Section 4B

QCI - AIMED Voluntary Initiative on Medical Devices

Indian Certification of Medical Devices (ICMED) Scheme

Certification Process for ICMED 13485 Plus

Certification Process for ICMED 13485 Plus

1. Scope

1.1 This document explains the process of the product certification level, ICMED 13485 Plus, under the Voluntary Certification initiative for Medical Devices (hereinafter referred to as the ICMED 13485 Plus certification) and the requirements that shall be followed in order to obtain, operate and maintain the Certification.

1.2 Certification shall be granted for Medical Device(s) after due verification of compliance to the prescribed criteria. The certification is granted only against the ICMED 13485 Plus Certification Criteria defined under the Scheme.

2. Objective

2.1 The objective of this document is to manage the operation of the ICMED Plus certification and promote uniformity in its implementation, operation, and the interaction between the Certification Bodies (CBs), the Medical Device manufacturers seeking product certification, Test Laboratories, and the Scheme Owners.

3. Scope of Certification

3.1 The certification shall be available for certification of medical device(s) as per 'Certification Criteria for Product Certification' under ICMED 13485 Plus to assure the safety, quality and performance of medical devices.

3.1.1 This document specifies the conformity assessment procedures to be followed by the manufacturers in India seeking and thereafter maintaining ICMED 13485 Plus certification under the ICMED Scheme, and the Certification Bodies (CBs) to evaluate the medical devices manufacturers in order to establish conformity to applicable Certification Criteria. The certification is granted only against the ICMED 13485 Plus Certification Criteria defined under the Scheme.

3.1.2 For any manufacturer to qualify for ICMED 13485 Plus certification, compliance to the domestic regulations shall be a prerequisite. It shall be demonstrated by providing a copy of the registration or license, as applicable, issued by the regulatory authorities, if applicable.

3.2 The following are evaluation mechanism/elements of the conformity assessment for a medical device:

3.2.1. a quality management system (QMS),

3.2.2. a system for post-market surveillance,

3.2.3. technical documentation, and

3.2.4. a declaration of conformity.

3.3 The certification process shall include evaluation of the safety, quality, and performance of the medical device(s) for compliance to relevant certification criteria through testing of products sampled from the manufacturing facility and/or the market or any other source.

3.4 The Scheme is open to medical device manufacturers in India.

3.5 The Scheme is managed and operated by QCI, and certification is undertaken by independent CBs duly accredited by NABCB and/or approved by QCI.

3.6 Brief conformity assessment process by which a manufacturing unit gains and maintains certification is summarized in Annex A "Conformity Assessment for ICMED - Device Certification". The entire process of how to obtain certification of medical devices is available on the QCI website (www.qcin.org).

3.7 The certification of medical devices as per Certification Criteria shall be carried out by the CBs provisionally approved and eventually approved (by Scheme Owner) based on accreditation for the certification scheme as per ISO/IEC 17065. To operate under the Scheme, the CBs will require the scope of ICMED 13485 Plus certification under the 'Indian Certification of Medical Devices (ICMED) Scheme' within the accreditation for ISO/IEC 17065 and comply with the provisions of this **"Certification Process for ICMED 13485 Plus Certification**".

Note: *Plant, unit, manufacturing facility, medical device manufacturing facility, premises, and manufacturer are interchangeable, and all these terms refer to an individual medical device manufacturing facility. CB eventually accredited by NABCB and approved by the Scheme owner would certify the manufacturers for the ICMED 13485 Plus scheme.*

4. Certification Process

4.1 Registration of Application

4.1.1 The CB shall provide the applicant, Medical Device manufacturer, with an up-to-date detailed description of the evaluation and certification procedures, the documents containing the requirements for certification, the applicant's rights, and the duties of Medical Device manufacturer (including fees to be paid by applicants or Medical Device manufacturer of certified products).

4.1.2 The above information along with the application format shall be made available on the CB's website.

4.1.3 The CB may design its own application format for the ICMED 13485 Plus Certification for Medical Devices, and while doing so shall ensure that as a minimum the following information is obtained from the device manufacturer pertaining to its manufacturing operations and each Manufacturing site involved in the medical devices to be certified.

4.1.3.1. The manufacturer shall be a legal entity, or a defined part of a legal entity that can be held legally responsible for all its manufacturing activities and products. A certificate of incorporation, or registration certificate or any other document indicating legal status and constitution details of manufacturer need to be submitted.

4.1.3.2. A copy of licence (or registration), if applicable for the manufacturing site or establishment or plant along with the general information about the Medical Device manufacturer including its name; the address of its physical location; contact details; its functions and relationship in a larger organization, if any.

4.1.3.3. Site or plant Quality Manual as per requirements of ICMED 13485 scheme.

4.1.3.4. Following device Details for a **Class A medical device (Technical Documentation, Annexure B, Section 1 to 9)**:

a. Device description, intended use of the device, specifications including variants and accessories.

b. Material of construction for medical devices other than *in vitro* diagnostic medical devices, or a summary of analytical technology, relevant analytes, and test procedure for *in vitro* diagnostic medical devices.

c. Working principle and use of a novel technology (if any).

d. Labels, package inserts (IFU, etc.), user manual, wherever applicable,

e. Summary of any reported Serious Adverse Event and action taken by the manufacturer for medical devices other than *in vitro* diagnostic medical devices, or analytical performance summary including sensitivity and specificity for *in vitro* diagnostic medical devices.

i. **Technical Documentation** for **a Class B, Class C or Class D medical device,** as specified in Annexure B, Section 8, for medical devices other than *in vitro* diagnostic medical devices, or Annexure B Section 9 for *in vitro* diagnostic medical devices.

Note: In certain regulations Technical Documentation is also referred to as Device Master File. For technical documentation details manufacturer to refer to "Certification criteria for product certification".

ii. **Essential Principles checklist** for demonstrating conformity to the Essential Principles of Safety and Performance (also referred as 'General Safety and Performance Requirements') of the Medical Device, including *in vitro* diagnostic medical device.

iii. Copy of ICMED 13485 certificate (if already certified) and copy of Quality Manual indicating that the manufacturing site is in compliance with the provisions of the ICMED 13485, as applicable.

iv. In case of in vitro diagnostic medical devices, a copy of performance evaluation report of manufacturer or evaluation report issued by a NABL accredited medical device testing laboratory.

v. Information about judicial proceedings relating to its operations/product, any proceedings by any Regulatory body or suspension/cancellation/withdrawal of any relevant certifications/approvals under any Regulations.

vi. General information about the applicant's activities, description of production processes, details of manufacturing facilities, technological context, facility layout, its human and technical resources (Internal as well as external, contracted, etc.), number of shifts of operation, information on in-house laboratory, if any, accessibility to external NABL accredited testing facilities.

vii. The controls exercised by the applicant for ensuring product conformity to the requirements described in the relevant certification criteria, including Quality Assurance measures/plan.

viii. Information concerning all processes outsourced, if any, by the applicant that have potential to affect conformity to requirements, with name(s) and address of the

outsourced organization(s). The controls the Medical Device manufacturer exercises for ensuring compliance to applicable certification criteria is required to be submitted at the application stage itself.

ix. All other information considered essential for man-day estimations, competence and audit plan.

4.1.4 The MD manufacturer shall apply to an approved Certification body (CB) on the application form as prescribed by the CB providing the information as listed in Section.

4.1.5 (Constitution of organization, company name and the address of its physical location(s); contact details; legal status; its functions and relationship in a larger organization, if any, list products and manufacturing processes to be certified, information about product design process, outsourced processes etc.). The manufacturer can apply for a number of sites in the same application.

4.1.6 The applicant MD manufacturer shall declare whether it has been an applicant or certified under this Scheme with or by any other certification body, and if yes then shall provide the previous evaluation reports to the new certification body. The certification body may verify the information provided by contacting the earlier certification body.

4.1.7 The prospective applicant for MD manufacturer shall along with the application declare any judicial proceedings relating to its operations, any proceedings by any Regulatory body or suspension / cancellation / withdrawal of any certification/ approvals/licenses/permissions under any Regulations or otherwise. Such declaration from the manufacturer shall be a part of the undertaking.

4.1.8 Certification is granted only against the current relevant certification criteria. The certification body shall review all applications for the above and ensure the same.

4.1.9 Whether consultancy relating to the management system and/or product conformity to be certified has been provided and, if so, by whom.

4.1.10 The applicant shall clearly indicate the type of certification it is applying for.

4.2 Application Review

4.2.1 The procedure for conducting the application review, shall clearly describe the process for application review, responsibilities and the competence of personnel performing the application review. A competent person of the CB shall undertake a review of the application received from the Medical Device manufacturer, as per its documented procedure for ensuring the following:

4.2.1.1. The information about the Medical Device manufacturer, the facilities, and the product(s) to be certified is sufficient for the conduct of the application review and the subsequent facility and product certification process.

