Section 6

QCI - AIMED Voluntary Initiative on Medical Devices

Indian Certification of Medical Devices (ICMED) Scheme

Rules for Use of Certification Mark

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, ICMED 13485 and ICMED 13485 Plus. 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 should have a strong market surveillance system to ensure that none other than the manufacturer certified as per the ICMED 13485 Plus are using the “Mark” on their products.

3.3. 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, which means that clients can use the ICMED Mark on products as mentioned in point 5 (Obligation of the Approved Certification Body) of this document.

3.4. For the ICMED 13485 Plus certified manufacturer, by affixing the Mark the manufacturer declares on his sole responsibility that the product conforms to all applicable Scheme requirements, and that the appropriate conformity assessment procedures have been successfully completed.

3.5. By affixing the Mark on a product, a ICMED 13485 Plus manufacturer is declaring, on his sole responsibility (and irrespectively of whether a third-party has been involved in

the conformity assessment process), conformity with all the Scheme requirements to achieve ICMED marking.

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 allowed.

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 17065/17021-1 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 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 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 conformity of a product:

5.10.1 in accordance with its intended purpose (as defined by the manufacturer), and
5.10.2 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, ICMED 13485 and ICMED 13485 Plus.

7.2 The certificates issued to the clients can be either for one Mark or a combination of either of the 3 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 clients that are certified as per ICMED 13485 Plus are only allowed to place their Mark on the product as per the laid down guideline in 5.9.

7.7 The ICMED Marks shall have distinct colours for each level

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

7.8 All the Marks in the 3 levels can also be printed in Grey Scale.

7.9 While the 7.7.1 and 7.7.2 are to be for off-product use only the 7.7.3 (ICMED 13485 Plus) may be used in on-product for ICMED 13485 Plus.

7.10 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”, “13485”, and “13485 Plus” shall be properly visible.

7.11 The height to width ratio shall be maintained as per the logo packs provided by 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.

7.12 The QCI logo shall not be used on any stationary/promotional material like visiting cards, certificates, pamphlets, reports, etc. / on virtual platforms. In the event of a CB or its clients wishes to use the QCI logo, explicit writing approval needs to be sought from the QCI.

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 9000 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

3. Marks for ICMED 13485+ Certification:

GREEN: C-50, M-0, 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

ANNEXURE I: Format for Application

APPLICATION FOR PERMISSION TO USE THE CERTIFICATION MARK

1	**Name of the applicant**	
2	**Address**	
3	**Telephone No.**	
4	**Mobile No.**	
5	**Email**	
6	**Organization Details**	
7	**Purpose of Usage**	
8	**Duration of Usage**	
9	**Name of medical device (for which Certification Mark is to be applied) (please specify the medical device, or type of products)**	
10	**Signature and Date**	

ANNEXURE II: Format for the agreement between the Certification Body and the certified medical device manufacturer for use of ICMED Scheme Certification Mark

AGREEMENT FOR USE OF ICMED CERTIFICATION MARK

M/s _____ (hereinafter referred to as applicant) situated at _____ has applied to M/s. Quality Council Of India, 2nd Floor, Institution of Engineers Building, 2, Bahadur Shah Zafar Marg, New Delhi - 110002, India (hereinafter referred to as QCI), for permission to use ICMED Scheme certification mark for the offices for which it has received certification from _____ (name of certification body) approved by QCI under the Indian Certification for Medical Devices (ICMED) Scheme (hereinafter referred to as the Scheme) owned by the QCI. This agreement is entered in connection with granting of permission to use the certification mark by QCI under the following terms and conditions agreed upon:

1. General Conditions

1.1. The applicant (certified organization) agrees to comply at all times with the requirements of the Scheme as applicable presently and as amended from time to time. The applicant shall also agree to pay the Annual fee to QCI, through its certification body.

1.2. The applicant shall agree to comply with conditions of the certification as per its contract with the certification body as well as QCI as contained in this contract.

1.3. This Scheme aims to certify the medical device manufacturer for their ability to meet the applicable Indian Certification for Medical Devices (ICMED) Scheme certification requirements.

