UL India Medical management system – ICMED Registration Program Requirements (Scheme)

At of the date of issuance of this document, UL India Pvt. Ltd. is accredited by the following Accreditation Bodies for its Medical Quality Management System Registration programs. This information may be used by registered organizations to fulfill supplier qualification of UL India Pvt. Ltd.

National Accreditation Board for Certification Bodies ISO 13485 and ICMED 13485 https://nabcb.qci.org.in/	NABCB **QM 070**

TABLE OF CONTENTS

1.0 Purpose

According to the ICMED accreditation requirements the CB has to publish the information describing the process of certification hence we are uploading the ICEMD program requirements document in UL India website.

2.0 Scope

2.1 This document describes the certification process to be followed for the Indian Certification for Medical Devices (ICMED) Scheme in processing applications received from medical devices manufacturers for certification as per criteria specified under the Scheme.

2.2 Type of Certification: **ICMED 13485** which is as per the requirements of ISO 13485 read with the additional requirements prescribed under the Scheme in ICMED 13485

2.3 The certification will be granted for each manufacturing facility/premises after due verification of compliance to the prescribed criteria.

2.4 Transfer certification - To define the process for transferring companies from their current Registrar to UL to obtaining ICMED registration.

NOTE: Plant, Unit, Manufacturing facility, Medical device manufacturing facility, Premises, Manufacturer are interchangeable and all these terms refer to an individual medical device manufacturing facility.

3.0 Applicable Documents

- ISO/ICE 17021-1: 2015 Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements
- ISO 19011:2018 Guidelines for auditing management systems
- ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes
- ICMED 13485 Issue 2 Indian Certification of Medical Devices ICMED (Scheme) - Technical Criteria for Certification of Medical Devices– ICMED 13485
- UL General Services Agreement and other certification contracts between UL and the client

4.0 Terms and Definitions

4.1 *Certificate of Registration* - A certificate recognizing the scope of registration that the quality management system, implemented by the organization having been assessed by UL, is in accordance with a specific management system standard and UL's Medical Quality Management System Registration Program requirements.

4.2 *Surveillance Audit* - An Audit performed by UL to determine an organization's continued compliance with the applicable standard and program requirements subsequent to facility registration. These Audits are typically scheduled 2 months in advance with agendas provided at least two (2) weeks prior to the visit date. UL also reserves the right to perform unannounced surveillance Audits.

4.3 *Registration* - A decision by UL that a facility's quality management system meets the requirements of a specific management system standard and UL's Medical Quality Management System Registration Program requirements. A certificate of registration is issued to the organization to indicate acceptance into the UL Medical Quality Management System Registration Program. An organization that has been granted registration by UL is a legal entity, an incorporated or unincorporated body that has been issued a certificate of registration. This organization subscribed to UL's Quality Management System Registration Program and is therefore responsible to comply with UL requirements and for UL invoices associated with the registration and associated Audits.

4.4 *Quality Management Standards* - The standards for quality systems published by the International Organization for Standardization. The certificate of registration may also denote conformance with equivalent series standards such as European Norm, American National Standards Institute and Canadian Standards Association standards.

4.5 *Management Representative* - A member of the organization’s management who represents the evaluated facility and is responsible for the facility's quality management system as it pertains to the relevant products and/or services covered in the organization's scope of registration.

4.6 *Organization* - The party that is responsible for the product, process or service and is able to ensure that quality assurance is exercised. This definition may apply to manufacturers, distributors, importers, assemblers, service organizations, etc.

4.7 *Quality Management System (QMS)* - The organizational structure, responsibilities, procedures, processes and resources for implementing a quality management system.

4.8 *Recertification Audit* - The evaluation performed by UL to confirm compliance of the organization's quality management system with the requirements of the applicable QMS standard(s) at the end of the organization's registration cycle.

4.9 *Registration Audit* - The evaluation performed by UL to determine the compliance of the organization's quality management system with the requirements of the applicable QMS standard(s).

4.10 *Scope of Registration* - A synoptic description outlining the relevant process, product and/or service areas that are provided under the organization's registered quality system. Proposed scope of registration is agreed on prior to the Registration Audit.

4.11 *UL. Online Certification Directory* - A listing of the facilities that have been issued certificates of registration to at least one of the QMS standards by UL. Descriptions shall define a facility's name, address, , facility scope of registration and the registration issue date. This is available electronically on UL's web site at www.ul.com.

4.12 *UL Registered Firm Mark* - The UL mark which is used by registered organizations in accordance with UL's registration agreements and Appendix A of these requirements to publicize their facility registration.

5.0 Application for Certification

5.1 Application Form

5.1.1 The manufacturer will apply in the application from prescribed by UL

5.1.2 The applicant will clearly indicate the type of certification it is applying for.

5.1.3 The applicant will provide information about each manufacturing facility to be certified.

5.1.4 The applicant will clearly indicate if any of the activities covered under the criteria for certification are being carried out at any premises other than the main premises. This is to plan and facilitate covering the applicable criteria under the same audit. For example Design or R &D or Testing or any outsourced processes

5.1.5 The applicant will specify/list all the activities to be audited and certified. It will mention whether all the activities are covered at single or multiple locations/sites. For multiple sites, overlapping activities, if any will also be mentioned.

