INFORMATION BROCHURE

OF

CONFORMITY CERTIFICATION SERVICES

Full Certification Scheme (Type 5)

PREPARED & REVIEWED BY	APPROVED BY

0.1 Approval and Issue

Prepared and Reviewed by: _____

Head (Quality)

Approved by: _____

Chief Executive Officer/ Head (Technical)

Note:

1. Head (Quality) is responsible for issue and distribution of this document including amendments.
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0.3 Amendment Record

Revision No.	Date of Revision	Nature of Revision	Page Ref	Remarks
Issue 01, Rev. 0	23.06.2015	Nil	All	
Issue 01, Rev. 01	21.03.2017	Clause 0.2 (Distribution List) shifted from page no. 3 to page no.2	2 & 3	
Issue 01, Rev. 02	19.06.2020	Additional Surveillance Measures Medical Devices	7	
Issue 02	08.07.2026	Change in nomenclature	All	The term" General Manager" has been changed to "Head"

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Full Certification Scheme: This scheme provides Third Party Product certification based on initial capability assessment of manufacturing facilities and product evaluation followed by periodical re-evaluation of product and factory surveillance. Capability assessment includes verification of incoming inspection systems, production, process control, in-process checks, testing set up, technical competence of personnel, packing and storage of products. Periodical re-evaluation entails taking samples of the product from the point of production as well as from dispatch points/ ware-houses for assessing their ongoing conformity. The sample is picked up and tested in accredited laboratory. After granting the certificate, at-least one surveillance is conducted once in a year.

Basis for granting Certification:
This Scheme provides grant of certifications based on the work done by CIIPL or by other accredited certification bodies with whom CIIPL has entered into formal agreements. The provision is normally applicable for:

- Initial capability assessment
- Initial product evaluation to international standards
- Periodic re-evaluation of capability and product

These agreements have been executed through mutual assessments, as appropriate, including the requirements of suitability and competence of body (bodies) or person (persons) carrying out testing, inspection and certification/registration as specified in International/National Standards.

In addition, CIIPL accepts IECEE-CB Certificates from all Participating NCBs in lieu of its initial product evaluation, taking into account National deviations as applicable.

Certification is valid for 3 years.

How the scheme operates:
The Full Certification Scheme corresponds to Type 5 depicted in ISO 17067:2013 and the process involves the following steps:

- Application by the Applicant defining the certification scope needed, the related standard, the type, grade, class of the products
- Application Review by CIIPL
- Initial evaluation of manufacturing facilities
- Sample selection/samples testing at accredited labs
- Review of Test Reports against requirements of Standard
- Communication of Non-conformance, if applicable
- Corrective action by the client
- Verification of corrective action taken by the client
- Review and Decision
- Issue of Certification document and authorization to use Certification Mark of CIIPL for a validity period of 3 years
- Signing of Certification Agreement by client and CIIPL
- Periodic surveillance involving re-assessment of manufacturing facilities and product testing from the production process, dispatch points and ware-house

- Yearly performance review
- Renewal application by client
- Renewal assessment before expiry of validity
- Review and Decision
- Renewal of Certification for a fresh validity 3 years

Who can apply:
This scheme is open to Manufacturers, in India or overseas location. The Client should be a legal entity, who would be required to execute the Certification Agreement, and shall be responsible for all legal obligations related to certification. Certification is granted individually for each manufacturing unit.

The Manufacturer is required to have suitable manufacturing /process /assembly facilities, as well as test facilities in his own premises for routine tests, and arrangements with external laboratories for other tests. The manufacturer should also have in his employment competent persons who can operate the certification scheme on a regular basis. In case a regulatory approval is required for manufacturing the product, it will be a pre-requisite for grant of CIIPL certification.

CIIPL reserves the right to verify the antecedents of the applicant, and to reject the application in case the same are not found to be fit for certification.

Certification Scope:
Full Certification can be granted for products for any of the following Scopes:
- Electrical and other Product Safety Standards
- Performance standards
- Energy performance Standards
- EMC & RoHS
- Any combination

Specific coverage of products is done based on type, grade, class, size ranges which are covered by the representative product samples evaluated by CIIPL.

