



1.0 Purpose

To describe the policy and instructions for use of certification mark by certified medical device clients.

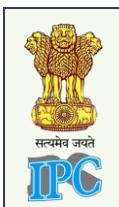
2.0 Scope

This document outlines the instructions and prerequisites for employing the certification mark in accordance with the stipulations of the ICMED scheme for certified clients.

3.0 Process

3.1 Requirements for Certification Mark Usage

- 3.1.1** Clients who have received certification under the ICMED scheme are entitled to use the ICMED scheme certification mark(s).
- 3.1.2** When employing the certification mark, it is essential to ensure that it is used exclusively in connection with the client's certified services/area. Its use should not imply certification for non-certified areas.
- 3.1.3** Certified clients must refrain from making any deceptive or misleading claims in connection with the certification mark.
- 3.1.4** Clients are prohibited from utilizing the certification mark in a manner that could tarnish the reputation of the scheme owner.
- 3.1.5** Any infringement on the proper usage of the certification mark may lead to the suspension or revocation of the certification. It is strictly prohibited to deviate from the approved color scheme under any circumstances. Should certification be suspended or withdrawn, the certified organization is required to promptly discontinue all utilization of the certification mark in any and all forms.
- 3.1.6** Following the suspension or withdrawal of certification, the certified organization must discontinue the use of all advertising materials that reference its certification status.
- 3.1.7** If it is observed that a client is using the certification mark in contravention of the specified conditions, appropriate actions will be taken by IPC-MvPI in accordance with the relevant requirements of ISO/IEC 17021-1, as well as those outlined in the "ICMED scheme certification process" and "ICMED scheme requirements for certification bodies" documents.
- 3.1.8** Depending on the extent of the violation, actions may range from advising corrective measures to the withdrawal of certification, especially in cases of repeated violations.
- 3.1.9** If a certified client fails to take appropriate action to rectify the misuse of the certification mark, IPC-MvPI reserves the right to suspend or withdraw the certification.



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3.1.10 In the event that a certified organization's certification is suspended, cancelled, withdrawn, or discontinued, it is the responsibility of the certified organization to cease using the certification mark from the effective date of the suspension, cancellation, withdrawal, or discontinuation. IPC-MvPI will ensure compliance with the aforementioned provisions.

3.2 Process for Use of Certification Mark

3.2.1 Certified clients are entitled to apply for the certification mark available under the ICMED scheme.

3.2.2 Applicants are required to submit their applications for the use of the certification mark using the specified format provided in Annexure I.

3.2.3 Prior to certificate issuance, certified clients must enter into a legally binding agreement with QCI. This agreement serves as the basis for authorization to use the Mark.

3.2.4 Once the agreement with the scheme owner is duly executed, the certified client will receive a certificate from IPC-MvPI bearing the relevant mark.

3.2.5 The certification mark corresponding to the respective ICMED scheme level should not be subjected to any photographic reduction or enlargement.

3.2.6 The color scheme of the marks must adhere to the specifications outlined in Appendix A. Clients should only affix the mark design that corresponds to the level for which they have been certified, and no other.

3.2.7 Any additional requirements detailed in the scheme documentation for using the certification mark should be considered in conjunction with the aforementioned conditions.

3.3 Mark and its Usage

3.3.1 Within the current purview of IPC-MvPI, two levels of certification marks shall be issued: ICMED 9000 and ICMED 13485.

3.3.2 Clients may receive certificates for a single mark or a combination of both marks.

3.3.3 Clients certified under ICMED 9000 and ICMED 13485 are permitted to display these marks on materials related to marketing and promotions, excluding the actual products themselves.

3.3.4 The off-product use implies that certified clients can employ the mark for which they are certified in promotional materials such as brochures, letterheads, and other similar stationery, as well as in communication media to enhance awareness of the scheme and the certification mark.

3.3.5 Clients may also incorporate the ICMED certificate, issued by IPC-MvPI, into their promotional materials.



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- 3.3.6** The ICMED Marks feature distinctive colors for each level: I) ICMED 9000 - printed in blue.
II) ICMED 13485 - printed in red.
- 3.3.7** These marks may also be rendered in grayscale.
- 3.3.8** All components of the ICMED marking should maintain a uniform vertical dimension, with a minimum height of 5 mm. This dimension requirement may be adjusted for small-scale devices. The certification mark itself must be at least 5 mm in height, and the inscriptions "9000" and "13485" must be clearly visible.
- 3.3.9** The height-to-width ratio should adhere to the guidelines outlined in the logo packs provided by QCI. The ICMED Logo's height should not be less than 5 mm, and the numbers "13485" and "9000" should have a minimum height of 1.5 mm to ensure legibility and clear printing.
- 3.3.10** The QCI logo is not permitted for use on certificates or any other promotional materials.

REVISION LOG		
Version	Description of Change	Release Date
00	New document for posting on IPC's website	11-OCT-2023



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



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Annexure: I

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.	Scope of Certification	
8.	Validity of Certificate (Issue date/ Valid up to)	
9.	Purpose of Usage	
10.	Duration of Usage	
11.	Name of medical device (for which Certification Mark is to be applied) (please specify the medical device, or type of products)	
12.	Signature and Date	