

ISO 13485 - Medical Devices Certification



Overview

ISO 13485 specifies requirements for a Quality Management System where an organization needs to demonstrate its ability to provide both medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support). ISO 13485 can also be used by suppliers or external parties that provide product, services to such organizations.

ISO 13485 reflects the increased regulatory requirements for organizations across the medical devices supply chain, namely:

- A greater emphasis on appropriate infrastructure, particularly for the production of sterile medical devices, and additional requirements for the validation of sterile barrier properties
- Increased alignment with regulatory requirements and, in particular, regulatory documentation
- More focus on post-market activities, including complaint handling and regulatory reporting
- Broadening of the standard's application to encompass organizations that interact with the medical devices manufacturer, including those involved in :

- Design and development or repair and maintenance of medical devices
- Supply of raw materials, components or subassemblies
- Performance of services such as contract manufacture, sterilization, logistics or calibration of measurement equipment
- Import or distribution of medical devices
- Additional requirements in the design and development of medical devices, taking into consideration their usability, the use of standards, and a more robust planning for the verification, validation, transfer and records maintenance of the design and development activities
- Harmonization of validation requirements for different software applications, such as QMS software, process control software, software for monitoring and measurement

Benefits of certification:

- Improve your company's credibility and image
- Increases customer's trust in you as a safe supplier
- Helps organization in streamlining their processes and achieve the business goals & objectives
- Increases effectiveness of the processes to achieve consistent and desired high quality output
- Demonstrate compliance with regulatory and legal requirements
- Ensure the establishment of QMS practices that



consistently yield safe and effective medical devices

- Manage risk effectively
- Improve processes and efficiencies as necessary
- Gain a competitive advantage

The route to certificate:

- Offer from TUV India based on the information provided
- Order for certification
- Stage 1 Audit: Assessment of readiness for certification
- Audit Planning
- Stage 2 Audit: Certification Audit
- Nonconformity management (where required)
- Release by the certification body
- Issue of the certificate and annual surveillance audits

Why to choose TUV India ?

- Approved for various national & international accreditations for provision of Certification services
- Wide pool of highly qualified and experienced Auditors & Tutors across India
- Comprehensive and diverse range of value-added services
- Key account management
- One-stop solution for your certification requirements

About Us:

TUV India Pvt. Ltd. (TÜV NORD GROUP) is a customer-focused, innovative, and independent, technical, quality & safety services organization, dedicated to providing future-proof solutions through technological excellence for the success of its customers with the highest level of integrity. With a presence at over 40 strategic locations in India; a branch office in Sri Lanka and Bangladesh; state-of-the-art laboratories at Pune, Bengaluru, Noida and Jamnagar; 100 important countries worldwide and through digital means, we are always connected to you, our esteemed customer, anywhere, anytime.

We are proud to provide increasing levels of services to the best known, largest global and national companies as well as medium and small industries in diverse sectors like Oil & Gas, Petro-chemical, Nuclear, Renewables, Infrastructure, Food, Power, Manufacturing, Chemicals, Pharma, Paper, Automobiles, Railways, Aerospace, Defence, IT, Health, Hospitality, Retail, etc.

Over 1400 competent and experienced TUV India experts spread across India and over 14000 TÜV NORD experts all over the world, enthusiastically support our clients by providing value-added services in Industry Inspection, European / International Approvals, Management System & IT Certification, Sustainability, Energy Audit, Water Audit, Carbon Services, Building Infrastructure & PMC, Renewable Energy, Food & Packaging Testing, Food Certification & Inspection; Testing of restricted and banned chemicals in Automotive and Electrical & Electronics components and other regulated industries, Product Testing – Electricals, Electronics and Industrial Machinery; Product Certification; Petroleum, Chemicals & Gas Cargo Inspection; Petroleum, Chemicals & Gas Testing; Railway Technology; Engineering, Safety Studies, and knowledge enhancing training programs under TUV India Training Academy.

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