Section 2

QCI - AIMED Voluntary Initiative on Medical Devices

Indian Certification of Medical Devices (ICMED) Scheme

Governing Structure

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1. Objective

1.1. The objective of this document is to provide guidance to the Scheme owner on the establishment of the governing structure required for setting up and operating the Indian Certification Scheme for Medical Devices (also referred to as 'the ICMED') in India.

2. Scope

2.1. This document describes the governing structure of the Scheme and the roles and responsibilities of various committees and organizations involved in establishing and operating the Scheme.

2.2. This document draws upon the guidance provided in the international standard "ISO/IEC 17067:2013 'Conformity assessment - Fundamentals of product certification and guidelines for product certification Schemes'.

3. Governing Structure

3.1. The Scheme shall have a multi-stakeholder committee – a Steering Committee at the apex level with the secretariat being held by the Scheme owner.

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3.2. The Steering Committee is to be supported by a Technical Committee and a Certification Committee. The Steering Committee will internalize the Scheme in the India and provide operational guidance.

3.3. The Technical and the Certification Committees shall be represented by a variety of stakeholders and experts in the related technical (medical devices, regulatory body, and other related subjects) areas and having knowledge of conformity assessment.

3.4. In case deemed appropriate, Scheme owner through the Steering Committee could constitute multiple committees in the form of task force (TF) to deal with different categories of medical devices such as class A, B, C and D.

3.5. The committees will be required to formulate the certification criteria, certification process and the certification body requirements aiming towards introducing quality med-tech sector.

3.6. The Technical and the Certification Committees shall be authorized to review the documents put up to them and approve the same. The approved documents shall be placed to the Steering Committee for their information only.

3.7. In case the Steering Committee has a particular view, the same would be put up to the respective Chair for review and internalization.

4. Composition and Terms of Reference of Committees

4.1. **General Principles:** In the appointment of various committees, the following general principles should be kept in mind:

4.1.1 Representation of a balance of interests in the Steering Committee such that no single interest predominates. While nominating representatives for

technical/certification committee, predominantly personnel from expert groups shall be ensured.

4.1.2 Key interests should include representatives of regulatory/standard bodies or other governmental agencies, representatives of user associations, industry associations, accreditation body and certification bodies (subject to availability), test laboratories, academic/research bodies, voluntary consumer organizations and representatives of non-governmental organizations working in the related areas.

4.1.3 The technical committee may have additional representations from persons competent in bio-medical engineering and related sciences.

4.1.4 The certification committee needs to have representation from experts that have understanding of conformity assessment.

4.1.5 Representation to individual experts should be given exercising due care in their selection.

4.1.6 It is desirable to invite organizations to nominate Principal and Alternate members in the interest of higher attendance and continuity.

4.2. Steering Committee: It may comprise of Government, regulatory bodies, medical devices' associations, export promotion bodies, research/academic bodies, accreditation bodies, testing laboratories, certification bodies, voluntary organizations, trade associations, and or any other technical expert(s) as invitees for specific meetings, as identified by the Scheme Owner.

4.2.1 SC may coopt any other members.

4.2.2 Quorum - The presence in person, at a meeting of the Steering Committee (SC) of the member representatives of at least 30% members of the SC shall constitute a quorum for a meeting.

4.2.3 Terms of reference - The SC is responsible for:

4.2.3.1 Overall development, modification, and supervision of the Scheme
4.2.3.2 Receiving recommendations of Technical/Certification Committees and deciding on it
4.2.3.3 Constituting any other committees, as needed

4.2.4 Meetings - The SC shall meet at least once every year.

4.3. Technical Committee (TC): It may comprise of Governments, regulatory bodies, medical devices associations, export promotion bodies, research/academic institutions, standards body, accreditation bodies, testing laboratories, certification bodies, voluntary organizations, trade associations, and or any other technical expert(s) as invitees for specific meetings, as identified by the Scheme Owner. This shall be in the form of Task Force constituted separately to handle each of the med-tech sector viz., consumables, disposables, equipment, instruments, electronics, diagnostics, and implants, etc.

4.3.1 TC may coopt any other members.

4.3.2 Quorum - The presence in person, at a meeting of the Technical Committee (TC) of the member representatives of at least 30% members of the TC shall constitute a quorum for a meeting.