4.2.1.2. Any known difference in understanding between the certification body and the applicant is resolved, including agreement regarding certification criteria.

4.2.1.3. the scope of certification sought is very well stated/defined.

4.2.1.4. the means are available to perform all evaluation activities.

4.2.1.5. the certification body has the competence and capability to perform the certification activity.

a. Information to determine the time required for conduct of the initial evaluation and surveillance evaluations. This shall be done in accordance with the CB's documented procedure for determination of audit and evaluation time, which shall be established based on the requirements described in this document (Refer Annexure A-1 and A-2).

b. To determine and nominate a competent team/evaluator (for evaluation of the Technical Documentation and onsite testing evaluation for ICMED 13485 Plus standard), for the certification scope applied for by the manufacturer. This shall be done in accordance with the requirements specified in the document– Requirements for Certification Bodies

4.2.2 Based on the review of application for certification, deficiencies observed, if any, these shall be informed to applicant within seven days of receipt of application. In case the information provided by the applicant is incomplete/insufficient for the purpose of conducting an application review, then the CB shall have procedure for obtaining additional information. The information thus received shall be recorded along with other information already received. Records of review shall be maintained.

4.2.3 Antecedents of the applicants shall be checked in relation to the Scheme. If the manufacturing license (or the registration) issued by Licensing authority has been suspended/cancelled for a product or the factory during the last one year, the application from such Medical Device manufacturer shall not be entertained.

4.2.4 Applications from Medical Device manufacturers who have earlier either misused the ICMED Plus Certification Mark, or have been implicated/convicted by the court, or whose earlier certificate was cancelled because of violation of terms & conditions/misuse of certification mark shall not be registered within three years of conviction/strictures by the court/cancellation of the certificate by any CB.

4.2.5 Applications from Medical Device manufacturers found to be misusing the ICMED Plus Certification Mark while their application is being processed for grant of certificate, shall not be processed any further, and rejected after a due notice of 15 days. Fresh applications from them shall be treated as per clause 4.2.4 above.

4.2.6 Requests for grant of certificates from ex-applicants shall be processed like a fresh applicant and the entire procedure for grant of certificate be adhered to subject to clauses 4.2.3, 4.2.4 and 4.2.5 above.

4.2.7 Certification Bodies shall reject or close all applications for certification under the following conditions;

a. if an evaluation is not carried out within 3 months of registration of application or the entire certification process is not completed within 6 months.

b. if the samples fail on testing during the evaluation and during the follow up evaluation carried out (after organization has confirmed necessary corrective actions).

c. if acceptance testing facilities are not functional within three months of evaluation, or else arrangements for testing for specified requirements in NABL accredited laboratories have not been made.

d. if during the evaluation it is observed that significant number of batches of the specific

product have not conformed to the specifications and or have been subjected to corrections and rework.

e. Inadequate corrective actions on the non-conformities raised within three months of evaluation.

f. Lack of competent personnel for production and testing.

g. If organization shows no progress towards completion of corrective actions within three months of evaluation and six months of registration of application.

h. Evidence of malpractice.

i. Voluntary withdrawal of application.

j. Non clearance of dues.

4.2.8 Following the review of the application, the certification body shall either accept or decline an application for certification. When the certification body declines an application for certification as a result of the review of application, the reasons for declining an application shall be documented and made clear to the client.

4.2.9 Only complete applications supported with all documents sought shall be accepted and registered in order of receipt with a unique identification number, acknowledged and records maintained. Registration shall be done within 7 days of receipt of application or information in response to the deficiencies communicated in Section 4.2.2 above. In case the applicant discloses any proceedings, suspensions etc., the applicant shall not be entertained for a period of one year from the date of conviction, suspension, withdrawal, deregistration etc.

4.2.10 In the event of a closure/rejection of an application, the application fee submitted with the application may be refunded as decided by the certification body.

4.3 Determination of Evaluation Time

4.3.1 The total evaluation time for ICMED 13485 Plus shall be the time required for auditing QMS as per ICMED 13485 (if not certified previously) and time required for auditing product related requirements including testing as prescribed Annex A-1 and A-2.

4.3.2 For a complete audit and /evaluation for ICMED 13485 Plus, the QMS audit shall follow the process documented in ICMED 13485 Certification in such cases, the time for stage 2 audit shall have additional time for the product related requirements prescribed for ICMED13485 Plus certification. If the manufacturer is previously certified to ICMED 13485, determination of evaluation time for remaining ICMED 13485 Plus criteria (only) can be done as per Annexure A-2.

4.3.3 The CB shall have documented procedures for determining time required for Medical Device Conformity Assessment offsite and including those at site (Evaluation and Testing of products etc.) as per the Annexure A-2 of this ICMED 13485 Plus scheme. The evaluation time determined for each client by the certification body, and the justification for the determination, shall be recorded. In determining the offsite (Technical documentation) and onsite (Product testing/witnessing/verification) evaluation time, the certification body shall consider, among other things, the complexity of operations, complexity of device, and the class of product offered for certification.

4.3.4 The minimum evaluation time as above does not include the time spent either on preparation for the evaluation or for preparing the evaluation report. The minimum evaluation time for each on site audit shall be at least one man-day (8 hrs. per day).

4.3.5 The certification body shall not carry out any conformity assessment of duration lesser than as specified above (4.3.1 and 4.3.2).

4.3.6 The CB shall prepare an evaluation plan based on its procedure and get manufacturer's agreement for the evaluation plan.

4.3.7 Document review, audit preparation and report preparation time shall be additional and shall be at least one man-day.

4.4 Preparation and Planning Audit/Evaluation

4.4.1 Prior to undertaking the site visit, the certification body, through the members of its nominated evaluation team, shall undertake certain offsite activities as part of preparation and planning stage. These are:

4.4.1.1 Study of all the information received and request for additional information, if required.

4.4.1.2 Examination of the information on the scope of certification, risk classification of device, certification criteria, and initially submitted documents, for preparation of evaluation plan.

4.4.1.3 The minimum evaluation time for each on site audit shall be at least one man-day (8 hrs. per day).

4.4.1.4 Preparation of a checklist for requirements to be verified and evaluated during the onsite evaluation. If required, make modifications in generic checklist developed by the certification body for facilitating the evaluation.

4.4.2 The certification shall be granted for each manufacturing facility/premises after due verification of compliance to the prescribed criteria. Sampling of sites is not permitted for ICMED 13485 PLUS certification.

4.5 Conformity Assessment Procedure

4.5.1 A brief ICMED 13485 Plus certification process is provided in Annexure A. Conformity assessment procedures (Annexure A, Section III.3 and III.5), as applicable, shall be used for the medical devices depending on the risk classification. Process of certification for a class D new medical device typically shall involve a combination of:

4.5.1.1. The ICMED 13485 certification process (if not certified previously) for the QMS.

4.5.1.2. Evaluation of the technical documentation along with the medical device evaluation (ICMED 13485 Plus, Annexure A).

4.5.1.3. Conformity assessment process, viz. Type examination, Product conformity verification (as applicable depending on risk classification) are subsets of complete certification covered in Section 4.5.1, I and II above.

For class C, B or A medical devices conformity assessment procedures shall be used depending on the risk classification, clinical evidence, involvement of product design process, availability of predicate device etc.

4.5.2 Man-days required for these certification activities shall be as per Annexure A-1 & A-2.

4.5.3 The QMS audit shall be performed as per ICMED 13485 scheme.

4.5.4 The medical device evaluation activities (manufacturing processes for specified products and testing of products etc.) shall be performed during the stage 2 QMS audit as per this ICMED 13485 Plus standard by spending additional time.

4.5.5 For manufacturers already certified to ICMED 13485, onsite evaluation shall be performed (can be clubbed with surveillance or recertification audit for ICMED 13485) separately for devices under certification.

4.5.6 The evaluation activities for ICMED 13485 Plus for medical devices under application can also be planned through additional onsite visit if not clubbed with surveillance or recertification audits.

4.6 Assessment of The Technical Documentation

4.6.1 The CB shall have a documented procedure for allocation of appropriately qualified, and authorized personnel, employed by it, for examination of individual aspects of devices with proven knowledge and experience regarding the technology (IAF MD 9, Annex A, Technical areas, product categories; and ISO 17065).

4.6.2 The CB shall have documented procedures in place relating to the assessment of manufacturer's procedures and technical documentation relating to use of device, biocompatibility, clinical evaluation (if applicable as per conformity assessment procedure and classification of device) both for initial conformity assessment and on an ongoing basis. The CB shall examine, validate, and verify the manufacturer's procedures and documentation (with respect to planning, conduct, evaluation, reporting and updating of the clinical evaluation, post-market surveillance and PMCF, the interface with the risk management process, the appraisal and analysis of the available data and its relevance with regard to demonstrating conformity with the relevant requirements). The technical documentation review/evaluation shall be carried out before the on-site audit or evaluation.