5.1.6 Irrespective of the number of facilities of a manufacturer, to be covered

under certification, each and every manufacturing facility will be audited for compliance to the Criteria as applicable.

5.1.7 The applicant will provide the list of medical devices to be covered under the scope of certification.

5.2 List of Documents

The applicant will submit all necessary documents (as per applied criteria) to UL for Document Review

5.3 Information for Applicants

The information describing certification processes for granting, maintaining, extending, renewing, reducing, suspending or withdrawing certification, and geographical areas in which it operates will be publicly available on UL website. The information will include:

a) An Application form;
b) Reference to the Certification Criteria,
c) Procedure for obtaining certification under the ICMED Scheme, a detailed description of the initial and continuing certification activity, including the application, initial evaluation, periodic surveillance, evaluations, and the process for granting, maintaining, reducing, extending, suspending, withdrawing certification and re-certification .
d) List of documents required to be submitted along with the application.
e) Information about the fees for application, initial certification and continuing certification and policy for the fee
f) Documents describing the rights and duties of applicants/ certified clients, and
g) Information on procedures for handling complaints, feedbacks and appeals.

5.4 Registration of Application

5.4.1 UL will respond to all enquiries received from prospective applicant organizations for certification with complete information for facilitating registration of application, within 7 working days of receipt of the query.

5.4.2 The applicant will declare (in the form of an undertaking in application) whether it has been an applicant / certified under this Scheme with or by any other certification body, and if yes then will provide the previous evaluation reports to the new certification body. UL may verify the information provided by contacting the earlier certification body.

5.4.3 The prospective applicant for Medical device manufacturer will 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 under any Regulations or otherwise. Such declaration will be a part of the undertaking mentioned in 5.4.3 above.

5.4.4 Certification is granted only against the current relevant certification criteria. UL will review all applications for the above and ensure the same.

5.4.5 All applications for certification will be reviewed by UL for adequacy and deficiencies observed, if any, will be informed to applicant within 7 working days of receipt of application. Review of applications will be done by a competent person. Records of review will be maintained.

5.4.6 Only complete applications supported with all documents sought will be accepted and registered in order of receipt with a unique identification number, acknowledged and records maintained. Registration will be done within 7 days of receipt of application or information in response to the deficiencies communicated as per 1.4.6 above. In case the applicant discloses any proceedings, suspensions etc as per 1.4.3 above, the applicant will not be entertained for a period of one year from the date of conviction, suspension, withdrawal, deregistration etc.

5.4.7 If the certification of any level under the Scheme has been suspended / cancelled by any approved CB, the application from such a manufacturer will not be accepted till suspension is revoked by the concerned CB or for one year from the date cancellation of certification.

5.4.8 This will be applicable only for the manufacturing facility whose certification has been suspended/cancelled. However, this will not be applicable to other manufacturing facilities under same legal entity.

5.4.9 The certifications (ISO 13485) by CBs other than IAF MLA signatory accredited CBs will not be accepted. Hence, the ICMED scheme audit will cover the audit to certify ISO 13485 accordingly and two separate certificates will be issued

5.4.10 Where manufacturing facility is certified for ISO 13485 by Certification Bodies accredited by NABCB, audit related to scheme criteria will be carried out covering additional requirements of the scheme only for ICMED 13485

5.4.11 Where the certification (ISO 13485) is carried out by IAF MLA signatory accredited CBs other than NABCB, full audit as per scheme criteria requirements will be carried out .

5.4.12 If ISO 13485 certification of the applicant is under suspension, application for certification will not be entertained till the suspension of ISO 13485 certification is

revoked. In case ISO 13485 certification of a manufacturing facility is cancelled by any CB, the application certification Under the Scheme may be carried out considering manufacturing facility as new client.

5.4.13 The antecedents of the applicants will be checked in relation to the Scheme. Applications from manufacturers who have earlier either misused the Certification, or whose earlier certificate was cancelled because of violation of terms & conditions / misuse of certification or have been implicated / convicted by the court in relation to their manufacturing activities, will not be entertained for a period of one year of conviction / strictures by the court / cancellation of the certificate by any CB.

5.4.14 Applications from manufacturer found to be misusing the certification while their application is being processed for grant of certification, will not be processed any further, and rejected after a due notice of 15 days. Fresh applications from them will be treated as per clause 1.4.13 given above.

5.4.15 Requests for grant of certification from previous applicants as per 1.4.16 (a), (b) &(c) / expired certificates will be processed like fresh applications and the entire procedure for grant of certification will be adhered to subject to clauses 1.4.8 to 1.4.12 above.

5.4.16 An application will be rejected or closed under the following conditions;

- if Initial Evaluation is not carried out within 3 months of registration of application
- if the entire certification process is not completed within 6 months of registration of application
- if the applicant shows no progress towards completion of corrective actions within 3 months of Initial Evaluation and 6 months of Registration of application.
- Misuse of certification under the Scheme
- Evidence of any malpractice
- Voluntary withdrawal of application.

