TÜVNORD

Inspired by
Knowledge

Certification of QM systems to EN ISO 13485

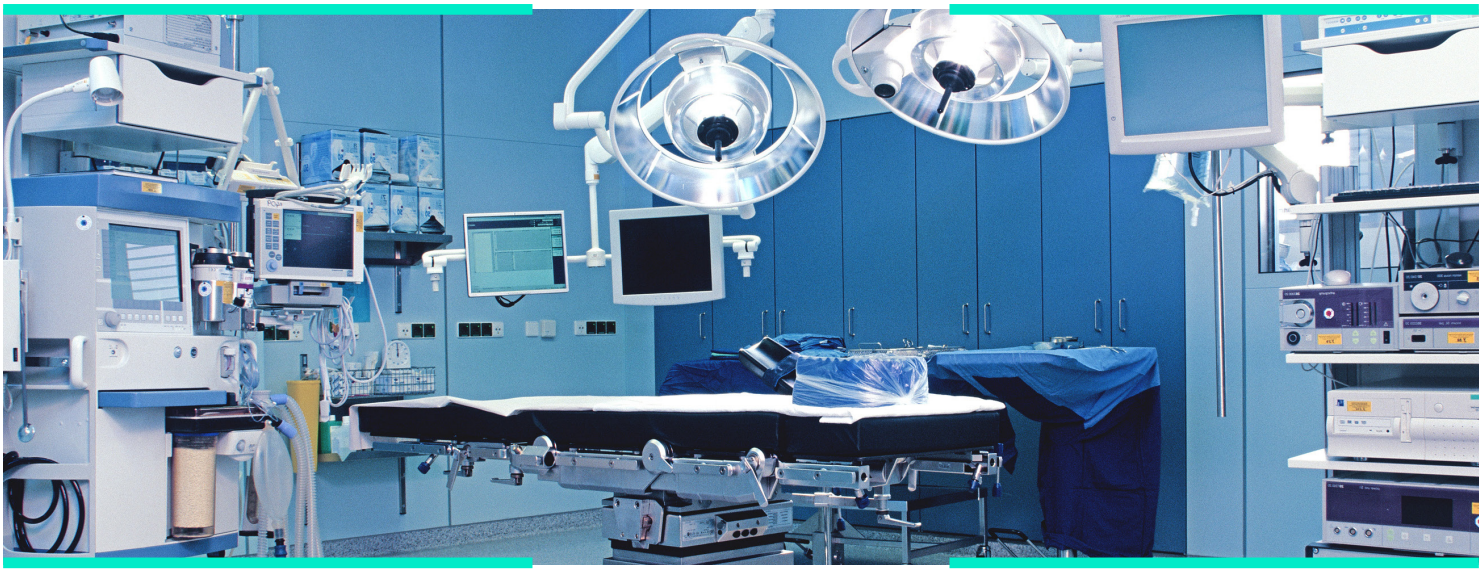
Adherence to clearly defined quality standards is becoming increasingly important in today's world, especially in international business. This includes, among others, continual learning and improvement processes and service and the ability to adapt to ever-changing markets and customer requirements.

These complex requirements can be met by a process-oriented QM system according to EN ISO 13485. EN ISO 13485 for quality management systems for medical devices describes the requirements for regulatory purposes and deals with the development, implementation and maintenance of a quality management system. It is intended for manufacturers and suppliers of raw materials and components as well as distributors of medical devices and service providers.

Originally developed in the 1990s, the standard contains detailed requirements for a quality management system for organizations involved in the lifecycle of a medical device, including development, production, storage, distribution, installation and maintenance, as well as the provision of related activities.

Although EN ISO 13485 was developed on the basis of EN ISO 9001 and therefore has similarities as regards its scope and objectives, it also contains additional requirements for medical devices and excludes certain provisions of EN ISO 9001. Therefore in most countries, certification according to DIN EN ISO 9001 is not an acceptable substitute for certification according to EN ISO 13485.

Based on a functioning management system, individual corporate structures can be tailored precisely to the specific needs and specifications of customers and regulatory bodies. Operations can then be made flexible so that everyone can benefit.



As a certification body for management systems for medical devices, we are already accredited by the German Accreditation Body (DAkkS) in accordance with DIN EN ISO 13485:2021 (EN ISO 13485:2016 + AC:2018 + A11:2021). In addition, TÜV NORD CERT is designated as a notified body for active and non-active medical devices for conformity assessment procedures under the Medical Devices Regulation (EU) 2017/745 (MDR) by the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (ZLG) (Notified Body, ID No. 0044).

Target Groups for Certification

A QM system in accordance with EN ISO 13485 forms an ideal basis for modern national and international organizations of all sizes to demonstrate their competence and efficiency.

Internal work processes, responsibilities and competencies are taken into account as well as the regulation of processes for dealing with customers and business partners.

Benefits of Certification

- Sustainable Quality Assurance
- Identification of potentials for improvement and savings
- High customer and employee satisfaction
- Image enhancement
- Risk reduction
- Improved cost-effectiveness through process improvement
- Increased competitiveness
- Fulfilment of specific customer requirements

Your path to DIN EN ISO 13485 certification in 6 steps

1

You download the relevant questionnaires from our website and return them to us.

2

TÜV NORD CERT prepares a proposal based on the information provided

3

Order placement and scheduling

4

Determination of certifiability by TÜV NORD CERT, Audit Planning

5

Audit phase and non-conformity management procedure, (if necessary)

6

Release of the certification and issuance of certificate (validity 3 years, annual surveillance)

Our know-how for your success

TÜV NORD CERT is an internationally recognized and reliable partner for testing and certification services. Our experts and auditors have in-depth knowledge and generally have a permanent position at TÜV NORD. This ensures independence and neutrality as well as continuity in serving our customers. The benefit to you is clear: our auditors accompany and support the development of your company and provide you with objective feedback.

Contact

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Further information and contact form

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Further information and contact form

24-0573-11/23