4.6.3 The CB may require the application to be completed by having further tests carried out or requesting further evidence to be provided to allow assessment of conformity with the ICMED 13485 Plus criteria.

4.6.4 The CB shall assess the clinical evidence (as per conformity assessment procedure applicable) presented by the manufacturer in the clinical evaluation report and the related clinical evaluation that was conducted. The CB shall employ device reviewers with sufficient clinical expertise and, if necessary, use external clinical experts with direct and current experience relating to the device in question or the clinical condition in which it is utilized, for the purposes of that review.

4.6.5 The CB shall, in circumstances in which the clinical evidence is based partly or totally on data from devices, which are claimed to be equivalent to the device under assessment, assess the suitability of using such data, taking into account factors such as new indications and novel features of the device. The CB shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity.

4.6.6 For any characteristic of the device claimed as innovative by the manufacturer or for new indications, the CB shall assess to what extent specific claims are supported by specific pre-clinical and clinical investigations, data and risk management.

4.6.7 The CB shall verify that the clinical evidence and the clinical evaluation are adequate and shall verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements, and also manufacturer's post-market surveillance plan, including a review of the need for, and the adequacy of, the PMCF plan proposed, where applicable.

4.6.8 The CB shall clearly document the outcome of its assessment in the technical documentation and clinical evaluation assessment report.

4.7 **Onsite Evaluation**

4.7.1 The evaluation plan covering the relevant evaluation objectives shall be prepared and communicated to the applicant well in advance. Objectives of the evaluation for ICMED 13485 Plus certification shall be:

4.7.1.1. The evaluation shall cover on-site testing and laboratory testing (additional testing if any) for each type of the medical device(s) applied for in the scope of application. Witnessing of testing shall be carried out as part of the evaluation (preferably performed during stage 2 audit).

4.7.1.2. Establish a test plan with relevant/critical parameters (with rationale and agreed by manufacturer) for witnessing of testing by CB. The test protocol should be as per recognized product standards or in-house validated test methods adopted by manufacturer where no such national and other recognized standards exist.

4.7.1.3. Examine and assess technical documentation (prior detailed review is done offsite) to verify that the medical device has been manufactured as per the process described by the manufacturer.

4.7.1.4. CB shall carry out or arrange (if required, in an NABL accredited laboratory) for the physical and laboratory tests necessary to verify whether the solutions adopted by the client meet the general safety and performance requirements. The requirements against which the products of the client are evaluated shall be those contained in specified standards (or manufacturers own validated test methods).

4.7.1.5. The evaluation shall be carried out by a competent QMS audit team (audit only for clients with no ICMED 13485 certification) and/or a competent evaluation team (Technical documentation and product evaluation).

4.7.2 CB's cumulative competences shall be such as to enable it to assess the types of devices for which it is accredited.

4.7.3 Evaluation team to include qualified personnel for the assessment of the pre-clinical evaluation, clinical evaluation, tissues and cells of human and animal origin, functional safety, software, combination products depending on the type and complexity of the medical device.

4.7.4 The certification body shall communicate the composition of the evaluation team to the applicant Medical Device manufacturer for identification of conflict of interest, if any. If required sufficient background information in respect of the evaluation team members shall be provided to the applicant for this purpose. Any objections (conflict of interest)

to the team by the applicant shall be examined on merit and decided on.

4.7.5 Timings and date of audit and/or evaluation shall be fixed in consultation with the manufacturer ensuring that production processes representative of normal operations will be open for witnessing during the planned evaluations, if so required. The duration and plan for evaluation shall be provided to the applicant in advance.

4.7.6 The evaluation of the device design, technical file (performed before the onsite audit/evaluation) and the processes at the site of the applicant shall be conducted within three months of registration of application and or satisfactory fulfilment of all application requirements.

4.7.7 For the evaluation of Medical Device, the certification body shall list the applicable domestic regulatory requirements, and shall:

4.7.7.1. Verify compliance to the registration and licensing requirements for the subject premises and medical devices.

4.7.7.2. Review the Technical File/Device master file as per requirements of the certification criteria. Technical documentation submitted shall be reviewed before the onsite QMS audit and onsite product evaluation activities.

4.7.7.3. Evaluate the status of the ICMED 13485 Plus certification scope for its appropriateness and adequacy.

4.7.7.4. Ascertain the availability of adequate equipment for production for the devices under certification.

4.7.7.5. Ascertain the availability of competent personnel for production and testing.

4.7.7.6. Verify adequacy of testing facilities in respect of the in-house tests carried out by the applicant, if any, and/or the arrangement with NABL accredited laboratories for the medical devices under certification.

4.7.7.7. Verify competence of testing personnel and testing facility by witnessing testing of representative number of sample(s) in the premises of the applicant Medical Device manufacturer.

4.7.7.8. The CB may in specific situations like absence of testing facility with the manufacturer or complaints or adverse incidents and especially where there may be any doubt about compliance of the medical device to the prescribed standards, decide to draw a sample for independent testing with justification to be provided to the manufacturer.

4.7.7.9. Software and firmware shall be evaluated for safety and security requirements in an NABL accredited laboratory by the manufacturer. To enable this, necessary information relating to architecture, design and source code and other information to enable their evaluation shall be required and collected from the applicant. On the basis of the satisfactory reporting, the evaluation team shall validate the same on-site at the applicant's site for compliance.

4.7.7.10. When the NABL accredited labs located at a distant location are difficult to access, the testing being conducted by the applicant onsite shall be witnessed by the CB evaluation team.

4.7.7.11. When the testing being conducted by the applicant onsite is witnessed by the CB evaluation team this would be considered equivalent to independent testing of medical device.

4.7.8 Evaluation team shall prepare an audit report (if QMS is part of this certification) and/or an ICMED Plus evaluation report (if client already has ICMED 13485 certified). Any deficiencies observed with respect to the applicable certification criteria shall be informed in writing to the applicant.

4.8 Grading of Non-Conformities

4.8.1 The nonconformities observed during evaluations of Medical Device under the scheme shall be classified as Major or Minor depending on their severity.

4.8.1.1. A nonconformity is classified as Major when it relates directly or indirectly to the safety and performance of the product and the Medical Device manufacturer's capability to produce a product that would conform to the certification criteria. It should also be raised as major in case it is observed that the information provided as part of technical documentation or the significant evidence supporting the same are observed to be not available or observed to be not analyzed appropriately. In respect of Quality Management system, nonconformity that affects the capability of the management system to achieve the intended results shall be categorized as major NC. A number of minor NCs on the same aspect shall be clubbed together and raised as single major NC.

4.8.1.2. A nonconformity is classified as Minor when it relates to the implementation issues which do not directly affect either the safety and performance of the product or the Medical Device manufacturer's capability to produce a product conforming to the certification criteria and are isolated instances of lapses. In respect of Quality Management System, a *nonconformity* that does not affect the capability of the management system to achieve the intended results shall be categorized as minor NC.

4.8.2 In case of major and minor NCs, the Medical Device manufacturer shall carry out root cause analysis and inform the same along with correction and corrective actions, within a period of one month and 3 months respectively.

4.8.3 All non-conformities are required to be closed before initial certification through verification of adequacy of the correction and corrective actions. Non-conformity which raises any doubt as to the conformity of the product must be addressed and the correction/corrective actions verified by the certification body (by site visit or other appropriate forms of verification) before certification is granted. All major non-conformities shall invariably require a follow-up audit.

4.9 Evaluation Report

4.9.1 The ICMED 13485 Plus evaluation team shall prepare an audit and/or evaluation report and any deficiencies observed with respect to the applicable certification criteria during the evaluation shall be informed in writing to the applicant. A separate ICMED 13485 audit report, if applicable, shall be prepared for manufacturer not certified previously.

4.9.2 The evaluation reports for evaluation of medical device under the ICMED 13485 Plus scheme shall clearly provide evidence and conclusions about the fulfilment of the evaluation objectives as described above and shall contain sufficient detailed information regarding conformity with all the relevant certification requirements, including the Certification Criteria. The Certification Body shall develop appropriate report format(s) including checklist used for evaluating compliance to the certification criteria and Annexures A and B, and report writing guidance document to ensure that the report provides, adequate and complete details for ensuring appropriate, evaluation, review and decision in respect of grant of certification. A checklist, providing

only conclusions “Yes” and “No” against each criteria element, without substantiating the reasons for reaching that conclusion and providing references to evidence examined shall not be accepted as adequate form of reporting.

4.9.3 The certification body shall send the evaluation report to the applicant manufacturer within 7 days from the date of completion of the evaluation.