Technical Areas presently covered:
- Electrical appliances
- Industrial Electrical equipment
- Electronics
- Information Technology, Office Machines
- Telecommunication, Audio & Video Equipment
- Biomedical Equipment
- Personal Protection Equipment
- Mechanical systems and Components for general use
- Paints & Dyes
- Construction material
- Light and luminaries & Image Technology
- Batteries
- Rubber and Plastic products

Applicable Standards:

Product Certification shall be granted for conformance to Standards published by International Standards organizations such as ISO, IEC, ITU, National standards Bodies such as ANSI, BSI, Accredited SDOs such as ASTM, VDE, Regulatory standards, Private standards (issued by bodies complying with code of good practices for standardization).

Certification Marks:

CIIPL allows the use of following types of Marks under the Full Certification Scheme:

a) CII Certification Mark for general performance standards
b) CII Safety Mark for Electrical and other product safety
c) CII EMC Mark
d) CII Energy labelling Mark

The terms of use of these marks are governed by the Certification Agreement.

Issue of Certificate of Conformity and Mark of CIIPL:

The client is issued a Certificate of Conformity, with CII Logo, the related Standard, and the declared type, grade, class, size and any special declarations, and a restriction of the period for which the certification shall remain valid. This information can be provided in supplements to the Certificate.

The customer is informed the manner in which he is authorized to use the statement of conformity given in the certificate, through a Certification Agreement forwarded along with the Certificate, highlighting the following:

- Validity of Certification. This will in no case exceed 3 years from the date of issuing certificate.
- The stipulation that the client shall implement the agreed QAP
- The stipulation that the Mark of CII shall not be used on any other product, than those certified
- The stipulation that the client shall keep record of all production on which the Mark of CII shall be applied and to make available such information to CIIPL when requested
- To permit entry of CIIPL's assessors to its factory premises and ware-houses for conducting inspection and for taking samples, whether pre-informed or without intimation
- The consent that CIIPL shall publish information relating to the certification in its certification directory and to make available such information to any person on request
- The stipulation that the client shall inform CIIPL of any changes in its legal status, Administrative set-up, technical process changes, changes in product, etc.
- The stipulation that client shall implement any changes in the scheme as and when notified by CIIPL
- The manner in which the Client can claim certification of the products for supplying to any customer or in the market place, and where applicable to demonstrate compliance to regulations
- The stipulation that the Client shall not issue any misleading statement in respect of the type of certification and the scope
- Conditions under which Certification will be Suspended, withdrawn, cancelled, reduced in scope
- The conditions under which certification shall be renewed
- The conditions for timely payment of certification fees and costs

A copy of the Type Test Report is also issued to the Client. The Certificate is listed in the Certified Clients Register.

Surveillance:

Under the Certification Scheme, CIIPL shall undertake the following surveillance activities:

a) At least one Surveillance assessment shall be conducted at the client site once in a year during which:
   i. The factory arrangements including plant, machinery, test set-ups, storage conditions shall be re-verified for continued suitability and for any changes.
   ii. The QAP is being fully implemented by the client and records are available for evidence.
   iii. The plant's personnel are competent.
   iv. Spot checking of product conformance using test set up within the factory.
   v. The correct application of Certification Mark as per CIIPL's guidelines.

b) Re-testing of samples in accredited laboratory. The samples shall be drawn during Factory surveillance visits.

c) At least one un-announced activity, such as picking of sample for testing in accredited laboratory from factory premises or ware-house. Where previous performance is not satisfactory, or complaints on products have been received, unannounced factory surveillance visits shall be carried out.

The sample selection shall be done in a manner, that different varieties, grades are tested during an accreditation cycle.

The Surveillance Assessment is conducted as per **CCS/F 03** which includes:

- General information of the client
- Verification of purchased components and materials which have a safety implication on the certified product (Incoming Inspection)
- Production Control, Inspection and Routine Tests
- Functional Check on Test and Measuring Equipment used for Safety Tests (Dummy Test)
- Products seen in Production during visit
- Calibration of Safety Test and Measuring Equipment
- Handling and Storage
- PVT
- Correct use of CII Mark
- Corrective actions in response to inspector's evaluation
- Implementation of QAP
- Customer Complaints
- Changes to Certified Products
- Selection of Sample(s)
- Assessor's Evaluation

For Medical Equipment Annexure 'MED to CCS F03' is also used to additionally cover QMS and Regulatory Requirements applicable for Medical Devices (as per ISO 13485) including