4.3.3 Terms of reference - The TC is responsible for:

4.3.3.1 Developing and maintaining any standards or technical documents needed by Scheme Owner
4.3.3.2 Defining the certification criteria, and
4.3.3.3 Resolving any related issues;

4.3.4 Meetings - The TC shall meet at least once every year.

4.4. Certification Committee (CC): It may comprise of members as mentioned in the Technical Committee with greater representation to have accreditation/ certification bodies having insight into certification processes. There will be a single Certification Committee that shall handle all the categories of medical devices.

4.4.1 CC may coopt any other members.

4.4.2 Quorum - The presence in person, at a meeting of the Certification Committee (CC) of the member representatives of at least 30% members of the CC shall constitute a quorum for a meeting.

4.4.3 Terms of reference - The CC is responsible for:

4.4.3.1 Developing, maintaining, and revising as appropriate the certification process
4.4.3.2 Developing, maintaining and revising as appropriate the requirements for Certification bodies for the operation of the Scheme
4.4.3.3 Developing guidance document to assist producers to apply for Certification
4.4.3.4 Designing the Certification Marks, if any
4.4.3.5 Developing, maintaining and revising as appropriate the rules for the use of Certification mark or logo and
4.4.3.6 Resolving any issue relating to certification

4.4.4 Meetings - The CC shall meet at least once every year.

5. Roles of Organizations

The Quality Council of India (QCI) shall be the Scheme Owner and own the Certification Mark(s). It shall establish the MSC and shall be responsible for the overall management of the Scheme. The QCI shall provide the Secretariat to the Scheme and the MSC. It shall set up the Technical and Certification Committees and provide secretariat to them.

QCI as a Scheme owner and as the provider of approval of certification body (CB) shall through a legally enforceable agreement, with the approved CB, ensures that the CB abides by the requirements of the Scheme. The CB shall provide reasonable access and co-operation as necessary to enable QCI assessment team that includes assessors, technical experts and observers to assess conformity.

AIMED is an umbrella Association of Indian Manufacturers of Medical Devices covering all types of Medical Devices including consumables, disposables, equipment, instruments, electronics, diagnostics, and implants. It represents the interest of over 1200 manufacturers of medical devices to address the manufacturer's problems. It aims towards imparting

information and encourage quality in the services and products to promote global harmonization of the Indian medical device industry.

The **National Accreditation Board for Certification Bodies** (NABCB) a constituent Board of the QCI shall be responsible for accrediting certification bodies desirous of participating in the Scheme to appropriate international standards. NABCB shall through a legally enforceable accredited agreement with the accredited CB ensure that the CB shall offer NABCB and its representatives including assessors, experts, observers, regulator appointed in the assessment teams such reasonable access and co-operation as necessary to enable NABCB assessment team to monitor conformity with the Agreement and the relevant standard(s). The accredited CB shall also use reasonable endeavours to provide access to NABCB assessors, experts and observers to its customers' premises to conduct assessment activities.

The **National Accreditation Board for Testing and Calibration Laboratories** (NABL) a constituent Board of the QCI shall be responsible for accrediting testing and calibration laboratories to appropriate international standards to support the Scheme.

6. Complaints

6.1 The entire system has provisions for accepting complaints from any stakeholder against any component of the Scheme – the manufacturing units certified under the Scheme, the certification bodies approved under the Scheme, the laboratories utilized under the Scheme, and the accreditation bodies, NABCB/NABL, are all required to have a complaints system in place as per standards applicable to them. Anyone having a complaint is encouraged to utilize the available mechanisms.

6.2 Any complaint received directly by any entity shall be referred to QCI who in turn will make a reference to the appropriate body against which the complaint is made and monitor it till it is decided upon.

6.3 A statement on complaints as received above with their status shall be reported to the MSC in each meeting.

7. Appeals

7.1 There are provisions for entertaining appeals from the manufacturing units certified/desirous of certification under the Scheme, the certification bodies approved under the Scheme, and the laboratories utilized under the Scheme, which shall invariably be utilized.

7.2 In case anyone aggrieved by the decision of the TC/CC appeals, it shall be handled by the MSC.

7.3 In case anyone aggrieved by the decision of MSC appeals, the Chairperson, MSC shall appoint an independent appeals panel to look into the appeal and recommend action to him/her

7.4 In handling appeals, the broad principle that the appeal is handled independently of the personnel involved in the decision appealed against shall be maintained.