4.10 Independent Testing of Samples

4.10.1 The Certification body may in specific situations like absence of testing facilities with the manufacturer or complaints or adverse incidents and especially where there may be any doubt about compliance of the medical device to the prescribed standards, decide to draw a sample for independent testing with justification to be provided to the manufacturer.

4.10.2 The samples shall be drawn in a manner so as not to contaminate the product while sampling and packing.

4.10.3 The samples(s) shall be packed and sealed such that the product integrity is maintained for its intended shelf life.

4.10.4 The samples shall be clearly identified with their name, batch identification and suitable identification to enable traceability to the applicant and the Evaluation.

4.10.5 As far as feasible, the identity of the sample with respect to its Brand name, and the name of manufacturer as depicted on the original packing, shall be masked.

4.10.6 The samples shall be drawn in quantities adequate to facilitate their testing for identified parameters specified in the standard/product Criteria.

4.10.7 If the product is affected by the conditions of temperature, handling, and storage, then care shall be taken to ensure that the sample is drawn and maintained under those conditions for testing its conformity to specified criteria.

4.10.8 The samples of Medical Device(s) drawn for independent testing shall be forwarded to an NABL accredited testing laboratory for ascertaining conformance to specified criteria. The specified criteria shall be clearly mentioned and communicated to the testing laboratory. The samples(s) shall be duly coded and as far as possible, the identity of the manufacturer shall be hidden (where possible). The sample(s) shall be so dispatched that they do not get damaged and or contaminated, undergo deterioration, and the product integrity is maintained.

4.11 Independent Review of Evaluation Report

4.11.1 An independent (personnel other than those involved in the audit/evaluation activities) review of evaluation report shall be carried out by person(s) or a committee having the relevant competence. The responsibility for review function, shall however be that of the certification body and it needs to confirm that all activities of the certification plan have been completed.

4.11.2 Any information on which opinion and decision is based and which comes from any source other than the evaluation process, for example complaints, information received from regulators etc. should be made known to the applicant and given an opportunity to comment on it.

4.11.3 The nonconformities and their resolution should be documented and made available for the purpose of review.

4.11.4 The records of review shall be retained and shall provide adequate confidence that all relevant aspects were examined prior to making recommendations.

4.11.5 The recommendation for certification decisions, whether positive or negative, shall be supported by a documented justification.

4.12 Certification Decision

4.12.1 Certification decision shall be the sole responsibility of the certification body and the decision shall be taken by competent personnel (individual or committee) nominated by the CB.

4.12.2 The person(s), who take(s) the decision on granting/withdrawing certification within the Certification body (as per its documented procedure) shall have a level of knowledge and experience sufficient to evaluate the information obtained from the evaluation process and the review recommendations. Review and the certification decision may be completed concurrently by the same person(s).

4.12.3 Impartiality and absence of conflict of interest shall be ensured before entrusting the task of certification decision making.

4.12.4 Prior to making a certification decision the CB shall verify that the offsite technical documentation evaluation report (design review, clinical evaluation etc. as per criteria), on-site evaluation report(s) and supporting documentation needed for decision making, including concerning resolution of non-conformities noted during assessment, are complete and sufficient with respect to the scope of the application. All non-conformities shall have been resolved before grant of initial certification.

4.12.5 The certification body shall grant certification for product(s) after ensuring complete compliance to the Certification Criteria and Scheme requirements and all nonconformities have been addressed. There shall be no conditional grant of certification.

4.12.6 In case, based on the evaluation, the Certification Body decides, not to grant certification to the medical device(s) applied for, then it shall notify the applicant of the decision not to grant certification and shall identify the reasons for the decision. If the applicant expresses interest in continuing the certification process, the certification body can resume the process for evaluation from the process as described above.

4.12.7 The applicant may if he wishes appeal against the decision not to grant certification.

4.13 Certification Agreement

4.13.1 The certification agreements describe the terms and conditions which the medical device manufacturer is required to abide by after the grant of certification. Since the Scheme bestows self-marking rights to the certified medical device manufacturer, it is required to pledge its commitment for ensuring conformity of products and processes to the Certification Criteria and the Scheme requirements on a continuing basis. The details of the certification agreement have been covered in the document “Rules for use of certification Mark. The Certification Agreement shall also include requirements with respect to use of certificates and marks of conformity on the products by the certified Medical Device manufacturer.

4.14 Certification Documentation and Validity

4.14.1 On grant of certification, the certification body shall inform the manufacturer and issue a Certificate, uniquely identified, with the following information:

4.14.1.1 The name and address of the certification body, and certification mark of the certification body, other marks, and Scheme logo,

4.14.1.2 The name and address of the Medical Device manufacturer and the address of the site(s) certified. For a company with multiple sites, an annexure to certificate mentioning the sites and their addresses.

4.14.1.3 The effective date (the date on which certification is granted, which shall not precede the date on which the certification decision was completed) and the expiry date of certification. The date of granting, shall also include date of extending or renewing the certification, if applicable.

4.14.1.4 The expiry date or recertification due date consistent with the recertification cycle.

4.14.1.5 The certification criteria (certification scheme) against which the certification has been awarded, complete with issue number and/or revision.

4.14.1.6 The scope of certification with type of activities, and with name/identification of medical device as given on the manufacturing and product approval licenses. The conformity assessment procedure/type (full quality assurance, design, or type examination etc.).

4.14.1.7 Any other information required by the certification criteria used for certification.

4.14.1.8 In the event of issuing any revised certification documents, a means to distinguish the revised documents from any prior obsolete documents.

4.14.1.9 The formal certification documentation shall include the signature of the individual(s) of the certification body assigned such responsibility.

4.14.2 Formal certification documentation shall only be issued after, or concurrent with, the following:

4.14.2.1 the decision to grant or extend the scope of certification has been made.

4.14.2.2 certification requirements have been fulfilled.

4.14.2.3 the certification agreement has been completed/signed. The contents of the certification agreements have been detailed in the document “Rules for use of certification Mark”.

4.14.3 No Brand names of the Medical Device shall be mentioned on the Certificate document or any other document intimating grant of certification.

4.14.4 The certificate for product certification shall be valid for a maximum period of 3 years from the date of decision to grant the product certification subject to successful surveillance annual audit of conformity to the ICMED 13485 and ICMED Plus requirements.

4.14.5 The certification agreement with the manufacturer shall clearly convey the manufacturer that they have to seek approval from QCI for using the ICMED 13485

Plus Certification Mark. The CB shall get the QCI agreement signed by the manufacturer and send the agreement to QCI for its signatures.

4.14.6 The CB shall promptly add the name of the newly certified, manufacturer with all details in the directory of certified clients maintained by it.

4.15 Surveillance Evaluation

4.15.1 Onsite Surveillance evaluation of the certified clients shall be carried out at a frequency of at least once in calendar year as per ISO 17021-1:2015. The Certification Body may allow a grace period (as per ICMED 13485 scheme) based on valid grounds beyond which any delay shall lead to suspension of the certificate.

4.15.2 Surveillance for ICMED 13485 Plus shall include the audit time for ICMED 13485 (as per ICMED 13485) and product evaluation. The man-days for surveillance evaluation shall be determined depending upon the number of devices to be sampled and complexities. The evaluation of product related requirement shall be carried out at each site covered under certification in each surveillance.

4.15.3 The surveillance evaluation shall be carried out on site at the certified premises. The objectives for this evaluation shall generally be the same as evaluation objectives.

4.15.4 An evaluation plan shall be prepared in advance and forwarded to the certified unit along with names of the evaluation team members, their role in the evaluation, sites/products to be evaluated, duration of evaluation and evaluation dates.

4.15.5 The certification body shall ensure that critical steps in a production operation or a combination of production operations on given days are witnessed and their controls verified, and witness testing of products (sampled) in progress for assessing continued competence of testing personnel and testing capability. Planning for surveillance evaluations shall ensure this.

4.15.6 The certification body may in specific situations like absence of testing facilities with the manufacturer or complaints or adverse incidents and especially where there may be any doubt about compliance of the medical device to the prescribed standards, decide to draw a sample for independent testing with justification to be provided to the manufacturer.

NOTE: Short notice or unannounced audits may be required if available post-market surveillance data known to the CB on the subject devices indicate a possible significant deficiency in the quality management system or a significant product safety related information becoming known to the CB.

4.15.7 During the surveillance evaluation, the evaluation team shall as a minimum verify and report on the following:

4.15.7.1. Compliance to the requirements of the certification criteria and other requirements of the certification process.

4.15.7.2. Status of manufacturing practices and technical file up-dations.

4.15.7.3. Records required to be maintained.

4.15.7.4. Continued compliance of the medical device, manufactured since the last assessment, for batches manufactured. Validation records for any changes in process, ongoing

stability records for the products have also to be verified.

4.15.7.5. Compliance to the quality assurance procedures.

4.15.7.6. Handling and disposal of non-conforming products.

4.15.7.7. Actions taken on discrepancies observed during the previous evaluation, failure of samples if any reported and informed to the Medical Device manufacturer.