5.4.17 The application fee, if charged will be nonrefundable.

6. Audit Programme

6.1 Audit Programme

Considering the type of the certification sought, the following program will be followed:

Certification activity	ICMED 13485
Certification Audit – Stage 1	√
Certification Audit – Stage 2	√
Surveillance –"Once in a year", Second surveillance audit will be a unannounced audit which will be carried out within period of 9 to 12 months from previous surveillance audit."	√

For ICMED 13485 the audit cycle will include

- Initial certification audit in two stages (Stage 1 and Stage 2) as per ISO 17021-1:2015 ; and
- Recertification audits (generally 3 months before the end of 3 year validity)

6.2 Sampling of manufacturing facility to be Audited

All manufacturing and design facilities to be audited during all certification, surveillance and recertification audits.

6.3 Audit man-days

6.3.1 The man-days required to conduct an effective audit will be calculated in accordance with the following Table:

Audit Man-days
Bifurcation of Stage – I (20%) and Stage - II (80%)

Certification activity	ICMED 13485
Certification Audit – Stage 1	√
Certification Audit – Stage 2	√
Surveillance –"Once in a year", Second surveillance audit will be a unannounced audit which will be carried out within period of 9 to 12 months from previous surveillance audit."	√

6.3.2 Time duration will be calculated for each manufacturing facility and each manufacturing facility will be individually audited

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

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

7 Preliminary information to be provided to UL

7.1 Preliminary information to be provided to UL

7.1.1 UL will inform client regarding documentation to be provided by manufacturing facility for "Document review" in compliance to scheme criteria requirements as applicable

7.1.2 Before starting the application review, the applicant will provide UL with the documentation in compliance to ICMED 13485 requirements, as applicable.

7.1.3 Apart from information regarding the equipment and facilities of manufacturing facility particularly sterilization process, the applicant will provide information regarding the plan and frequency of controls carried out on incoming material, production facilities and testing equipment in order to allow auditors to have a preliminary overview of the manufacturing facility.

7.1.4 The documentation to be provided will include the following:

a) Quality Manual – Addressing all the requirements as per criteria document
b) Procedures – (Procedures related to process and general area of operation such as purchase, H.R. etc.)
c) Quality Plan – Addressing controls applied & verification frequency of inspection of Incoming material, Process controls and final Product(s) etc.
d) Standard operation procedures/ Work instructions
e) Form and Formats

7.2 Audit Team

UL will appoint an Audit Team having the necessary competences ~~and skills~~ required to conduct the audit.

Audit Type	Audit Team composition
Certification Audit	Auditor + Technical Expert (if Auditor is not qualified for medical device sector)
Surveillance	same as above

7.3 Audit Plan

7.3.1 UL will ensure that the Audit is conducted during working days in which all manufacturing and support processes are functional.

7.3.2 No audit will be planned in case the manufacturing facility is non-operational

7.3.3 The Auditors, if more than one, may conduct part of the audit in parallel being focused on specific processes/ areas.

7.3.4 All the activities as included in the scope of certification of manufacturing facility such as design, manufacture, construction, marketing, installation, servicing or supply of the medical device etc. will be audited irrespective of location.

7.3.5 The audit of the controlling/ head office will be planned in case it is catering to multiple manufacturing facilities to verify all the functions of its activities.

8. Certification Audit

8.1 Stage 1 Audit

The stage 1 audit is performed to:

- Audit the client's management system documentation;
- Evaluate the client's location and specific conditions and to undertake discussions with the client's personnel to determine the preparedness for the stage 2 audit;
- Review the client's status and understanding regarding requirements of the standard, in particular with respect to the identification of key performance or significant aspects, processes, objectives and operation of the management system including scheme requirements;
- Collect necessary information regarding the scope of the management system, processes and location(s) of the client, and related statutory and regulatory aspects and compliance (e.g. quality, environmental, legal aspects of the client's operation, associated risks, etc.);

- Review the allocation of resources for stage 2 audit and agree with the client on the details of the stage 2 audit;
- Provide a focus for planning the stage 2 audit by gaining a sufficient understanding of the client's management system and site operations in the context of possible significant aspects;
- Evaluate if the internal audits and management review are being planned and performed, and that the level of implementation of the management system substantiates that the client is ready for the stage 2 audit.
- Auditors will identify personal protective equipment which may be reasonably required during while auditing processes in stage – 2 audit and report in stage – 1 audit and ensure availability of the required personnel protective equipment during Stage – 2 audit.
- If manufacturing facility operating in shifts, Justification will be recorded if shifts are not to be audited

8.1.1 The Stage – I audit will be carried out by a competent audit team on site to judge the adequacy of the system to meet requirements of applicable and ICMED 13485 criteria. It will result in a formal report

8.1.2 The stage 1 audit will be carried out at the client's premises in order to achieve the objectives

8.2 Stage 2 Audit

8.2.1 The Objectives of stage 2 audit will be to verify compliance to the applicable certification criteria, regulatory requirements, verification of documents and records, and interviews with personnel involved in various relevant activities. The stage 2 audit will be conducted on site.

