# Medical Device Consultant Certification Scheme

## Certification Scheme Manual



### Scheme Owner

Life Sciences Sector Skill Development Council

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## 1. Introduction

LSSSDC is a Vocational Education Awarding Body recognized by the National Council of Vocational Education and Training (NCVET) and operates under the Ministry of Skill Development & Entrepreneurship (MSDE). Established in 2014 by the National Skill Development Corporation (NSDC) with industry representatives, LSSSDC aims to create a sustainable vocational education ecosystem for the Life Sciences sector. LSSSDC covers a broad range of industries within Life Sciences, including:

- Pharmaceuticals ( ASU&H, Cosmetics, Vet-Drugs, Nutraceuticals, CRAMS)
- Biotechnology (Biologics, Agri Biotech, Allied Biotech)
- Medical Devices (Implants, Diagnostic Imaging, In-Vitro Diagnostics)
- Research & Development Services (CROs, CRAMs, SMOs)

LSSSDC is also an Authorized Advisory and Monitoring Body under MSDE for apprenticeship programs through the Apprenticeship Act. As the only Sector Skill Council dedicated to the Life Sciences domain from the 'Bench to Clinic' stage, LSSSDC is tasked with developing a skilled workforce for the entire lifecycle of life sciences products, from research and development through to manufacturing and supply.

LSSSDC aims to identify emerging and future job roles, map the necessary competencies and skills, and curate vocational programs in collaboration with NCVET. The Council is committed to delivering these programs through a network of affiliated vocational training organizations and educational institutions. Additionally, LSSSDC plans to train and certify proficient educators, consultant and trainers, with a goal of empowering approximately 6.15 million skilled professionals in the sector over the next decade.

LSSSDC has taken the initiative to develop a Certification Scheme for Medical Device Consultants in accordance with the International Standard for Personnel Certification, ISO/IEC 17024:2012, thereby enabling the availability of skilled & certified resources in India. LSSSDC, as the Scheme Owner, aims to promote uniformity in the implementation of certification among the Personnel Certification Bodies (PrCBs), thereby developing an ecosystem for the certification of **Medical Devices Consultants.**

The objective of this document is to define the process for certifying **Medical Device Consultants** under the LSSSDC mandate.

This Certification Scheme Manual defines the structure, requirements, and processes for certification of Medical Device Consultants. The scheme establishes a structured mechanism to assess competence, ensure consistency, and enhance confidence in professional consulting services in the medical device domain.

## 2. Purpose and Objectives

The objectives of this scheme are to:

2.1. Establish minimum competence requirements for Medical Device Consultants

2.2. Enable objective and impartial assessment of candidates

2.3. Support regulatory compliance and industry confidence

2.4. Align personnel certification with ISO/IEC 17024

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## 3. Scope

This document explains the certification process under the Medical Devices Consultants Certification Scheme (MDCCS) [hereinafter referred to as the Scheme] and the requirements to be followed to obtain and maintain certification for Medical Devices Consultants based on the competence standard prescribed under the Scheme [document no. LSSSDC/MDCCS/CS/D/V0.2].

The certification shall be categorized into three levels based on their qualification, work experience, and the number of projects delivered.

Level 1 – Consultant
Level 2 – Senior consultant
Level 3 – Principal consultant

**Note:** Device-specific or clinical specialization certifications are outside the scope of Version 1.0.

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## 4. Normative References

- ISO/IEC 17024:2026

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## 5. Definitions

Definitions used in this scheme shall be in accordance with ISO/IEC 17024:2026 and applicable regulatory standards.

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## 6. Application

6.1. Applications would be made by individuals through a prescribed application form and in accordance with the eligibility requirements mentioned in the competence standard prescribed under the Scheme [document no. LSSSDC/MDCCS/CS/D/V0.2].

6.2. The Format of the application form is provided in Annexure I.

6.3. Registration of Application

6.3.1 The applicant Consultants shall apply to any of the LSSSDC- approved PrCBs in the prescribed application form. Format of the form is given in Annex I.

6.3.2 The approved PrCB shall respond to all queries received from prospective applicants for certification as Certified Consultants / Senior Consultants / Principal Consultants with complete information on the certification process, appropriate to the certification scheme (including fee structure), a list of documents containing the requirements for certification, the applicant's obligations and rights, and the duties of a certified professional which includes an agreement and code of conduct, within 7 days of receipt of the query.

6.3.3 The Consultant shall declare whether he/she has been an applicant under this scheme by any other PrCB and, if yes, shall provide details of the status of application / certification, scope, and period of certification.

6.3.4 The applicant Consultant shall, along with the application, declare any pending judicial proceedings relating to his/her conduct, and/or any pending proceedings by any relevant body, concerning to the Consultant's activities, and application from such an applicant shall not be entertained.

