

Services to meet Indian Certification for Medical Devices (ICMED) Program

UL is a Certification Body under ICMED

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) has established a voluntary quality certification scheme for medical devices in India, ICMED 13485 to help ensure quality in manufacturing of medical devices.

The program is based on the international harmonized quality management systems with additional requirements specific to the India market.

ICMED 13485 - Based on the International Harmonized Standard (ISO 13485) "Quality Management Systems for Medical Devices" plus additional requirements specified under the scheme.

ICMED 9000 - Based on the International Harmonized Standard (ISO 9000:2008), "Quality Management Systems"



ICMED 13485 regulatory framework

Under ICMED 13485, manufacturers are expected to comply with the following:

- Meet essential principles of safety and performance based on any one of the International Medical Device Regulators Forum (IMDRF) requirements and manufacture medical devices in accordance with ICMED 13485 guidelines
- Apply for product registration
- Monitor safety and performance and to take corrective actions on adverse events related to products in the market based on Materiovigilance Programme of India (MvPI) guidelines

Who can apply?

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

Benefits of ICMED 13485 registration

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

Deliverables

Upon successful completion of the program, UL will issue a certificate and add your company name to a public accessible database so that your customers and distributors can verify. UL delivers certification services through specific certification bodies to support your submission requirements for application to the major medical markets including the US, Canada, the European Union, Brazil, China and beyond.

For more information, contact us at:

Email: sales.in@ul.com or Phone: +91.80.4138.4400

Empowering Trust™

UL and the UL logo are trademarks of UL LLC © 2019.