- Medical Device file, its control and control of related records
- Special Resource Management like Environment and Contamination Control
- Special Product Realization measures like Traceability
- Compliance to Updated Regulatory Requirement
- Release of Non-compliant goods with concession
- Sterilisation, Installation and Service Provisions
- Reporting to Regulatory Authorities

(The additional checks as per Annexure A may be exempted if the manufacturing process is independently certified to ISO 13485)

Any deficiencies observed in the Factory Inspection Report shall be communicated to the client by the Project Coordinator. The client shall be asked to propose the corrective actions, which shall be verified for suitability and effectiveness. The continuity of certification shall be based on satisfactory acceptance of the Corrective Actions/ Plan.

Where the results of a surveillance assessment or activity demonstrate that the certification cannot be maintained, the Project coordinator shall prepare a case file recommending suspension or withdrawal of certification. The review and decision shall be taken in such cases, in the same manner as grant of certification.

In case of a complaint and reasonable justification not being available for the complaint, CIIPL may pick up samples from the market for testing. In case of failure in test results certification shall be suspended till the corrective actions are taken by the client and evaluated for further necessary action.

Re-certification:
The purpose of re-certification audit is to confirm the continued conformity and effectiveness of the client's production and quality system as a whole and its continued relevance and applicability for the scope of certification. The Re-Certification audit shall include site audit and shall consider the performance of production and quality system over the period of certification and shall also include a review of previous surveillance audit reports.
CIIPL shall conduct the re-certification audit at least 60 days in advance to the expiration of certification so that the client has time to implement corrective actions before the expiry of the certification.
For non-conformities raised during the audit, the conditions specified become applicable. CIIPL shall submit a formal report to the client.

Extension of the scope of certification:
A licensee wishing to extend the scope of certification to additional types or models of products, to the same specified requirements as the products for which a certification is already granted, should apply to CIIPL using the application form **(CCS/F 08).** In such cases the CIIPL may decide not to carry out an assessment of production process or quality system but to require test samples of the additional types of products to determine that they comply with the specified requirements. If the tests are successful, the scope of certification should be extended and the licence agreement may be modified.

If the licensee wishes to apply the certification to additional types of products, but to different specified requirements, or if the licensee wishes to apply for certification to be used in an additional facility that is not covered by the earlier license, it will be necessary to carry out those parts of the original application procedure which do not cover the new circumstances.

Conditions for Suspension/ Cancellation/ Reduction in Scope/ Withdrawal of the Certification:
Suspension:
A Certification may be suspended if it has been established that:
a) The Client has failed to take suitable improvement actions within 30 days, after CIIPL has served show cause notice following failure of product is observed during surveillance operations.
b) The Client has failed to take suitable improvement actions within 30 days, after CIIPL has served show cause notice following failure in respect of deficiencies observed in Client's quality control system, or non-adherence to the provisions of QAP, during factory surveillance operations.
c) In case, a repeat failure is observed in respect of a requirement for which the Client has already taken corrective action, CIIPL shall suspend the certification without any show cause notice.
d) The Client has used the mark in respect of a type or grade, or brand which is not covered in the Certification, as observed during factory or market surveillance operations. CIIPL reserves the right to issue suspension directly or issue a show cause notice depending on the facts of the case.
e) The Client has failed to submit proper justification within 7 days, after CIIPL has served show cause notice following a factory surveillance inspection where the Client has failed to provide reasonable facilities for completing the factory surveillance.
f) the Client has failed to comply with any other conditions of the Certification, within 30 days of show cause notice period;

Removal of suspension:

a) In cases of product non-conformance, suspension shall be removed after CIIPL has agreed to the proposed corrective actions, verified the same during factory surveillance, and the product sample is found conforming during repeat testing in accredited laboratory.

b) In cases of other deficiencies observed during factory surveillance, suspension shall be removed after CIIPL has agreed to the proposed corrective actions, and verified the same during factory surveillance.

c) In cases involving marking of variety which is not covered in the certification, decision for revocation will be taken after CIIPL is satisfied that the violation was due to bonafide reasons or genuine error, based on the submission of details by the Client. Where the violation is determined to be willful, the procedure for cancellation of certification, prosecution shall be initiated.

d) In cases involving not providing facilities for inspection, or failed to comply with any other conditions of the Certification, decision for revocation will be taken after CIIPL is satisfied that it was due to bonafide reasons based on the submission of details by the Client. Where the reasons are determined to be willful, the procedure for cancellation of certification shall be initiated.

