QCI - AIMED
Voluntary Initiative on Medical Devices

INDIAN CERTIFICATION OF MEDICAL DEVICES (ICMED) SCHEME

RULES FOR USE OF CERTIFICATION MARK
(Applicable for ICMED 9000 and ICMED 13485)
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RULES FOR USE OF CERTIFICATION MARK

1. Objective

1.1. Medical device manufacturers that have been certified under the ICMED Scheme by the QCI approved certification bodies and have entered into a written contract with QCI (Scheme Owner), are eligible to use the ICMED Scheme Certification Mark as per the provisions mentioned against each of the levels.

1.2. This document describes the rules for use of the certification mark for the ICMED scheme by the certified medical device manufacturer and mentions the process required to be complied in detail with for enabling the medical device manufacturer to use the Mark as per the specifications.

1.3. The ICMED Scheme certification mark is a protected mark owned by QCI, being the scheme owner of the ICMED scheme, indicating that the processes of the relevant medical device manufacturer are in conformity with specified criteria under the scheme. The “Mark” is also commonly known as a “Logo”, however for the sake of aligning it with the international requirements the same will henceforth be referred to as the “Mark”.

2. Scope

2.1. ICMED scheme specifies three levels of certification, ICMED 9000 and ICMED 13485. This document covers requirements for use of the certification mark with respect to certified medical device manufacturers as per the Scheme requirements of all the three levels.

3. Responsibility

3.1. The Scheme Manager is responsible to establish, implement, and amend this procedure in consultation with the Certification Committee. The approved certification bodies (CBs) are responsible to comply with the procedure at all times specifically so when undertaking surveillance audit or re-certification audits.

3.2. The CBs shall also have a mechanism to see that the clients that are certified to the ICMED 9001 and 13485 levels are using the Mark off-product.

4. Requirements for Use of Mark

4.1. The medical device manufacturers that have been certified under the Scheme, are eligible to use ICMED Scheme certification mark(s).

4.2. The approved/accredited certification body shall make provision for ensuring the same in its system for certification under ICMED Scheme and shall make this requirement a part of its legally enforceable contract with the certified client.

4.3. Any infringement may lead to the suspension or cancellation of the certificate. In no circumstances are different combinations of the colour scheme not used.

4.4. While using the above documents care shall be taken to ensure that the Mark is used only with respect to the medical device manufacturer certified and it shall not give the
impression that the non-certified, other than certified scope products, products from offices not included in scope or a related company are also certified.

4.5. The certified medical device manufacturer shall not make any misleading claims with respect to the Certification Mark.

4.6. It shall not use the Certification Mark in such a manner as to bring the Scheme Owner into disrepute.

4.7. The certified organisation, upon suspension or withdrawal of its certification, shall discontinue use of the Certification mark, in any form.

4.8. The certified organisation, upon suspension or withdrawal of its certification, shall discontinue use of all advertising matter that contains any reference to its certification status.

4.9. In case the Certification Mark is observed to be used by a certified medical device manufacturer contrary to the conditions specified, suitable actions shall be taken by the certification body in accordance with the relevant requirements of ISO 17021-1 and those specified in the documents “ICMED Scheme Certification Process” and “ICMED Scheme Requirements for Certification Bodies”.

4.10. Depending upon the extent of violation, suitable actions may range from advice for corrective actions to withdrawal of certification especially in situations of repeated violations.

4.11. In case the certified medical device manufacturer does not take suitable action to address the wrong use of the Certification Mark, the certification body may suspend/withdraw the certification.

4.12. If a certified organisation’s certification is suspended; its certificate cancelled, withdrawn or discontinued, it is the certified organisation’s responsibility to discontinue the use of the Certification Mark from the date from which the certificate stands suspended, cancelled, and withdrawn or discontinuation comes into force. The certification bodies that have certified the medical device manufacturer needs to ensure compliance as stated above.

5. **Obligation of the Approved Certification Body**

5.1. Once the medical device manufacturer is certified by the QCI approved certification bodies, then the certification body shall require the certified medical device manufacturer to fill up in duplicate the agreement form, the template for which is enclosed in Annexure I to this document.

5.2. The certification body after the decision of the certification but before the issuance of the certificate and shall forward the filled agreement form to QCI, for the purpose of signing and completing the agreement formalities.

5.3. Along with the contract agreement form, the relevant certification body shall also forward the details of the certified organisation, covering as a minimum the following information:

5.3.1 Name and address of the certified organisation.
5.3.2 Legal entity Status (with evidence).
5.3.3 Names of the top management/ownership details.
5.3.4 Details of the Certification granted – level, number, validity, etc.
5.3.5 Any other significant detail as considered relevant.