8.2.2 Competence of people at manufacturing facility will be audited to verify the effective knowledge QA/ QC and of internal procedures, applicable standards related to medical device being produced. The competency of the personnel will be as per applicable regulation. The requirement is as follows:

"The manufacture & Quality Assurance will be conducted under the active direction and personal supervision of competent technical staff consisting of at least one person each for manufacturing & Quality Assurance who is a whole time employee and who is

- a Graduate in Engineering or Pharmacy from a University recognized

by the Central Government for such purposes and has had at least eighteen month practical experience in the manufacturing or Quality Assurance of devices after his graduation; or

- a Graduate in Science, from a University recognized by the Central Government for such purposes and has had at least three years practical experience in the manufacturing or Quality Assurance of devices after his graduation; or
- a Diploma in Engineering or Pharmacy from a Board or Institute recognized by the Central Government or the State Government, as the case may be, for such purposes and has had at least four years practical experience in the manufacturing or Quality Assurance of devices after his diploma; or
- having a foreign qualification, the quality and content of training of which are comparable with those specified in clause(i), clause (ii) and clause (iii) above and is permitted to work as competent technical staff. “

8.2.3 Safety during audits

8.2.3.1 The Audit at medical device manufacturing facility involves risks linked to work environment. The responsibility for risk analysis and the identification of the most suitable means of protection is will be that of the manufacturer.

8.2.3.2 Auditors must have personal protective equipment which may be reasonably required to while auditing different manufacturing processes of manufacturing facility particularly sterilization.

8.3 Non conformities

8.3.1 Any non-conformities observed during audit, with respect to the certification criteria will be informed in writing to the applicant for taking necessary action. The non-conformities will be classified as Major or Minor depending on their severity.

a) Major Non conformity – A non-conformity that affects the capability of the management system to achieve the intended results. A number of minor NCs on the same aspect will be clubbed together and raised as single major NC.

b) Minor Non conformity – All other gaps and non-conformities will be classified as Minor. These will generally be related to other implementation issues which do not directly affect the capability of the management system to achieve the intended results.

8.3.2 In case of major and minor NCs the organization will carry out root cause analysis and inform the same along with correction and corrective actions, within a period of one month or 3 months respectively. All non-conformities are required to be closed before initial certification through verification of adequacy of the correction and corrective actions. All Major non-conformities, will invariably require a follow-up audit.

8.4 Audit Report

8.4.1 UL will send the Audit Report within 7 working days from the date of the completion of the audit to the client.

8.4.2 The audit reports for stage 1 and stage 2 will clearly provide evidence and conclusions about the fulfilment of the audit objectives as described above and will contain sufficient detailed information regarding conformity with all the relevant certification requirements, including the Certification Criteria. The Audit report will have the following as minimum:

a) Scope of the Certification,
b) Name and address of manufacturing facility (ies) audited
c) Name(s) of auditor/members of the team
d) Date & time of audit
e) Audit Criteria
f) Structure of the audited manufacturing facility
g) Report on auditing including that for all “Additional Requirements” with evidence of compliance
h) Nonconformities, if any
i) Processes excluded by the Scope of the certification, if any,

NOTE: ISO 17022 may be referred to for further guidance on Audit reporting

9. Certification Decisions

9.1 Certification decision will be the sole responsibility of UL and the decision will be taken by its internal person(s) competent for the job provided they have not been involved in the process of audit of the organization. Impartiality and absence of conflict of interest will be ensured before entrusting the task of certification decision making

9.2 Conditions for granting a certificate:

UL will grant the certification when all the following conditions are met with:

a) The audit report with suitable recommendation is available
b) All NCs raised have been closed.
c) There are no other issues impacting grant of certification

There will be no conditional grant of certification.

10. Certificate

10.1 The manufacturer may achieve one of the following certificates**:**

Certificate	**Object**	**Extension**	**Certificate Number**
Single Manufacturing Facility	All the processes carried out	Single manufacturing facility	One certificate number
Multi-Site	Group of manufacturing facilities sharing common facilities or processes	Group of Manufacturing facilities	One number (the certificate will have an annexure with the list of certified Manufacturing facilities)
Company	Entire company	All manufacturing facilities	One number per company (the certificate will have an annexure with the list of certified manufacturing facilities)

10.2 **Certification Documentation** - The certificate will include the following information:

a) Certificate number
b) Certification scheme name
c) Reference to certification criteria
d) Manufacturer's name (that of the legal entity) with all locations in the schedule
e) Certified Manufacturing facility address
f) Scope of certification
g) Scheme logo
h) logo of UL
i) Accreditation number with logo
j) Date of certification
k) Expiry date
l) Signature of the authorized representative

In case of multisite company certification, Annex to the certificate the list of the certified manufacturing facilities. The temporary sites will not be included in the list.

10.3 **Validity**

The certificate will be valid for 3 years from the date of issue.

11. Surveillance audits

11.1 Surveillance audits, announced and unannounced will be carried out on site at a frequency mentioned in clause 6.1, by a competent audit as as per clause 7.2 above. The audit man-days for surveillance audits will be as defined in clause 6.3

11.2 Non conformities observed during surveillance audit will be categorized as major and minor as defined in clause 8.3.1

11.3 Second surveillance audit is unannounced audit. In case for the organizations of having registration for both ISO 13485 and ICMED 13485, the second surveillance audit for ISO 13485 will be announced and the additional requirements for ICMED 13485 will be covered in an separate unannounced audit between 9 to 12 months from the previous surveillance audit (i.e. first surveillance audit).

