

QCI - AIMED Voluntary Initiative for Medical Devices

Certification Scheme for Indian Certification for Medical Devices (ICMED)

INTRODUCTION

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Quality interventions in the manufacturing of medical devices have been of prime concern and eventually have gained momentum in recent times especially in situation such as COVID-19; a global pandemic.

In view of the above, it is imperative to have quality management systems for medical device industry which:

- a) needs to demonstrate its ability to consistently provide medical devices that meet customer and applicable statutory and regulatory requirements, and
- b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

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 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.

These 2 levels of voluntary certification schemes have been designed and developed to bridge the gap of prerequisite certification or mark for the Indian manufacturers of medical devices for both product and processes in order to make sure that the country of origin meets the specific requirements of importing countries.

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.

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 labelling requirements for ensuring consumer protection. The Certification is available through NABCB accredited certification bodies of international repute for this Scheme.

It is pertinent to mention that VCS for ICMED 9000 and ICMED 13485 are equipped in its capacities to cater to the medical devices' requirements for domestic acceptance. However,

the domestic manufacturers still require to adhere to the norms & regulations of FDA/CE certification to broaden their scope for global acceptance.

In order to bridge this gap, ICMED 13485 Plus is developed envisaging an equivalence to the essence of those product certification requirements leading to superior domestic and wider global acceptance. The scheme was launched on 18th June 2021.

This development as an extension of the ICMED scheme i.e. ICMED Plus will pave ways in establishing quality assurance of domestic medical devices adhering to global benchmarks, eventually granting the manufacturers a foreign market access and give comfort to domestic buyers that they need not seek USFDA / CE Certification, which at many times is false and unauthenticated.

ICMED Plus is an upgrade of the already existing ICMED Scheme that comprises of ICMED 9000 and ICMED 13485 focusing on quality management system. The ICMED Plus Scheme is a product certification scheme that aims towards establishing quality assurance of medical devices product manufactured in India. This initiative aims eventually to equip the manufacturers to upgrade themselves for meeting the requirements (including testing) of the importing countries thereby facilitating global market access.

Presently, the scheme is operational through approved certification bodies for the following levels:

Level I : ICMED 9000

Level II : ICMED 13485

Level III : ICMED 13485 Plus

Scheme Documents:

The QCI has designed the ICMED scheme comprising the following documents:

Section 1: Introduction

Section 2: Governing Structure

Section 3: Certification Criteria

Section 4: Certification Process

Section 5: Requirements for Certification Bodies

Section 6: Rules for Use of Certification Mark

1.1 Acronyms

AIMED	Association of Indian Medical Device Industry
CE	Conformité Européenne
COVID	Coronavirus Disease

FDA	Food and Drug Administration
ICMED	Indian Certification of Medical Devices
MDR	Medical Devices Rules
NABCB	National Accreditation Board for Certification Bodies
QCI	Quality Council of India
VCS	Voluntary Certification Scheme

1.2 Definitions

Certification	Certification is the provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements. Certification is also known as third party conformity assessment.
Testing	Testing is the determination of one or more of an object or product's characteristics and is usually performed by a laboratory. For example, testing of components for parameters such as safety, performance etc. which involves analysing against a number of characteristics to determine compliance to the ICMED Scheme.
Medical Device	A medical device can be any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose. (refer Medical Devices Rules 2017)