4.15.7.8. Samples drawn for factory testing.

4.15.7.9. The continued availability of the manufacturing machinery and test equipment and changes since the previous evaluation. In the event of changes the evaluator shall ascertain if they are adequate for control of processes and testing of the products.

4.15.7.10. A review of the processes of complaint handling, post-market vigilance reporting, actions on the non-conforming products detected after delivery, advisory notices as per regulatory requirements, field corrective actions, recalls and any subsequent corrective & preventive actions.

4.15.8 If any non-conformities are observed, the same shall be categorized as either a Major or a Minor as per description on non-conformity given in Clause 4.8.1. The non-conformity report shall be provided to the client in writing, for root cause analysis, correction and corrective action (timeline for closure as in 4.18.2). Details of the same shall be reported in the Surveillance evaluation report.

4.15.9 If the surveillance valuation results in an infructuous visit due to any reason, and neither the production, nor testing of products are witnessed, the CB shall conduct another surveillance evaluation. Such additional evaluations may be charged to the certified unit as decided by the certification body.

4.16 Market Samples

4.16.1 The certification body may in specific situations like complaints or adverse incidents and especially where there may be any doubt about compliance of the medical device to the prescribed standards, decide to draw a sample for independent testing from the market with justification to be provided to the manufacturer.

4.16.2 Market samples shall be drawn in the original packaging and product integrity shall be ensured by the certification body.

4.17 Dealing with Failure of Samples Reported in Independent Laboratory Reports

4.17.1 Failure of sample of certified product, drawn from the factory or the market, to comply with the criteria shall be communicated to the certified Medical Device manufacturer for investigation, root cause analysis and proposed corrective actions within 15 days of intimation. The CB shall respond to the proposed corrective actions within 5 days and the manufacturer shall implement the corrective actions within one month from acceptance of the corrective actions by the CB.

4.17.2 Depending on the nature of the failure reported, the CB shall decide on one or more of the following:

4.17.2.1. Draw additional samples of the product manufactured around the same time from the

factory or market.

4.17.2.2. Organize for an additional surveillance evaluation immediately.

4.17.2.3. Increase the frequency of surveillance evaluation if require for future surveillance.

4.17.2.4. Increase the number of samples drawn for testing. The manufacturer shall be informed of the decision taken.

4.17.3 In case of failure of the product sample, for safety requirements, the CB shall advise the manufacturer to:

4.17.3.1. Stop dispatches of the failing batch if stocks are available either at the site or in their warehouses.

4.17.3.2. Recall the failing batch from the market.

4.17.3.3. Suspend the certification, till adequate and effective corrective actions are taken.

4.17.4 Based on the satisfactory demonstration of root cause analysis and correction/corrective actions to prevent such recurrences by the manufacturer, the decision to revert back to the normal operation of certification shall be taken by the CB. Testing of fresh samples of the device manufactured after implementation of corrections/corrective actions may be one of the mechanisms of satisfactory demonstration. Based on the specific situations the certification body shall decide the appropriate actions and record the justification for the same.

4.18 Renewal

4.18.1 The CB shall send the Renewal notice to the certified units at least four months prior to expiry of certificate validity period.

4.18.2 The Medical Device manufacturer shall apply for renewal in the prescribed format along with fee, if any prescribed by the CB at least 3 months before expiry of the certification.

4.18.3 The on-site recertification evaluation conducted towards the end of third year and before the expiration of the certificate shall be same as the initial evaluation during which the CB shall verify fulfilment of all the requirements of certification criteria including technical file changes, if any.

4.18.4 The CB shall review the performance of the certified unit who has sought renewal of the Certification, with respect to compliance to certification criteria during the certification cycle, prior to a decision on the renewal of the certificate.

4.18.5 The review shall be based on:

4.18.5.1. Surveillance and renewal evaluation reports carried out during the certification cycle.

4.18.5.2. The NCs raised since last surveillance and the satisfactory submission of corrective action (for minor NCs) and closure (of major NCs), and resolution of the any other issues raised and their effectiveness.

4.18.5.3. Handling and disposition of nonconforming products.

4.18.5.4. Test reports for samples drawn from the factory and the market.

4.18.5.5. Any suspension of certificate during the previous validity period.

4.18.5.6. Corrective actions taken.

4.18.5.7. Complaints if any received.

4.18.5.8. Adverse post market information, if any.

4.18.6 The review shall be conducted by competent person(s) designated for this activity.

4.18.7 The decision for renewal of certificate shall be taken by the competent personnel authorized for the same, based on the satisfactory performance of the certified Medical Device as revealed through the review process.

4.18.8 The certification body shall not renew certification with conditions for compliance to be verified subsequently. There shall be no conditional renewal of certification.

4.18.9 When performance of the certified units is not satisfactory, the certification body shall withhold the renewal of the certificate to the manufacturing organization clearly stating the reasons and give time for effecting corrective actions. The verification and decision on renewal should be taken within 3 months of the expiry date.

4.18.10 The renewal shall be effected from the date of the expiry of the previous certificate and the intervening period shall be treated as period of suspension and clearly stated on the Certificate. The Medical Device manufacturer shall not claim certification during this period.

4.18.11 In case the Medical Device manufacturer does not complete satisfactorily actions within three months, the certificate shall stand expired from the date of expiry of previous validity.

4.18.12 When a certificate is not renewed it shall expire at the end of validity period.

4.19 Suspension

4.19.1 When a nonconformity with certification requirements is substantiated, either as a result of surveillance or otherwise, the certification body shall consider and decide upon the appropriate action, such as those stated below:

4.19.1.1. continuation of certification under conditions specified by the certification body (for example increased surveillance).

4.19.1.2. reduction in the scope of certification to remove nonconforming product variants.

4.19.1.3. suspension of the certification pending remedial action by the client.

4.19.1.4. withdrawal of the certification.

4.19.2 The suspension action shall also be decided based on any of the situations as stated below:

4.19.2.1. The client's certified quality management system has persistently or seriously failed to meet certification requirements, including requirements for the effectiveness of the

management system.

4.19.2.2. Repeated failure to take actions in respect of Major NCs, within the time limit prescribed or Major NC raised on the same issue in two consecutive on-site evaluations.

4.19.2.3. Unsatisfactory performance during two consecutive Surveillance evaluations on account of any of these aspects is observed.

a. Important testing equipment not calibrated, and no action taken by the certified unit.

b. Testing equipment out of order and no alternate arrangements for testing.

c. Non availability of competent technical personnel and absence of alternate arrangements.

d. Failure of sample picked up from client/market and manufacturer fails to investigate and correct the reason for failure of the product.

4.19.2.4. Evidence of falsification of information provided in the Technical Documentation, if observed during surveillance.

4.19.2.5. Complaints of serious nature, regarding performance and/or safety of the medical device, if substantiated.

4.19.2.6. The certified client does not allow surveillance or recertification audits to be conducted at the required frequencies.

4.19.2.7. The certified client has voluntarily requested a suspension.

4.19.3 The certification body shall issue due notice of at least 15 days for suspension of certification to the Medical Device manufacturer. In case of very serious failures or issues, the notice may not be required, and the case may even be directly processed for withdrawal of certification.

4.19.4 On receipt of instructions for suspension of certification, the certified units shall suspend using ICMED Plus certification mark on Medical Device being manufactured by them with immediate effect. The Medical Device manufacturer shall be advised to undertake a root cause analysis and identify the necessary corrective actions for resolving the same.

4.19.5 While under suspension, the certification body shall ensure that dispatches of certified products to the market/customer are withheld until the product in stock has been reassessed for conformity to the criteria. The Medical Device manufacturer shall reassess the quality of the products in stock and the CB shall verify this reassessed stock for conformity to the certification criteria before allowing its dispatch.

4.19.6 When certification is suspended, the certification body shall require that, during the period of suspension, the certified unit makes no misleading claims and should advise relevant existing and potential purchasers regarding the status of certification and ceases to use the certification mark on the products manufactured since the date of notification of suspension. The certification body shall ensure that the Medical Device manufacturer has procedures in place to ensure that a nonconforming certified Medical Device that gave rise to suspension of certification is recalled.

4.19.7 The information about the suspension and withdrawal of certification shall be made publicly available by the certification body on its website.

4.19.8 The certification body shall revoke suspension only when:

4.19.8.1. Corrective actions have been taken and verified by the certification body.

4.19.8.2. Reports of Samples of Medical Device manufactured after corrective actions, both during factory and/or independent testing confirm compliance to Criteria requirements.

4.19.9 Suspension shall not exceed a period of six months. The Medical Device manufacturer's inability to resolve issues relating to suspension within this period shall lead to withdrawal of certification.