5.4. The certification body shall also forward the copy of the draft certification document it intends to issue to the certified organisation.

5.5. Upon receiving the signed agreement form from QCI, the certification body shall issue the certificate, inform the certified medical device manufacturer regarding permission to the respective manufacturer using the ICMED Mark and also forward the signed contract form to them. The certification validity shall commence from the day the contract with QCI is signed.

5.6. The certification body shall also make provision for collecting on behalf of QCI, the annual fee/certification fee for use of ICMED Scheme Certification Mark from the certified medical device manufacturer and forwarding the same to QCI.

5.7. The certification body shall also make provision for informing QCI, about any changes in the certification status, like suspension, withdrawal, etc.

5.8. The contract between QCI and the certified agency shall be valid as long as the agency holds valid certification under the ICMED Scheme or unless otherwise advised to do so.

5.9. Only after the certification body obtains NABCB accreditation for ICMED schemes the certification body shall use the NABCB Accreditation Mark. The NABCB accredited CBs and their clients shall follow the requirements to use accreditation symbol/Mark/status as per policy defined by NABCB.

5.10. As far as market surveillance activities are concerned, market surveillance through CBs are required to check the certification requirements.

5.10.1 in accordance with its intended purpose (as defined by the manufacturer) and under the conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.

6. Process for Use of Certification Mark

6.1. A certified medical device manufacturer may apply for certification as available under the ICMED Scheme.

6.2. The applicants shall submit their applications for the use of certification mark in the prescribed format enclosed vide Annexure I.

6.3. Before the issue of the certificate, the certified medical device manufacturer shall sign a legally enforceable agreement with QCI in the format enclosed vide Annexure II, based on which it will be allowed to use the Mark.

6.4. The certified manufacturer shall be issued a certificate by the certification body which carries the appropriate mark once the contract has been signed with the Scheme Owner.

6.5. This process shall be facilitated by the QCI approved certification body.

6.6. The certification mark pertaining to the respective ICMED Scheme level may be used as any photographic reduction or enlargement.
6.7. The colour scheme of the Marks shall be the same as described in Appendix A. The client shall only affix the design of the Mark as per the level the manufacturer has been certified and none other.

6.8. Any other requirement stated in scheme documentation for use of certification mark to be considered along with above requirements.

7. **Mark and its Usage**

7.1 Under the ICMED scheme three levels of Mark shall be issued - ICMED 9000 and ICMED 13485.

7.2 The certificates issued to the clients can be either for one Mark or a combination of either of the 2 Marks.

7.3 While the clients certified as per ICMED 9000 and ICMED 13485 are allowed to place their marks on off-products for marketing and promotional purposes they are not allowed to place the Mark on their product.

7.4 The off-product use means that the certified clients can use the Mark to which they are certified in publicity material, pamphlet, letterheads, other similar stationary, media for exchange of any communication, for promoting the awareness of the scheme, the Certification Mark, etc.

7.5 The medical device manufacturer may also use the ICMED certificate issued by the certification body as part of publicity material.

7.6 The ICMED Marks shall have distinct colours for each level

7.7.1 ICMED 9000 - to be only be printed in the Blue
7.7.2 ICMED 13485 - to be only in printed in Red

7.7 Both the Marks in the 2 levels can also be printed in Grey Scale.

7.8 The various components of the ICMED marking must have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices. The height of the Certification Mark shall be 5 mm minimum and the size of inscriptions “9000” and “13485” shall be properly visible.

7.9 The height to width ratio shall be maintained as per the logo packs provided QCI. The height of the ICMED Logo needs to be minimally 5 mm and the height of the numbers 13485 / 9000 needs to be minimally 1.5 mm for enabling clear printing and readability.

7.10 The QCI logo shall not be used on issued certificates or any other documented information.

8. **Fee**

8.1 The certified medical device manufacturer shall pay an annual fee to QCI, for the use of ICMED Scheme Certification Mark as prescribed from time to time. This payment shall be made to its certification body for onward submission to QCI.
Appendix ‘A’ Marks for ICMED Certification

1. Marks for ICMED 9001 Certification:

   BLUE: C-100, M-0, Y-0, K-0
   BLACK: C-66, M-65, Y-60, K-56

   GRAY: C-43, M-33, Y-35, K-2
   BLACK: C-66, M-65, Y-60, K-56
2. Marks for ICMED 13485 Certification:

RED: C-0, M-100, Y-100, K-0
BLACK: C-66, M-65, Y-60, K-56
GRAY: C-43, M-33, Y-35, K-2
BLACK: C-66, M-65, Y-60, K-56