12. Suspension

12.1 UL will issue instructions to the certified organization for suspension of

certification when

a) The major NCs issued are not closed in timelines prescribed
b) Repeated major NCs are raised in consecutive surveillance assessments
c) There is failure to organize a surveillance audit within the specified time period
d) There is nonpayment of outstanding dues
e) Any major changes have taken place in the legal status, ownership, name etc without prior information to UL
f) Any willful misuse of the logo of the Scheme is detected
g) Any willful false declaration in the application form or otherwise is detected
h) Excessive or serious complaints against the certified organization management system are received and are found to be valid
i) the certified organization voluntarily requests a suspension. Such request must be submitted in writing to UL along with the reasons. UL may decide to accept the request but may not allow the client to revoke suspension on its own.

12.2 UL will issue due notice of at least one week for suspension of certification to the certified organization.

12.3 When certification is suspended, UL will require that, during the period of suspension, the certified organization makes no misleading claims.

12.4 UL will revoke suspension only when Corrective actions have been taken and verified by UL.

13. Renewal of certification

13.1 The certification will be renewed at the expiry of 3 years validity period. However the renewal process and the renewal of certification decision will be taken on or before the certificate expiration date. In order to achieve the same UL will send the Renewal notice to the certified units at least four months prior to expiry of certificate validity period. However, provision given in Clause 9.6.3.2.4 and 9.6.3.2.5 of ISO 17021-1: 2015 will also apply as below:

- If the recertification audit has not completed or unable to verify the implementation of corrections and corrective actions for any major nonconformity prior to the expiry date of the certification, then recertification will not be recommended and the validity of the certification will not be extended. The client will be informed and the consequences will be explained.
- Following expiration of certification, we can restore certification within 6

months provided that the outstanding recertification activities are completed, otherwise at least a stage 2 will be conducted. The effective date on the certificate will be on or after the recertification decision and the expiry date will be based on prior certification cycle.

13.2 The certified organization will apply for renewal in the prescribed format along with fee, if any prescribed by UL at least 3 months before expiry of the certification.

13.3 The onsite surveillance audit conducted towards the end of third year and before the expiration of the certificate will be considered as the recertification audit (refer clause 2.3). The objectives of this audit will be a combination of stage 2 and surveillance audits, unless there has been any changes in product and process requirements, which would then also require assessment of the organization's revised processes, controls and systems.

13.4 UL will review the performance of the certified unit who has sought renewal of the Certificate, with respect to compliance to certification criteria during the entire certification cycle, prior to a decision on the renewal of the certificate. The review will essentially be based on the following:

- Surveillance and recertification audit reports for the audits carried out during the certification cycle. The NCs raised and the satisfactory resolution of the issues raised and their effectiveness.
- Any suspension of certificate during the previous validity period;
- Corrective actions taken
- Complaints if any received
- Adverse information from stakeholders and regulators, if any.

13.5 The review will be conducted by competent person (s) designated for the job.

13.6 The decision for renewal of certificate will be taken by the competent personnel authorised for the same, based on the satisfactory performance of the certified organization.

13.7 UL will not renew certification with conditions for compliance to be verified subsequently. There will be no conditional renewal of certification.

13.8 When performance of the certified unit is not satisfactory, UL will withhold the renewal of the certificate 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 certification expiry date.

13.9 The corrective actions will be verified generally on site unless UL can verify the same off site prior to considering for renewal of certificate. The justification for off site review will be recorded.

13.10 In case the manufacturing unit does not complete satisfactorily actions within three months, the certificate will stand expired from the date of expiry of previous

validity.

13.11 When a certificate is not renewed, it will expire at the end of validity period.

14. Withdrawal

14.1 Certification body will withdraw the certificate when

a) Certified organization contravenes the terms and conditions of certification and provisions of the ICMED scheme

b) The certified organization is not conforming to the requirements of the Certification Criteria and the corrective actions taken are not ensuring compliance,

c) The proposed plan for corrective actions will take a considerable time beyond 6 months for implementation;

14.2 UL will withdraw the certificate at the request of the certified plant, if the operation(s) in the certified organization can no longer be carried due to reasons of natural calamities such as flood, fire, earthquake etc, lock out declared by the management, or closure of business operations etc.

15. Change of location/Ownership/Name

15.1 The certified organization will inform UL of any change in the location of the manufacturing unit.

15.2 On receipt of such information, UL will issue instructions to the certified organization for suspension of certification with immediate effect.

15.3 The manufacturing unit will be subject to an onsite audit at the new site like an Initial audit of an applicant.

15.4 If the audit is satisfactory, UL will transfer the Certificate to the new location.

15.5 UL will endorse the change of premises on the Certificate.

15.6 In the event of change of Ownership, the organization will provide necessary documentary evidence. The new management of the organization will submit its acceptance to the agreement with UL, and payment of fees. The same process will be followed as and when an existing applicant undergoes a change in management. Such changes will not call for a visit to the production site.

15.7 In case of change of Name, the manufacturer will inform the change in the name to UL supported with documentary evidence, and if satisfied UL will endorse the Certificate in the new name.

16. Complaints and appeals

16.1 UL will have a documented procedure for handling of complaints and appeals.

16.2 The procedure for complaint handling will include complaints from all stake holders, especially its certified organization as well as customers of its certified organizations..

16.3 The procedure for receipt and handling of complaints will be made available to public on the website and will also be easily accessible on the website.

16.4 Upon receipt of a complaint or appeal, UL will confirm whether the complaint or appeal relates to certification activities for which it is responsible and, if so, will address it. UL will acknowledge receipt of a formal complaint or appeal.

