Fact Sheet

TÜV NORD CERT – Certification of QM systems according to EN ISO 13485

In today´s world, adherence to clearly-defined quality standards is increasingly important, especially in international business. Amongst other aspects, this includes ongoing learning and continual improvement processes, service and the ability to adapt to constantly evolving 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 designed for manufacturers and suppliers of medical devices.

Originally developed in the 1990s, the standard contains detailed requirements for a quality management system that meets both customer requirements and regulations in the European Union (EU), Canada and other key jurisdictions around the world. EN ISO 13485 is similar in scope and intent to EN ISO 9001, but contains additional requirements for medical devices and excludes certain EN ISO 9001 regulations. Therefore, EN ISO 9001 certification is not an acceptable substitute for EN ISO 13485 certification in most countries.

Through a functioning management system, individual company structures can be tailored exactly to the specific needs and specifications of the customer. Business processes can then be flexibly designed so that everyone can profit from it.

We are accredited as a certifier of management systems for medical devices according to EN ISO 13485 by the German Accreditation Body (DAkkS).

Further TÜV NORD CERT is named for active and non-active medical devices as well as active implantable medical devices by the Central Agency for Health Protection of Medicinal Products and Medical Devices (ZLG) (Notified Body, Identification Number 0044).

TÜV NORD
TÜV NORD CERT GmbH
EN ISO 13485

TÜV®

TÜV NORD Certification

TÜV NORD GROUP

Target groups for certification

A QM system according to EN ISO 13485 forms an ideal basis for modern organizations of all sizes at national and international level to demonstrate their competence and efficiency. Internal work processes, responsibilities and competences are taken into account as well as the regulation of processes in dealing with customers and business partners.

Benefits of certification

- Sustainable quality assurance
- Identification of potential for improvement and savings
- High level of customer and employee satisfaction
- Image enhancement
- Risk minimization
- Better cost-effectiveness through process improvement
- Enhanced competitiveness
- Fulfilment of specific customer requirements

Certification content

- Continuous improvement
- Non-conformity prevention
- Reduction of variation and waste in the supply chain
- Identification and monitoring of quality-related costs
- Product liability and product safety
- Determination of employee and customer satisfaction
- Separate consideration of product and process development
- Interdisciplinary co-operation

The way to the certificate

Download the customer questionnaire from our website and send us the completed forms

Based upon the information provided, TÜV NORD CERT will prepare an offer for you.

By accepting the offer you order TÜV NORD CERT to certify QM-systems

Determination of certifiability

Audit planning

Certification audit

Non-conformity management (where required)

Release of the certification process

Issue of certificate (validity: 3 years), annual surveillance audits

Are you interested?
Please send us your response by fax.
We are looking forward to hearing from you.

☐ **Yes, I am interested in certification of QM systems according to EN ISO 13485. Please contact me.**

Sender (Please use block capitals)

Company ..... Postcode/Town .....

Ms./Mr. ..... Phone .....

Position ..... Telefax .....

Street, No. ..... E-mail .....

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