4.20 Withdrawal of Certificate

4.20.1 Certification body shall withdraw the certificate when:

4.20.1.1. Certified unit contravenes the terms and conditions of certification and provisions of ICMED Plus certification scheme or any of the reasons as stated in section 5.19.

4.20.1.2. Medical Device and/or device manufacturer are failing and not conforming to the requirements of the Certification Criteria repeatedly and the corrective actions taken are not ensuring compliance, or the proposed plan for corrective actions will take a considerable time beyond 6 months for implementation.

4.20.1.3. In cases where the certification has been under suspension for any of the reasons specified in section 5.19 for more than 6 months.

4.20.2 Certification body shall terminate the product certificate at the request of the certified unit, if the operation(s) in the certified unit premises can no longer be carried due to reasons of natural calamities such as flood, fire, earthquake etc., lockout declared by the management, or closure of business operations etc.

4.21 Changes Affecting Certification

4.21.1 When the certification scheme introduces new or revised requirements both in Certification criteria and Certification process requirements that affect the Medical Device manufacturer, the certification body shall ensure these changes are communicated to all applicants and the certified units. The certification body shall verify the implementation of the changes by its applicants and certified units and shall take actions required by the scheme.

4.21.2 The contractual agreement with the certified unit shall have clearly defined clause which shall make it mandatory for the certified unit to agree to implement the changes in his processes and product, necessitated by the changes in above requirements.

4.21.3 Following decision on, and publication of, the changed requirements, the certification body shall verify that each certified unit makes necessary adjustments within such time as, in the opinion of the certification body, is reasonable, unless the Certification Scheme owner itself has decided the timelines. The verification may involve steps like onsite re-evaluation, testing of samples in an independent laboratory, evaluation, review and decision and issuance of revised formal certification documentation to extend or reduce the scope of certification, etc. The

records shall provide justification for choice of activities chosen for the purpose verification of changes.

4.21.4 The manufacturer shall also be bound by the certification agreement to inform the certification body about changes initiated by it, including changes in process and product design, changes in technology of manufacturing etc., which have the potential to affect the Medical Device compliance to the certification criteria. Based on the nature of changes informed, the certification body shall decide the verification activities and all other process steps, as relevant for certification process.

4.22 Change of Location/Ownership/Name

4.22.1 The certified Medical Device manufacturer shall inform the CB about any new location of manufacturing. The manufacturing unit shall be subject to an onsite audit at the new site like an Initial audit of an applicant. This audit shall confirm that the manufacturing processes for the subject products are same (no significant changes affecting the safety and performance of the products) and have been validated to meet the product requirements (specifications/standards). The certification body shall verify that each manufacturing unit complies with the requirements and if satisfied the CB shall endorse the Certificate for the new location.

4.22.2 In the event of change of Ownership, the Medical Device manufacturer shall provide necessary documentary evidence of having informed the change to the Licensing authority and its acceptance by the Licensing authority. The new management of the Medical Device manufacturer shall submit its acceptance to the agreement for Certification with the CB and required payment of fees. The same process shall be followed as and when an existing applicant undergoes a change in management. Such changes shall not call for a visit to the production site.

4.22.3 In case of change of Name, the manufacturer shall inform the change in the name to the CB supported with documentary evidence including a copy of the manufacturing license issued by the Licensing authority, and if satisfied the CB shall endorse the Certificate in the new name.

4.23 Extension of Scope

4.23.1 The certified unit shall be required to make a formal application for the purpose of inclusion of additional Medical Device(s) in the scope of certification, on an application form, prescribed if any, to the certification body.

4.23.2 The process steps of receipt of application, information, application review, planning for evaluation, determination of competence of evaluators and others like for evaluation, review and decision-making functions shall be the same as that for initial evaluation. The evaluation time shall be estimated as per details provided at Section 4.3 above. Such scope extension evaluation can also be clubbed with the surveillance/recertification audits.

4.23.3 Extension of scope of certificate for inclusion of additional Medical Device under the same certificate shall be done after:

4.23.3.1. ascertaining that the certified organization has requisite resources required e. g. raw materials, process controls, manufacturing machinery, test facilities and technical skills for Medical Device under extension of scope, through an evaluation.

4.23.3.2. Verification if the specific additional Medical Device under extension of scope have

been manufactured in accordance with data supplied by the Medical Device manufacturer to the Licensing authority that formed the basis for their product approval, and

4.23.3.3. Conformity of samples of Medical Device, to requirements of the Certification Criteria when tested at manufacturing site and/or in an independent laboratory.

4.23.4 The extension of scope shall be clearly mentioned in the certificate document along with its date of inclusion for avoiding any misrepresentation or misinterpretation. Irrespective of the date of inclusion, the validity of the Certificate shall remain unchanged.

4.24 Fee

4.24.1 A fee to be charged to the organization for various activities (TD assessment/review, evaluation and testing activities for the products etc.) of the ICMED Plus product certification scheme, without any discrimination between units, geographical location, size of the unit.

4.24.2 The CBs fee structure shall be publicly accessible and also be provided on request.

4.24.3 CB shall notify and obtain consent to its fee structure from the Medical Device manufacturers prior to grant of certification. As and when the fee undergoes a change, the same shall be communicated to all including applicants and the Medical Device manufacturers certified under this scheme of certification for their acceptance.

4.25 Records

4.25.1 The certification body shall have a documented policy and documented procedure in respect of the retention of records to demonstrate that all certification process requirements have been effectively fulfilled (Requirements for the Certification Bodies).

4.26 Handling of Complaints Related to Certified Medical Device and/or Manufacturer

4.26.1 The certification body shall have a procedure to handle the complaints. If the complaint relates to a manufacturer and the certified Medical Device supplied by the manufacturer, depending on the device classification and seriousness of adverse event, the examination and evaluation of the complaints shall take into consideration the effectiveness and implementation of the manufacturer's certification system.

4.26.2 The process of establishing validity of the certified Medical Device, should generally, involve processes like conduct of additional surveillance activities–visit to manufacturer's premises for special evaluation, testing and evaluation of certified product, against which the complaint had been received, etc. The decisions on complaint shall then be based on the result of additional surveillance activities. Rest of the requirements shall be as per ICMED 13485 scheme.

4.27 Handling of Appeals

4.27.1 Appeal from the manufacturer with respect to certification of the medical devices shall be registered, and evaluated by CB as per its documented procedure. The process shall involve the receiving, validating, investigating, corrective actions and decision making of an appeal.

4.27.2 CB shall be responsible for all the investigations and decisions for all the appeals.

4.27.3 CB shall ensure that the personnel processing and investigating the appeals shall be independent and not be involved in the certification process of the manufacturer and their products.

4.27.4 The CB shall be responsible for the resolution (without any discriminatory action) of the appeal and provide the appellant the decision and a formal notice at the end of the process.

ANNEXURE A

Conformity Assessment for ICMED Plus - Device Certification

A.1 Scope

1.1 This annexure explains the elements of Conformity Assessment for ICMED Plus - Device Certification under the 'Indian Certification of Medical Devices' - ICMED Plus (hereinafter referred to as the Scheme) that shall be followed in order to evaluate a Medical Device and its manufacturer.

1.2 This annexure specifies requirements for conformity assessment of a medical device, for the purpose of its certification, by the manufacturer to demonstrate compliance with the Certification Criteria.

A.2 Objective

The annexure provides guidance on:

2.1 the evidence and procedures that shall be used to demonstrate that a medical device conforms to the 'General Safety and Performance Requirements' for Medical Device.

2.2 the conformity assessment elements that apply to each class of device such that the rigor increases with the risk presented by a particular medical device.

2.3 the manufacturer's written attestation that it has correctly applied the conformity assessment elements relevant to the classification of the device and,

2.4 the process by which CB shall confirm that such elements are properly applied by the manufacturer.

A.3 Quality Management System (QMS) and Conformity Assessment Procedures

3.1 The manufacturer shall implement, document, and maintain a QMS that ensures the medical devices it designs, manufactures, and supplies to the market are safe, perform as intended and comply with the relevant provisions of the regulations. The scope and complexity of the QMS are influenced by the range of different medical devices that are under QMS control, the processes employed, the size, and structure of the organization, and the specific regulatory requirements.

3.2 Processes required by the QMS but carried out on the manufacturer's behalf by third parties remain the responsibility of the manufacturer and are subject to control under the manufacturer's QMS. As part of the CB's conformity assessment process, it shall assess the adequacy of this control.

3.3 Conformity assessment of the manufacturer's QMS is influenced by the class of the medical device, as follows.

i. Manufacturers of **Class A** devices shall implement and maintain an effective QMS that complies with ICMED 13485 but has the option of excluding design and development controls from it.

ii. Manufacturers of **Class B** devices shall implement and maintain an effective QMS that complies with ICMED 13485 but has the option of excluding design and development controls from it.

iii. Manufacturers of **Class C and D** devices shall implement and maintain an effective QMS that includes design and development controls and complies with full ICMED 13485.