16.5 UL will be responsible for gathering and verifying all necessary information (as far as possible) to progress the complaint or appeal to a decision.

16.6 The procedure will include the process steps for receiving and recording, evaluating and establishing validity of the same, investigating and make decisions on complaints and appeals. The process step will also include the activities of root cause analysis, correction and corrective actions.

16.7 If the complaint relates to a certified organization, then the examination and evaluation of the complaints will take in to consideration the effectiveness and implementation of the certified organizations system.

16.8 The complaint handling process will document the actions to be taken by UL as well as the certified organization,. Some of these actions/conditions will also be included in ULs legally enforceable contract with the certified organization.

16.9 UL will record and track complaints and appeals, as well as actions undertaken to resolve them.

16.10 The decision resolving the complaint or appeal will be made by, or reviewed and approved by, person(s) not involved in the certification activities related to the complaint or appeal. To ensure that there is no conflict of interest, personnel (including those acting in a managerial capacity) who have provided consultancy for a certified organization, or been employed by the certified organization, will not be used by the certification body to review or approve the resolution of a complaint or appeal for that certified organization within two years following the end of the consultancy or employment.

16.11 Whenever possible, UL will give formal notice of the outcome and the end of the complaint process to the complainant.

16.12 In respect of appeals ensure that the individual(s)/committee entrusted with handling of appeal and its resolution decision will be independent of the persons

involved in certification related recommendations and decision and their position hall be such that it will not be possible to influence their decisions with respect to the subject of the appeal.

16.13 The procedure will also have provision for giving a written statement to the appellant, of the appeal findings including the reasons for the decisions reached and also communicating to the appellant about the provision for giving an opportunity to formally present his case.

16.14 Based on the presentation made, the individual or a committee appointed for hearing the case will take a final decision on the appeal and a formal notice of the outcome and the end of the appeal process will be given to the appellant.

16.15 UL will give formal notice of the outcome and the end of the appeal process to the appellant.

16.16 UL will take any subsequent action needed to resolve the complaint or appeal.

17. Fee

17.1 A fee to be charged to the organization for various activities of the certification scheme, without any discrimination between manufacturing facilities, geographical **location, size of the manufacturing facility.**

17.2 The fee structure will include the breakup of costs of application fee, man-day rate for onsite, offsite and audit review, travel time cost, travel and living cost, certificate issuance and maintenance fee. This fee structure is available on request at UL India Front Office located at UL India Private Limited, Kalyani Platina – Block I, 3rd Floor, No.24, EPIP Zone, Phase II, Whitefield, Bangalore – 560066, India or can be obtained through UL India website address https://india.ul.com/contact-us/

17.3 UL will notify and obtain consent to its fee structure from the organizations prior to grant of certification. As and when the fee undergoes a change, the same will be communicated to all including applicants and the manufacturing facility certified under this scheme of certification for their acceptance.

17.4 The calculation of fee structure for registration or certification audit consists of application fee, man-day rate for onsite, offsite and audit review, travel time cost, travel and living cost, certificate issuance and maintenance fee. The calculation of fee structure for surveillance audit consists of man-day rate for onsite, offsite and audit review, travel time cost, travel and living cost, certificate maintenance fee. The calculation of fee for recertification is the sum of man-day rate for onsite, offsite and audit review, travel time cost, travel and living cost, certificate renewal and maintenance fee.

Note: Audit man-days is calculated as per section 6.3.

18. Transfer Certification

Responsibilities –

Lead Auditors - Ensure all audit documentation is provided for review.

Reviewers - Conducted reviews on all audits.

Reviewers - Conduct certification decision reviews.

Process.

18.1 *The objective of a quality system transfer assessment is to determine whether UL can accept the work of the previous registrar in order to issue a UL certificate in place of the previous registrar's certificate.*

18.1.1 The intent is for UL to continue the existing audit and certification cycle began by the previous registrar.

18.1.2 UL must be assured that the work of the previous registrar has been in accordance with all accreditation requirements for the desired program and UL's own requirements, in addition to ensuring that the subject QMS conforms with the requirements of the assessment standards and other criteria.

18.1.3 Stage 1 Audits do not apply to transfer assessments. However normal Stage 1 rules will apply for any scope expansions, recertification audits or changes to registration status conducted after the initial transfer.

18.2 *A desktop transfer assessment.*

18.2.1 The desk review will include a review of all assessment reports since the registration assessment or the last triennial reassessment (if one has been performed since the registration audit), evidence of customer corrective action completion from the most recent assessment, and a copy of the current certificate.

18.2.2 For the desktop approach to be valid the following must be confirmed.

- A continuous assessment or reassessment visit has been performed within the last year (based on the clients current audit frequency).
- Minimum clauses have been audited at every surveillance audit and that a reasonable risk based process approach to auditing the subject QMS has been conducted.
- Evidence is provided that any major non-conformances issued over the cycle have been resolved. If any major non-

conformances were issued on the last assessment, evidence must be provided of an on-site special assessment or UL must conduct an on-site conversion assessment.

- Evidence must be provided that the prior registrar closed any minor non-conformances from their last assessment. If the prior registrar did not close the non-conformances, then the corrective action taken for each is to be provided to UL for review. Before a transfer can be approved, acceptable responses must be provided to show closure.
- There are no unresolved significant customer complaint trends.

