Section 1

QCI - AIMED Voluntary Initiative on Medical Devices

Indian Certification of Medical Devices (ICMED) Scheme

INTRODUCTION

Introduction

1. Background

1.1. Quality Council of India (QCI) in association with the Association of Indian Manufacturers of Medical Devices (AIMED) has designed the Scheme for certification of Medical Devices (ICMED 13485 Plus) to strengthen the Quality in the Indian medical devices' ecosystem.

1.2. The scheme is aimed to significantly eliminate the use of trading of sub-standard products or devices of doubtful origins. Quality interventions in the manufacturing of medical devices have been of prime concern and eventually have gained momentum in recent times.

1.3. This scheme is an institutional voluntary mechanism for assuring quality and safety by helping procurement agencies that require evidence of product conformance. It encourages domestic manufacturers especially start-ups to become self-reliant eventually establishing them to follow a robust mechanism to counter menace of counterfeits and non-authenticate certifications.

1.4. The ICMED 13485 Plus scheme is a step towards aiding procurement and safe guarding private buyers and common consumers. This scheme will provide to the public procurement agency a verified certification data.

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

1.5.1. demonstrates its ability to consistently provide medical devices that meets customer and applicable statutory and regulatory requirements, and

1.5.2. 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.

1.6. Therefore, to fill the then 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) rolled out the 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.

1.7. 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.

1.8. The ICMED Plus Scheme is an upgrade of the earlier scheme since it also takes care of product quality and product certification in India. It also comprises of ICMED 9000 and ICMED 13485 that focuses 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.

1.9. The additional features in the Plus Scheme includes performance verification of medical devices including biocompatibility, biological safety, software verification, validation, animal studies, pre-clinical and clinical data, and shelf-life management etc.

1.10. 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.

1.11. 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.

1.12. The Scheme is to be operated through accredited certification bodies in India who have competence to check both the process and product (medical device) before grant of certification.

1.13. The products and their performance will also be tested in a NABL accredited lab. In case if the Scheme requires certain testing to be carried out for which no NABL accredited lab is available, only in such case Govt. approved laboratory shall be used. The CB needs to submit proof that the particular test is not available under the NABL scope.

1.14. 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 adhering to the norms & regulations of FDA/CE certification to broaden their scope for global acceptance.

1.15. 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.

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 the global benchmarks, eventually granting the manufacturers a foreign market access and give comfort to domestic buyers that they need not seek USFDA / CE Certification. The scheme thus follows a consolidated conformity assessment framework in order to bring in medical devices at par with global quality standards in terms of their manufacturing.

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

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

Section 1: Introduction
Section 2: Governing Structure
Section 3A: Certification Criteria for ICMED 9000
Section 3B: Certification Criteria for ICMED 13485
Section 3C: Certification Criteria for ICMED 13485 Plus
Section 4A: Certification Process for ICMED 9000 and ICMED 13485
Section 4B: Certification Process for ICMED 13485 Plus
Section 5: Requirements for Certification Bodies
Section 5A: CBs Auditor Competence Requirements
Section 6: Rules for Use of Certification Mark
Section 7: Provisional Approval System for CBs

2. Acronyms

AIMED	Association of Indian Medical Device Industry
CE	Conformitè Europëenne
FDA	Food and Drug Administration
ICMED	Indian Certification of Medical Devices
ISO	International Organization for Standardization
MDR	Medical Devices Rules, 2017
NABCB	National Accreditation Board for Certification Bodies
NABL	National Accreditation Board for Testing and Calibration Laboratories
QCI	Quality Council of India
VCS	Voluntary Certification Scheme

3. 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. (Also refer Medical Devices Rules 2017 and certification criteria document for definition)
Quality Management Systems	A quality management system (QMS) is defined as a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives.
Conformity Assessment Framework	Conformity assessment is the activity of verifying that a standard or technical specification was applied in the design, manufacturing, installation, maintenance or repair of a device or system or a process.
Biocompatibility	Biocompatibility has also been described as the ability of a material to perform with an appropriate host response in a specific application.

Amendment Sheet

RECORD

The history of changes made in the Scheme.

S. No.	Section/ Clause	Date of Amendment	Page No.	Amendment details