Cancellation of Certification:

Certification shall be cancelled if the following conditions apply:

a) In cases involving product non-conformance or deficiencies observed during surveillance, if the Client does not take action to rectify the deficiencies that led to the suspension, the Certification shall be cancelled after a period of six months from the date of suspension. A show cause notice for a period of 30 days shall be issued to the Client before deciding on the cancellation of certification.

b) In cases involving marking of variety which is not covered in the certification, which is determined to be willful, the certification shall be cancelled without any further notice to the Client, in case the notice for suspension was given earlier. In case notice was not served before suspension, a show cause notice for a period of 15 days shall be issued to the Client before deciding on the cancellation of certification.

c) In cases involving not providing facilities for inspection, or failed to comply with any other conditions of the Certification, if the Client does not take action to rectify the deficiencies that led to the suspension, the Certification shall be cancelled after a period of 30 days from the date of suspension.

d) CIIPL reserves the right to cancel a certification in case a certified product is found to be failing in a critical requirement affecting public health and safety without invoking the show cause/ suspension process.

e) If more than two suspensions for the same or similar deficiencies occur within a period of two years.

Reduction in scope of certification:

a) CIIPL reserves the right to reduce the scope of the certification, in case it is found that specific varieties of the product covered under the certification are not conforming to the Standard and the reasons for the non-conformance do not affect the conformance of the other varieties.

b) On request by the Client.

c) When certain varieties are removed from the scope of the Standard following revisions or amendments.

Withdrawal of certification:

a) On request by the Client.

b) When a requirements standard such as the Standard is withdrawn by the Standards body, or reduced in scope, or merged with other standards and CIIPL takes a policy decision to withdraw certifications having such varieties in the scope.

c) following revisions or amendments.

Use of Certificate or mark of conformity:

CIIPL exercises proper control over ownership, use and display of its Certificates and Marks of Conformity. A Supplier may use a Mark of Conformity of the Certification Body on a product that has been certified by the Certification Body. The use of the Mark of Conformity is permitted on current manufactured goods only till the products continue to remain under active certification.

Use of Mark

Guidance on use of certificates and marks is provided to the suppliers. On grant of CIIPL Safety Certification (CIIPL Product Certification based on Safety Standards) the certification holder is automatically authorized to use the following mark of conformity on approved products.

On grant of CIIPL EMC Certification (CIIPL Product Certification based on EMC Standards) the certification holder is automatically authorized to use the following mark of conformity on approved products.

The relevant Mark/s of Conformity may be used on the products certified by CIIPL as per its Product Certification Scheme.

The relevant Mark/s of Conformity may be used in Colour or Monochrome. The Mark should have a minimum dimension of 5mm when applied so that it is discernible. The mark may not be put on any misleading part, place or position. It shall not be used on Stationary without permission of Conformity India International Pvt. Ltd.

Prohibiting Misuse of Mark

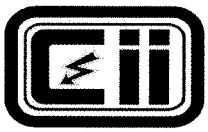
CIIPL will take suitable action to deal with incorrect references to the certification or misleading use of certificates/licenses and logos/marks found in advertisements, catalogues etc. Such action could include corrective action, withdrawal of certificate, publication of the transgression and, if necessary, other legal action.

The extract of general conditions regarding the use of mark/logo of respective certification schemes are given below.

Use of Safety / EMC Mark

As far as possible, Safety Mark / EMC Mark as given below shall be applied on the product itself. It can be applied on the packaging also. If a product is very small for the marking than it may be applied on packaging only. The Marks can also be applied on publicity material.

Any unauthorized or misuse of the Marks shall lead to suspension/withdrawal of certification and penalty as deemed necessary by CIIPL.



FCS-IEC60XXX
CII SAFETY MARK

NCS-CISPRXX
CII EMC MARK

Following are some of the recognized methods of applying Safety Mark on the product:

a) Printing on a label
b) Printing on an anodized name Plate
c) Printed stickers
d) Adhesive tape
e) Stencil
f) Embossing or punching
g) Casting where no other specified system exists

Apply Safety/ EMC Mark only on the models/varieties and batches/lots of products which confirm the requirements under the Scheme. The minimum size of the Marks for display is not specified. However, these shall not be displayed in a size which becomes unidentifiable or unreadable to unaided eye.

