

Indian Certification for Medical Devices (ICMED) Scheme

To fill the regulatory vacuum in quality certification space for medical devices in the country, the 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. ICMED Certification <http://www.qcin.org/icmed-medical.php>, on March 15, 2016 World Consumer Day.

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 and for enabling capacity building for Manufacturers for Regulatory Approvals. 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.

The Certification Scheme was created by a Technical and a Certification Committee under a Steering Committee with Representation from 22 Organizations like DOC, MOH&FW, CDSCO, NHSRC, QCI, NABCB, NABH, NABL, BIS, CCC, IMA, AHPI, AiMeD, CII, EEPC etc. under the Chairmanship of Dr. M K Bhan and is available as ICMED 9000 for Low Risk Devices and ICMED 13485 for Moderate Risk and High Risk Devices .

To ensure need to have the highest Quality Standards, 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 Labeling Requirements for ensuring Consumer Protection. The Certification is available through NABCB Accredited Certification Bodies of International repute for this Scheme viz. Intertek, UL, TUV Intercert, TUV SUD & TUV Rheinland. Other Certification Bodies that have sought Approval / Accreditation from NABCB are DNV, Quality Austria, BSI, ICS, IR CLASS, Zenith & AGSI.



A healthcare professional, likely a dental hygienist, wearing a light blue scrub top, a white surgical mask, and clear safety glasses, is attending to a male patient in a dental chair. The patient is smiling and looking towards the professional. The setting is a modern dental clinic with large windows in the background. A red vertical bar is on the right side of the image.

*You can trust
ICMED certified
companies to
meet patient
safety needs.*