



International Certification Services

ICMED 13485

Why do you need ICMED 13485 ?

ICMED 13485 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.

ICMED 13485 - An Overview ?

With the launch of Medical Product Regulations since 2017, all medical products falling under CLASS 1, CLASS2 and CLASS 3 shall have to undergo certification to Quality Council of India QCI accredited ICMED Indian Certification for Medical devices.

The legal requirements will be in force w.e.f 2018 and shall comply to all the specifications and requirements for factories manufacturing, trading or supplying medical products falling under CLASS 1, CLASS 2 or CLASS 3 type.

QCI has launched ICMED in 3 categories for certification

- ICMED 9000 – based upon ISO 9001 plus additional requirements
- ICMED 13485 — based upon ISO 13485 plus additional requirements
- ICMED 13485 Plus – based upon ICMED 13485 plus Product specifications prescribed by MoH

All organizations supplying, trading or manufacturing have to mandatorily achieve certification by QCI accredited Notified body.

Who need it ?

- Indian medical device manufactures/ exporters
- Local authorized representatives of medical device manufactures/ distributors



Benefits of ICMED 13485 ?

- Establish brand confidence of medical devices manufactured in India
- Enhance patient safety
- Provide health care users with quality medical devices manufactured in a certified facility

How to go about ICMED 13485 ?

- Define the scope of QMS - Medical device implementation, which may cover part or all of core functions of the organization.
- Identify organization processes & controls over them.
- Prepare Quality Manual & procedures outlining the organization Profile.
- Define Quality Policy & Objective.
- Get Approval from management ensuring statutory Regulatory compliances.
- Implementation of measuring & monitoring thru Internal audits & Management Review.

Are you looking for ICMED 13485 ?

Call the further information at;

International Certification Services Pvt Ltd.

Corporate Office

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