TÜVINDIA

Inspired by Knowledge

ICMED 13485 & ICMED 9000

Overview

In order to fill the regulatory vacuum in quality certification space for medical devices in the country, the Association of Indian Medical Device Industry (AIMED) in collaboration with the Quality Council of India (QCI) and the National Accreditation Board for Certification Bodies (NABCB) is rolling out a voluntary quality certification scheme for medical devices.

The Scheme is intended to enhance patient safety, and provide enhanced consumer protection along with much needed product credentials to manufacturers for instilling confidence among buyers. This move is also intended to significantly eliminate trading of sub-standard products or devices of doubtful origins, a widespread and injurious phenomenon in the Indian market.

Association of Indian Medical Device Industry (AIMED) jointly with the Quality Council of India (QCI) and the National Accreditation Board for Certification Bodies (NABCB) rolled out a voluntary quality certification scheme for Medical Devices for level I and level II viz. ICMED 9000 and ICMED 13485 on March 15th, 2016 World Consumer Day. While on one hand ICMED 9000 certification scheme lays out the parameters of ISO 9001, on the other ICMED 13485 align itself with the ISO 13485 along with Indian MDR 2017 requirements.

ICMED 9000 certification which is as per the requirements of ISO 9001 read with the additional requirements under the Indian regulatory framework prescribed under the scheme in ICMED 9000.

ICMED 13485 which is as per the requirements of ISO 13485 read with the additional requirements under the Indian regulatory framework prescribed under the scheme in ICMED 13485.

The certification scheme is built over the base Standard ISO 13485 (Quality Management System for Regulatory Purposes) which had 184 Compliance Requirements. The ICMED 13485 has in addition 23 regulatory requirements, 13 essential requirements for ensuring patient safety and with 16 labelling requirements for ensuring consumer protection.

The certification is provided by TUV India under the NABCB accreditation within India. ICMED 9000 and ICMED 13485 are equipped in its capacities to cater to the medical devices requirements for domestic acceptance.

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

TÜVINDIA

Inspired by Knowledge

- 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 System Certification services
- Wide pool of highly qualified and experienced Auditors & Tutors across India
- Comprehensive and diverse range 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 TUV 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.

TUV India Private Limited
Registered & Head Office
801, Raheja Plaza-I, LBS Marg, Ghatkopar (W), Mumbai - 400086
T +91 22 664 77000, **T** 1800 209 0902
E infoindia@tuv-nord.com
W www.tuv-nord.com/in

TÜVNORDGROUP