1.4. The applicant may use the certification mark 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.

1.5. The applicant may also use the ICMED Scheme certificate issued by the certification body as part of publicity material. The applicant, however, agrees to take care, while using the above documents to ensure that the Mark is used only with respect to the medical device manufacturer and it shall not give the impression that the non-certified, other than certified scope products, product from offices not included in scope or a related company are also certified.

1.6. The applicant agrees to use the ICMED Scheme certification mark only with respect to the medical device manufacturer covered under certification granted to it and will continue to comply with the certification criteria.

1.7. The applicant agrees that he would always fulfil the certification requirements as per the existing Scheme and as modified from time to time and shall use the certification mark only during the validity period of the certificate and when its QCI approval is valid.

1.8. The applicant agrees not to make use of the ICMED Scheme Certification Mark or name of QCI which could be misleading or unacceptable to QCI.

1.9. The applicant agrees to make claims of certification only for the scope which are specifically covered under certification.

1.10. The applicant agrees not to use the marks in such a manner that would bring QCI or the Scheme into disrepute and/or lose public trust.

1.11. The applicant agrees to inform QCI in writing of any significant changes in the applicant's name, ownership, or location for which the applicant has obtained the certification.

1.12. The applicant shall inform QCI, without delay, of matters that may affect its ability to conform to the certification requirements.

1.13. The applicant agrees to provide any information sought by QCI regarding operation of the Scheme by the applicant.

1.14. The applicant agrees that its name, location, and the scope of certification is included in the directory maintained and published by QCI.

1.15. The applicant agrees for the conduct of announced / unannounced / decoy assessments in order to verify the compliance of the applicant with reference to the use of the Mark as allotted to it and with respect to the complaints received by QCI about the applicant and to pay such charge within the time as communicated by QCI.

1.16. The applicant agrees 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.

1.17. Upon suspension or withdrawal/cancellation of its certification, the applicant shall discontinue use of all advertising material referring to the use of certification marks with immediate effect and submit a declaration to this effect to QCI. It shall also refrain from making claim in any form regarding the certification under the ICMED Scheme.

1.18. The QCI logo shall not be used on any stationary/promotional material like visiting cards, certificates, pamphlets, reports, etc. / on virtual platforms. In the event of a CB or its clients wishes to use the QCI logo, explicit writing approval needs to be sought from the QCI.

2. Other Requirements

2.1. This agreement is entered for a period of the validity of the certification and shall be in force from the date of signing of this agreement.

2.2. All correspondence of QCI shall be in writing and shall be deemed to have been served/made when sent by courier/registered post or facsimile or email to the address

of the applicant as mentioned on the company information sheet or any change as subsequently communicated to QCI by the client in writing under QCI acknowledgement.

2.3. In case of any disputes/issues, the applicant agrees to go through the Appeal procedure under the Scheme and accepts its decision as final.

2.4. The applicant agrees to indemnify QCI in case of any loss or liability incurred by QCI in connection with the Scheme or misuse of mark(s) by the applicant.

2.5. Disputes, if any, arising out of the terms and conditions of the agreement between QCI and the applicant, shall be governed by Laws of India and subject to the jurisdiction of competent courts located in Delhi.

2.6. The applicant shall nominate the chief executive or an authorized signatory for the agreement as the point of contact with QCI.

2.7. For the ICMED 13485 Plus certified manufacturer, by affixing the Mark the manufacturer declares on his sole responsibility that the product conforms to all applicable Scheme requirements, and that the appropriate conformity assessment procedures have been successfully completed.

2.8. By affixing the Mark on a product, a ICMED 13485 Plus manufacturer is declaring, on his sole responsibility (and irrespectively of whether a third-party has been involved in the conformity assessment process), conformity with all of the Scheme requirements to achieve ICMED marking.

The applicant hereby accepts and agrees with the above terms as documented in this agreement.

1. Signature :

Name of Applicant : _____

(The chief executive of the organization or an authorized signatory)

Title : _____

Address : _____

_____

_____

Date : _____

2. Quality Council of India

QCI hereby accepts the above application and agrees to the terms thereof.

Authorized Signatory: _____

Name : _____

Title :_____

Date : _____