18.2.3 It is important to be cognitive that UL is assessing the subject QMS and not the performance of the previous registrar.

18.2.3.1 If over the certification cycle any clauses or sub-clauses, in the opinion of the assessor, do not appear to have been adequately addressed by the previous registrar and which therefore may indicate ongoing certification risk, the assessor may take into consideration other management system performance information.

18.2.3.2 Such indicators may include, but not be limited to, management review output, internal audit output, CAPA effectiveness and adverse customer complaint trends.

18.3 *If it is not possible to ascertain that the subject QMS is operating effectively in the desktop assessment, an onsite assessment will be required.*

The onsite assessment will include all elements of a regular surveillance audit (based on the point in the certification cycle the transfer is occurring) and additional processes where there is insufficient evidence of assessment / conformance from previous audit reports.

18.4 *Desktop and onsite transfer assessments are to be conducted by a Lead Assessor qualified in the applicable programs. The audit team will meet the qualifications for a Registration assessment.*

19. Certificates and Continuous Surveillance

19.1 *Upon concurrence of the reviewer, UL will issue certificates in the requested programs.*

19.1.1 The certificates will contain the following elements:

19.1.1.1 The scope of registration of the UL certificate(s) will be exactly the same as the scope of the previous registrar's certificates, unless that scope statement violates existing UL requirements and approval from the reviewer is obtained

19.1.1.2 The registered entity name, address, trade-names and all site/offsite locations will match the previous registrar's certificate unless that violates existing UL requirements and approval from the Reviewer is obtained

19.1.1.3 Unless time equivalent to a triennial audit and a full clause audit is successfully conducted, the expiry date of the UL certificate will match the expiry date of previous registrar's certificate.

19.2 *UL will continue the existing audit cycle of the previous registrar.*

19.3 *A desktop evaluation of transfer may not count towards any reduction of further continuous surveillances in the audit cycle or reduction of time for further surveillance.*

19.4 *UL will ensure that audits are scheduled and conducted within the waitlist period per UL program rules (dependent on annual surveillance).*

Appendix A - Conditions for Use of the UL Registered Firm Mark

A.1 General

A.1.1 Upon acceptance of the following conditions, the registered organization is entitled to use the UL Registered Firm Mark illustrated below. Camera-ready artwork of the UL Registered Firm mark is available for photo reproduction from the UL office handling the registration. An electronic form of the logo is also available from UL's web site (www.ul.com).

A.1.2 UL is the owner of the UL Registered Firm mark which incorporates the name, abbreviation or symbol of UL referred to as the "Mark") and which may, only under the conditions of this document, be used by the organization in connection with its quality system and the goods or services that are the subject of Registration to indicate that such goods or services are covered by UL and its registration. The organization shall not use such a Mark nor in any other way make use of UL's name, abbreviations, or symbols, or any other form or reference which may be interpreted to mean UL in connection with its quality system and goods or services not in compliance with this document and Requirements.

A.1.3 In the opinion of UL the promotional or advertising material shall not be in conflict with the findings of UL and that the reference to UL shall in no way create a misleading impression as to the nature of UL's findings and Registration. Except for the mark that is prescribed for use in Appendix A, no other UL mark may be used in the advertising and promotional material supplied unless otherwise specifically authorized in writing by UL. In those instances where a marking is used, any text, which is prescribed by this document, shall be used.

A.1.4 The UL Certificate of Registration and Mark shall be used in the manner authorized by UL and subject to the control of UL. Requests for use of UL's Certificate of Registration and Mark shall be processed through UL. Notwithstanding that the cost of displaying UL's Certificate of Registration and Mark is not paid by UL, it is agreed that the right to control the display or other use of the Certificate of Registration and Mark shall be vested in UL. UL's representative shall have the right, on demand, to acquire possession of the UL Certificate of Registration and Mark and any or all advertising and promotional material, or other means of displaying the Certificate of Registration and Mark when in the judgment of UL's representative, such action is warranted.

A.2. Requirements

A.2.1. The UL Registered Firm Mark may only be used on correspondence, advertising and promotional material and shall only be used in connection with the products and/or services described in the organization's scope of registration. The registered organization must identify the goods or services to which the Certificate of Registration applies when using the UL Registered Firm Mark in a context where the scope of application is

open to interpretation

A.2.2. The UL Registered Firm Mark shall not be used on individual product containers or individual product packaging.

A.2.3. The UL Registered Firm Mark may be used on bulk packaging only when specifically authorized in writing by UL, provided that in the opinion of UL, the mark's use in no way tends to create a misleading impression as to the nature of UL's quality management system registration.

A.2.4. The UL Registered Firm Mark shall not under any circumstances be used directly on or closely associated with products or services in any way that may imply that the products or services themselves are Listed, Recognized, Classified, or in any way certified by UL. This includes laboratory test, calibration or inspection records.

A.2.5. The registered organization agrees to discontinue any use of the UL Registered Firm Mark and any form of statement with reference to the authority of the registered organization to use the Mark, which is unacceptable to UL and that in the opinion of UL, might be misleading.

A.2.6. Upon the termination of registration, for whatever reason, the organization must discontinue all use of the Mark immediately.