The Safety/ EMC Mark shall be accompanied by the relevant test standard reference below them. On commencement of marking of certified product, the supplier may advertise product with Standard Mark during the validity of certification. The use of Certification Mark on letterheads and publicity literature is permitted subject to that in the event of cancellation or expiry of certification, the letterheads etc. with the Certification Mark will be destroyed/ obliterated.

Publicity by the Client:

A certified client shall have the right to publish the fact that it has been authorized to issue a mark of conformity for products to which it has received certification.
In every case the client shall take sufficient care of its publications and advertising that no confusion arises between certified and non-certified products.
The client shall not make any claim or the like in user information that could lead purchasers to believe that performance of the product or its use is covered by the certification when in fact they are not. For example a product certified for safety shall not be claimed for compliance to performance standards.

Confidentiality:

CIIPL is committed for the protection of the proprietary information of the certified product. Adequate arrangements consistent with applicable laws are in place to safeguard confidentiality of the information obtained in the course of the certification activities at all levels of organization, including committees and external bodies or individuals acting on its behalf. If felt necessary to place the part/ complete collected information in public domain, CIIPL will obtain prior approval of the client.

CIIPL ensures that where the law requires information to be disclosed to a third-party, the supplier is kept informed of the information provided as permitted by the law. CIIPL also ensures that the information about the client, if obtain from other sources, is kept confidential.

CIIPL is responsible for ensuring that confidentiality of information is maintained by its employees and those of its subcontractors concerning all information obtained as a result of their contacts with the licensee.

Misuse of a certificate or mark of conformity:

CIIPL takes action for unauthorized, incorrect, or misleading use of the certificates or a mark of conformity is found.

Incorrect references to the certification system or misleading use of certificates or the mark found in advertisements, catalogues, etc., shall be dealt with by cancellation of certification and in case of serious misuse followed by legal action.

Obligation to the Client:

An applicant holding a valid Certificate of Registration shall:

a) Comply in all respects with the appropriate System/and/or Product Standard;
b) Submit to CIIPL for prior approval, the form in which he proposes to use the Certification of Registration and/or logo/mark;
c) Not to use the Certificate of Registration or logo/mark in any manner which may mislead the interpretation;
d) Not make any change to the System/Product which formed the basis for grant or continuation of registration and which prevents compliance with the System/Product standards;
e) Document all changes made to the System/or Product and make available records of such changes to CIIPL.
f) Notify the CIIPL of any change of key personnel in relation to quality assurance, technological functions or senior management;
g) Give access to the assessment team appointed by CIIPL for the purposes of assessment/surveillance; or picking up of samples for testing;
h) Keep records of all customer complaints in respects of products, process or service and corresponding remedial measures related to System;
i) Upon suspension or cancellation/withdrawal of Certificate of Registration, discontinue of use of Certification of Registration and logo/mark in all advertising material and other matter which contains any reference thereto; and
j) Pay all financial dues to CIIPL as prescribed.

Note: The applicant is not entitled to any refund of fees paid or cost incurred in the event of non-renewal, suspension, withdrawal/cancellation, modification of Certification of Registration.

Appeals and Complaints:

Appeals: Client shall appeal to CIIPL in respect of the following,
1) Non acceptance of client's application for certification and inspection
2) Not granting, suspending, withdrawing or denying of certification

CIIPL shall deal with the appeals according to its procedure and shall be responsible for all decisions at all levels of the appeal handling process as per CIIPL procedure (CII/EP 08). CIIPL shall acknowledge the receipt of the appeal and shall provide the client with progress reports and the outcome.

Complaints: CIIPL shall investigate the complaint received about the client to decide what action need to be taken and the same shall be communicated to the client at an appropriate time as per CIIPL procedure (CII/EP 08). The identity of the complainant shall not be disclosed.

Liability

The liability analysis is elaborated in CII/F 24.

Fee Structure of CIIPL:

Application fee for Full certification scheme	: General information is detailed in CII/F 10.
Testing Charges (on actuals)	: As per the test lab charges.