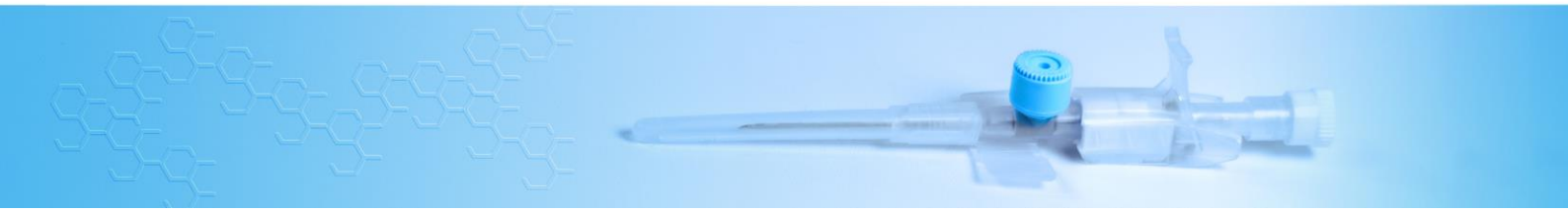
SAXOCON
Co-owned by Technical University of Denmark DTU



# Quality management systems for medical device manufacturers

Implementing and maintaining an effective and compliant quality management system (QMS) in accordance with Medical Device Regulations (EU) 2017/745 is a requirement when applying for or extending certification in Europe.

SAXOCON is an ISO 13485:2016-certified company, so we know what it takes to get certified. Our QMS consultants provide medical device manufacturers with the necessary templates, training, and consultations to achieve compliance. We work with organisations of all sizes, from early start-ups to mature businesses, helping design and maintain effective QMS systems that comply with ISO 13485:2016 and other relevant regulatory requirements.

## Why choose us?

SAXOCON services for medical device manufacturers give you access to:

- Tailored solutions based on your need for support
- Personnel with the experience and qualifications to professionally implement and audit your QMS and processes per the ISO 13485:2016 and ISO 14971:2019 standards
- Specialised technical knowledge regarding the biocompatibility aspects of the ISO 10993 series
- A multidisciplinary team of highly skilled toxicologists, material scientists, and supply chain professionals

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bsi. ISO 13485:2016 Medical Device Quality Management