A.3 Composition & Elements:

A.3.1. UL in a circle symbol encircled by the words "REGISTERED FIRM" in the bottom half as illustrated below:

A.3.2. Use of the UL Registered Firm Mark, when used, must always be in conjunction with the following elements (as illustrated in the examples below):

a) Registered organization's name
b) File number
c) Applicable ISO standard to which the organization is registered

Examples of acceptable compositions:

 **Certification Holder Name** **Registered to ICMED 13485** **Certification No. A99999 / A999999**	**A99999**  **ICMED 13485** **Certification Holder Name**

A.4 Application

The following guidelines describe acceptable applications of the UL Registered Firm Mark:

A.4.1. Minimum size is not specified as long as the words “REGISTERED FIRM" are clear and legible.

A.4.2. Black on a white background, or a background in another color which clearly contrasts with black.

A.4.3. White on a black background, or a background in another color which clearly contrasts with white.

A.4.4. Contrasting colors where the foreground and the background allow the details of the UL Registered Firm mark to be clearly distinguishable and legible (consult UL for acceptability of color scheme).

A.4.5. Embossed in such a way that the UL Registered Firm mark is clear and legible

A.4.6 Where the organization has been registered to an accredited registration program, the organization may include the standard number with reference to the applicable QMS standard (i.e. AS-9100).

A.5 Preferred Text

Registered organizations may use the following pre-approved statements in connection with the mark to describe their registration:

- The facility covered by this mark has been evaluated to international quality management system standards by UL.
- "Our facility has been registered by UL. to the International Organization for Standardization ISO 13485 Medical devices—Quality management systems. "Registered by UL to ISO 13485:2016."
- "The quality systems of this facility have been registered by UL to the ISO 13485:2016 Standard.'

Appendix B - Conditions for Use of an Accreditation Body Mark

1.1 *B.1 Requirements for Use of the NATIONAL ACCREDITATION BOARD FOR CERTIFICATION BODIES (NABCB) Mark*

B.1.1. This section applies only to those organizations with written authorization from UL to use the NABCB mark as evidenced by the NABCB mark on their certificate of registration. All organizations should follow NABCB procedure BCB 202 with out any deviations.

B.1.2. Only organizations authorized to use the NABCB mark are entitled to use the mark illustrated below.

B.1.3. Use of the NABCB mark must always be in conjunction with:

a) UL's Registered Firm mark
b) Registered firm's name
c) File number
d) Applicable ISO standard

B.1.4. The NABCB mark may be used on stationery and publicity material or other items relevant to their certificate in connection with those goods and/or services listed on their certificate of registration. Publicity material shall not include notices, labels, documents or written announcements affixed to or otherwise appearing on goods or products unless the goods or products have been manufactured under an accredited product conformity scheme. This restriction shall also apply to primary (e.g. blister packs) packaging and promotional products.

B.1.5. The NABCB mark shall not under any circumstances be used directly on or closely associated with any product, process or service in any way which may imply that the product, process or service itself is in any way certified or approved by UL or NABCB

B.1.6. Accreditation marks shall not be used in such a way to imply that NABCB accepts responsibility for activities carried out under the scope of accreditation and/or certification.

B.1.7. The registered organization agrees to discontinue any use of the NABCB mark and any form of statement with reference to the authority of the registered organization to use the NABCB mark that is unacceptable to UL or which in the opinion of UL might be misleading.

B.1.8. Upon the termination of registration, for whatever reason, the organization must discontinue all use of the NABCB mark immediately.

B.1.9. The NABCB accreditation mark shall normally have a minimum size 15 X 12 mm. Any enlargement or reduction shall retain the same proportions as those printed in this publication. The mark and the accreditation number shall be considered as a single entity for purposes of enlargement or reduction. Irrespective of the height of reproduction, the mark must, in the opinion of UL, be legible, with no infilling.

B.1.10. On unfolded stationery sized no greater than A4 the mark shall be no greater than 30mm. Authorized users shall ensure the form of the Accreditation Mark is legible.

B.1.11. Authorized users of the accreditation mark shall reproduce it in a single color only, which should be the predominant ink color of the document or, in the case of preprinted letterhead paper, the predominant color of the letterhead. Embossed, relief, or die-stamped versions may be used. The marks may be reproduced as watermarks.

B.1.12. The accreditation marks shall not be displayed on vehicles, except in publicity material containing an accreditation mark as part of a larger advertisement, provided the mark is used in the publicity material in accordance with the conditions stated above. The accreditation mark shall not be displayed on buildings and flags. Marks may be displayed on internal walls and doors, and on exhibition stands.

B.1.13. The Registered Firm's name, file number and applicable ISO standard to which the organization is registered, should appear below the UL Registered Firm mark as shown below.

Appendix C Conditions for use of Certification Mark – ICMED 13485 Logo

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

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

Requirements for Use of Mark

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

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

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

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

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

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

Process for Use of Certification Mark

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

This process shall be facilitated by the QCI approved certification body

The certification mark pertaining to the respective ICMED Scheme level may be used as any photographic reduction or enlargement.

The colour scheme of the Marks shall be the same as described in Appendix A. The client shall only affix the design of the Mark as per the level the manufacturer has been certified and none other.

ICMED 13485 - to be only in printed in Red
Mark levels can also be printed in Grey Scale.

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

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

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

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

Fee

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