3.4 CB shall consider any relevant existing certification and, if not satisfied, may carry out an on-site audit of the manufacturer's facility. Criteria for requirement to do on-site audit

on manufacturer shall be included in the CB documented procedure. Criteria for acceptance of existing certification shall include ICMED 13485 certificate issued by a CB approved under the scheme for the same scope.

3.5 **Conformity Assessment Procedures (For class A, B, C, and D medical devices):**

3.5.1 **Conformity assessment based on a quality management system and assessment of the technical documentation (technical file)/evaluation.**

i. The manufacturer shall establish, document, and implement a quality management system as described in ICMED 13485 scheme level 3, and shall ensure the application and maintain its effectiveness throughout the life cycle of the devices concerned. The documentation shall include the QMS procedures and techniques for monitoring, verifying, validating, and controlling the design of the devices (where applicable) and the corresponding documentation as well as the data and records arising from those procedures and techniques (Refer Criteria for ICMED Plus, these shall include the strategy for regulatory compliance, general safety, and performance requirements, clinical evaluation (including post market clinical follow-up).

ii. The CB shall audit the quality management system to determine whether manufacturer meets the requirements referred in ICMED 13485, level 3, and any other standards related to quality management system and shall assess conformity with those standards.

iii. The procedure shall include an audit at the manufacturer's premises. In the case of class A, B, C and D devices, the quality management system assessment shall be accompanied by prior evaluation of technical documentation for devices selected on a representative basis, which includes, in particular, the novelty of the technology, similarities in design, technology, manufacturing, and sterilization methods, the intended use, and the results of any previous relevant assessments such as with regard to physical, chemical, biological or clinical properties, that have been carried out. The CB in question shall document its rationale for the samples taken.

iv. When the quality management system conforms to the requirements (ICMED 13485 certification) the CB shall issue a quality management system certificate.

v. The CB shall perform the evaluation of the technical documentation applicable to class A, B, C, and D devices and which are covered by the quality management system. The documentation shall include the design (where applicable), manufacture and performance of the device. It shall include the technical documentation as referred to in Criteria for ICMED 13485 Plus. The CB shall carry out further tests (request manufacturer to carry out Physical or Laboratory tests) as per plan for further evidence to ensure assessment of conformity with the requirements. The CB shall review the clinical evidence (where applicable) presented by the manufacturer in the clinical evaluation report and the related clinical evaluation that was conducted.

vi. The CB shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity. The CB shall verify that the clinical evidence and the clinical evaluation are adequate and shall verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements. The CB shall provide the manufacturer with a report on the technical documentation assessment, including a clinical evaluation assessment report.

3.5.2 **Conformity Assessment based on Type Examination**

i. Products can be considered to be of the same type when the knowledge of the requirements, characteristics, and technology related to one product is sufficient to understand the requirements, characteristics, and technology of another product.

ii. Type-examination is the procedure whereby a CB ascertains and certifies that a device, including its technical documentation and relevant life cycle processes a corresponding representative sample of the device production envisaged, fulfils the requirements.

iii. The manufacturer shall provide to the CB, the technical documentation (Refer ICMED Plus criteria), a representative sample of the device (type).

iv. The CB shall assess the adequacy of the tests (may further carry out physical and laboratory tests or requesting further evidence) to allow assessment of conformity with the relevant requirements and examine and assess the technical documentation for conformity with the requirements. It shall review the clinical evidence, relating to device, with respect to the clinical condition in which it is utilized.

3.5.3 **Conformity assessment based on Product Conformity Verification**

i. The conformity assessment based on product conformity verification is to ensure that devices conform to the type for which a type-examination certificate has been issued, and that they meet the requirements. The manufacturer may either apply production quality assurance or product verification.

ii. For production quality assurance manufacturer shall ensure that the quality management system approved for the manufacture of the devices concerned is implemented, shall carry out a final verification.

iii. Product verification shall be the procedure whereby after examination of every manufactured device, the manufacturer, by issuing a declaration of conformity shall be deemed to ensure and to declare that the devices meet the requirements.

iv. Verification by examination and testing of every product: Every device shall be examined individually and the appropriate physical or laboratory tests as defined in the relevant standard or standards or equivalent tests and assessments, shall be carried out in order to verify, where appropriate. The CB shall affix, or have affixed, its identification number to each approved device.

3.5.4 For Type-examinations process the CB shall have documented procedures, sufficient expertise for the type-examination of devices.

i. Examine and assess the technical documentation.
ii. Verify that the type has been manufactured in conformity with that documentation.
iii. Establish a test plan identifying all relevant and critical parameters which need to be tested (rationale for test parameters selected).
iv. To carry out the appropriate examinations and tests in order to verify that the solutions adopted by the manufacturer meet the general safety and performance requirements.
v. Agree with the applicant as to where the necessary tests will be performed. Test reports submitted by the manufacturer shall only be taken into account if they have been issued by NABL accredited test laboratory (competent and independent of the manufacturer).

3.5.5 For verification by examination the CB shall carry out activities for every product for relevant and critical parameters for class B and C devices.

A.4 System for Post-Marketing Surveillance

4.1 Prior to placing the product on the market, the manufacturer shall establish, as part of its QMS, a process to assess the continued conformity of the device to 'General safety and Performance Requirements' of Medical Devices' and the applicable standards/ specifications through the post-marketing phase. This process shall include complaint handling, post-market vigilance reporting, field corrective actions, recalls and any subsequent corrective & preventive actions.

4.2 For Class A, B, C and D medical devices, the CB shall ensure that a post-marketing surveillance process is established, maintained, and implemented.

4.3 Furthermore, the scheme owner may require manufacturers to perform a specific post-marketing study of a particular type of device and report the outcome to the Scheme owner.

4.4 The scheme owner shall monitor any post-marketing study and consider whether any additional action is required after analyzing the outcome.

A.5 Technical Documentation (TD)

5.1 The TD, if applicable, the summary thereof to be drawn up by the manufacturer shall be presented in a clear, organized, and unambiguous manner and shall include in particular the elements listed below and those listed in the criteria document.

5.2 Manufacturers of all classes of device shall demonstrate conformity of the device to 'General Safety and Performance Requirements' of medical devices and the applicable standards of medical devices through the preparation and holding of technical documentation (refer Annex B) that shows how each medical device was developed, designed and manufactured together with the descriptions and explanations necessary to understand the manufacturer's determination with respect to such conformity. This technical documentation shall be updated as necessary to reflect the current status, specification and configuration of the device.

5.3 The manufacturer shall establish a technical documentation detailing:

i. The safety critical components used in the device.
ii. The risk assessment carried out as per ISO 14971.
iii. Usability engineering exercise carried out as per IEC 62366, if applicable.
iv. Internal compliance mechanism applied to regular production.

5.4 The TD reflects the status of the medical device at a particular moment in time (e. g. at the moment of initial submission or when requested by the Scheme for post-marketing purposes) and is prepared in order to meet regulatory and/or standard requirements. The extent of evidence in the TD shall increase with the class of the medical device, its complexity, and the extent to which it incorporates new technology.

5.5 When the TD is submitted to CB, it shall incorporate an attestation that the contents are truthful and accurate, and indicate the name, position and signature of the responsible person who has been authorized to submit it on the manufacturer's behalf.

5.6 The CB determines the adequacy of the documented evidence in support of the manufacturer's attestation of conformity to the 'General Safety and Performance Requirements', and other applicable standard and regulatory requirements, through a review of the TD. The depth and timing of the review by the CB shall be influenced by the class of the medical device, its complexity, and the extent to which it incorporates new technology.

A.6 Declaration of Conformity

6.1 The manufacturer shall attest that its medical device complies fully with essential principles of safety and performance, all standard / technical and regulatory requirements and submit a written 'Declaration of Conformity', as per ISO/IEC 17050-1: Supplier's declaration of conformity.

6.2 The declaration shall contain the following information:

i. An attestation that each device that is subject to the declaration complies with the 'Essential Principles of Safety and Performance of Medical Devices' and applicable Safety/ Performance/standard (including any common specification) and the applicable requirements of Labelling and Instructions for Use for Medical Devices.
ii. Information sufficient to identify the device/s (Name, registered trade name or trade mark) to which the Declaration of Conformity applies.
iii. The risk classification of the device/s and the device name, code, and category as per IAF ID 13: 2017.
iv. The date on which the Declaration of Conformity is issued.
v. The name and registered address of the device manufacturer.
vi. The name, position, and signature of the responsible person who has been authorized to complete the Declaration of Conformity upon the manufacturer's behalf.

6.3 The CB shall review and confirm the adequacy of the Declaration of Conformity and, if required, examine the supporting documents or other evidence. The CB shall ensure that the Declaration of Conformity has been signed by a person from the top management of the manufacturer or a person authorized to sign on his/her behalf.

A.7 Conformity Assessment System

7.1 The four tables below summarize conformity assessment elements that apply to Class A, B, C and D devices.

7.2 The scheme / CB may require more detailed initial submission and/or require a more rigorous audit and/or the provision of more clinical evidence than would apply normally to a device of that class when:

i. the device incorporates novel and innovative technology.
ii. an existing compliant device is being used for a new intended use.
iii. the device type is new to the manufacturer.
iv. the device type tends to be associated with an excessive number of adverse events.
v. the device incorporates innovative or potentially hazardous materials.
vi. the device type raises specific public health concerns.

7.3 A non-exhaustive and as a minimum checklist for Medical Device Conformity Assessment for use by a CB is given in Annex 'A'.

CLASS 'A' DEVICE

	Conformity Assessment Element	Manufacturer Responsibility	Evaluation Mechanism to be employed by the CB	Section
Conformity assessment of the QMS	Quality Management System	Establish and maintain a full QMS as per ICMED 13485 Or a QMS as per ICMED 13485 without design and development controls.	Verify the certification document (if submitted) if it is a certificate (ICMD 13485) issued by the CB under NABCB accreditation and covers the scope of the medical device under evaluation. Accept the same. Otherwise conduct a complete QMS audit (as per ICMED 13485) through visit to the manufacturer's premises.	AIII
	Post-market Surveillance	Establish and maintain an adverse event reporting procedure	May audit post-market surveillance procedures to investigate specific concerns.	AIV
Conformity assessment of device safety & performance	Technical Documentation (TD)	Establish and keep up to date, technical documentation, and prepare and submit TD at the request of a CB.	Initial submission of Technical Documentation (TD) normally not requested. Audit and verify implementation in onsite evaluations (Initial/ surveillance and recertification).	AV
	Declaration of Conformity	Prepare, sign, and maintain. Present upon request by the CB	Submission normally not requested. Audit and verify implementation in onsite evaluations (Initial/ surveillance and recertification).	AVI

CLASS 'B, C & D' DEVICEs

	Conformity Assessment Element	Manufacturer Responsibility	Evaluation Mechanism to be employed by the CB	Section
Conformity assessment of the QMS	Quality Management System	Establish and maintain a full QMS as per ICMED 13485	Verify the certification document (if submitted). If it is a certificate (ICMD 13485) issued by the CB under NABCB accreditation and covers the scope of the medical device under evaluation. Accept the same. Otherwise conduct a full QMS audit.	AIII
	Post-market	Establish and maintain	Audit the client's system	AIV

	Surveillance	a post-marketing surveillance process	for Post market surveillance process, as described in the TD for adequacy. Subsequently verify implementation during onsite evaluation.	
Conformity assessment of device safety & performance	Technical Documentation	Establish and keep up to date TD and submit TD for review.	Undertake an in-depth review of the TD sufficient to determine conformity to Standards (certification criteria).	AV
	Declaration of Conformity	Prepare, sign, and maintain.	Review and verify compliance with requirements.	AVI

ANNEXURE A-1

Determination of Man-Days for QMS Certification

1. The certifications document (ISO 13485) of manufacturer issued by a CB which is NABCB accredited or accredited by an IAF member shall be accepted.
2. QMS audit related to Scheme criteria shall be carried out for additional one day to cover the additional requirements of ICMED 13485.
3. The certification document (ICMED 13485) of manufacturer issued by NABCB accredited CB and/or QCI approved CB, shall be accepted and no further QMS audit will be required in such cases.
4. In either case, manufacturer shall be evaluated offsite for ICMED 13485 Plus requirements (Technical documentation), and also onsite for the ICMED 13485 Plus requirements (Medical device testing etc.).

ANNEXURE A-2

Determination of Man-Days for Evaluation of Technical Documentation

S. No.	Medical Device	Base Duration	Additional Time for Sterile Devices	Additional Time per Variant	Additional Time for Accessories, up to 5 Nos.	Additional Time, if any	Remarks
1	A	1	0.5	0.5	0.5	Based on Additional Standards Applicable	For Certified Accessories
2	B	2	0.5	0.5	0.5	"	"
3	C non-implantable	3	0.5	0.5	0.5	"	"
4	C Implantable	5	0.5	0.5	0.5	"	"
5	D	6	0.5	0.5	0.5	"	"
6	For products with medicinal or other substances: Additional time to be considered.						
7	Additional time for repeat reviews for clarifications of initial review discrepancies.						

Note 1: CB shall develop procedures for man-days (time duration) required for the review and conformity assessment activities related to Product Technical documentation of the client's medical devices and it should consider the following:

i. number of products,
ii. whether product design & development process is included,
iii. previous & similar generation of products,
iv. families of products,
v. complexities & risk classification of products (Class A, B, C & D, and/or combination

medical devices), and

vi. the clinical evaluation reports and/or preclinical & clinical data files.

Note 2: Review of Technical Documentation (TD):

i. The review of the TD is generally performed offsite by the CB before the site visit for QMS audit (ICMED 13485) of the manufacturer.
ii. All product certification related activities (on site testing etc.) are performed during the QMS audit (Stage 2) of the manufacturer.
iii. In case the manufacturer is already certified for ICMED 13485 by the CB or other CB accredited by NABCB, the product certification related activities can be clubbed with the ICMED 13485 surveillance or recertification audit.
iv. In case of the ICMED 13485 certified manufacturer requests faster product certification, additional visit (if surveillance/ recertification not due for some time) to the site shall be performed to complete the product certification related activities. CB shall have a documented procedure to perform such visits for the man day needed.

ANNEXURE B

List of Documents to be submitted to Certification body Along with Application for ICMED 13485 Plus Certification (*List is Indicative Only*)

1. Documents confirming the Indian legal status of the manufacturer.
2. Documents relating to authorizations and permissions required as per regulations, if applicable.
3. Copy of registration of the manufacturing site or establishment or plant.
4. Documentation on Suspension/ cancellation/ withdrawal of any relevant approvals/certifications under any Regulations by Regulatory Body or otherwise.
5. Copy of registration of the manufacturing site or establishment or plant.
6. Quality Manual, addressing all requirements as per ICMED 13485 requirements.
7. Standard Operating Procedures related to process.
8. Technical documentation (other than *in vitro* medical devices)
   - 8.1. Device description and specifications, including variants and accessories.
   - 8.2. Reference to previous and similar generations of the device.
   - 8.3. Information to be supplied by the manufacturer (Label, unit pack, instruction for use etc.)
   - 8.4. Design & Manufacturing information (design stages applied to device, specifications, manufacturing processes etc.).
   - 8.5. Quality Plan – Addressing controls applied & verification frequency of inspection of incoming material, in-process controls and final Product(s) testing etc.
   - 8.6. General safety and performance requirements.
   - 8.7. Benefit-risk analysis and risk management.
   - 8.8. Product verification and validation.
   - 8.9. Pre-clinical and clinical data.
   - 8.10. Post-marketing surveillance plan.
   - 8.11. Additional information required in specific cases: Where a device incorporates, as an integral part, a substance medicinal substance, devices manufactured utilizing tissues or cells of human or animal origin, devices containing substances that are absorbed in human body, devices containing endocrine disrupting substances, devices placed in market in sterile condition, devices with measuring function, if the device is to be connected to another device.

9. Technical Documentation (*in vitro* medical devices)

   - 9.1. Device description and specification (including variants and accessories), its functions.
   - 9.2. Product or trade name, product code, catalogue number.
   - 9.3. Risk classification and justification for the classification.
   - 9.4. intended purpose and intended users.
   - 9.5. Description of any software to be used with the device.
   - 9.6. An overview of the previous generation of the device produced by the manufacturer

or overview of the similar devices on market.

9.7. A complete set of labels on the device and on its packaging, unit packing, Instructions for use.

9.8. Design information to allow design stages applied to the device, description of the ingredients of device (antibodies, antigen, enzymes, etc.). For instruments a description of the subsystems, analytical technology, operating principles/control mechanism.

9.9. Manufacturing information.

9.10. General safety and performance information on device, harmonized or other solutions applied.

9.11. Benefit-risk analysis and risk management.

9.12. Product verification and validation.

9.13. Analytical performance of device, specimen type, accuracy (trueness, precision, and sensitivity).

9.14. Analytical specificity.

9.15. Measuring range of assay.

9.16. Analytical performance report.

9.17. Clinical performance and clinical evidence.

9.18. Stability and shelf life.

9.19. Software verification and validation.

9.20. Technical documentation on post marketing surveillance.

9.21. Additional information required in specific cases: Devices utilizing tissues or cells of human, animal origin or microbiological origins, devices placed in market in sterile condition (information on packaging, sterilization etc.), devices with measuring function, if the device is to be connected to another device.