## 7. Review of Application

7.1 All applications for certification shall be reviewed for completeness, adequacy, and deficiencies observed, if any, shall be informed to the applicant within 7 days of receipt of the application. Records of application review shall be maintained.

7.2 All applications found complete shall be registered within 7 days of receipt of application/additional information, in order of receipt with a unique identification number, acknowledged, and records maintained. Registration shall be done if found complete.

7.3 Applications from applicants found to be violating the terms and conditions of the scheme while their application is being processed shall not be processed any further and rejected after due notice of 15 days.

7.4 Applications from applicants who have misused the earlier certification or whose earlier certification was cancelled/application rejected or whose earlier application was rejected because of violation of terms & conditions shall not be registered within one year of cancellation of the certificate/rejection of the application.

7.5 Requests for certification from ex-applicants shall be processed like a fresh applicant.

7.6 The PrCB shall reject or close all applications under the following conditions:

7.6.1 If deficiencies observed in the application are not completed within one month;

7.6.2 If the applicant does not take the assessment within 3 months of registration of the application;

7.6.3 Misuse of the certification mark, if any;

7.6.4 Evidence of malpractice;

7.6.5 Voluntary withdrawal of the application.

7.7 In the event of closure/rejection of an application, the PrCB may act as per its policy.

## 8. Appointment of Examiners

8.1 Examiners shall meet the requirements of the certification body. The selection and approval processes shall ensure that examiners:

8.1.1 understand the certification scheme;

8.1.2 can apply the examination procedures and documents;

8.1.3 have competence in the field to be examined.

8.1.4 are fluent, both in writing and orally, in the language of examination.

8.1.5 have identified any known conflicts of interest to ensure impartial judgements are made. A certificate of no conflict of interest shall be obtained.

8.1.6 performance of the examiners shall be monitored and the reliability of the examiners' judgements assessed. Where deficiencies are found, corrective actions shall be taken.

8.2 Examiners shall meet the basic criteria set for Principal Consultant as given in the competence standard prescribed under the Scheme [document no. LSSSDC/MDCCS/CS/D/V0.3]

8.3 Examiners must have a minimum of 15 years of experience in the Medical Device Domain (For example, Industry, Auditing, Consulting, Academia, or Research, etc.) with exposure to medical device regulatory/QMS activities and consultative.

## 9. Assessment

9.1 Assessment shall be carried out in fair, impartial and a structured manner to ensure that the scheme requirements are objectively and systematically verified with documented evidence to confirm the competence of the candidate.

9.2 Candidates shall be informed about the assessment criteria prior to the commencement of assessment process.

9.3 Assessment shall demonstrate.

9.3.1 Validity - accuracy of evidence,

9.3.2 Reliability- Consistency of evidence,

9.3.3 Sufficiency - adequacy of the appropriate evidence to make accurate assessment

9.3.4 Currency- evidence collected is recent and still relevant

9.3.5 Authenticity - evidence collected and presented for assessment is of the candidate being assessed

9.3.6 Flexibility- assessment considers effects of variables to ensure accuracy

9.3.7 Fairness-assessment tools, systems and procedures are consistent with “equal opportunity” principle

9.3.8 Transparency -candidate is kept informed about the assessment criteria and is provided accurate and timely feedback

9.4 Examination Process. Examinations shall be conducted in accordance with laid down procedure maintaining impartiality, confidentiality, fairness and transparency

**9.5 Approved Assessment Tools**

The following methods may be used singly or in combination, depending on the consultant level

9.5.1 Written Assessment

a) Objective and descriptive questions
b) Tests regulatory, standards, and foundational knowledge

9.5.2 Take-home Case Study

a) Practical, scenario-based assignment
b) Evaluates application of knowledge, reasoning, and documentation skills

9.5.3 Technical Interview / Discussion

a) Structured interview aligned to competence domains
b) Explores depth of understanding, judgment, and experience
c) To assess the contextual Intelligence (Industry fluency), Technical synthesis (Ability to grasp complex technical data to understand existing gaps), Diagnostic ability to identify root cause analysis, goal focus, client orientation. Conflict mediation, Decision making and varied communication styles

9.5.4 Evidence Review

a) Review of submitted project documents and records
b) Confirms authenticity and relevance of experience

**9.6 Assessment Methodology**

9.6.1 Written Test methodology

a) For the Written test, MCQs shall be used with min 3-5 questions on each domain
b) The maximum time for the written test would be 1 hour.

9.6.2 Evidence review methodology

a) Evaluation for evidence review is to be done by a panel of 3 examiners.
b) The submitted evidence from applicants shall be provided to the panel for review one week before the interview.
c) Maximum time for evidence review would be 1 man-day per candidate.

9.6.3 Take-home case study evaluation methodology

a) Evaluation for the take-home case study by a panel of 3 examiners.
b) The submitted take-home case study from applicants shall be provided to the panel one week before the interview.
c) During the interview, the viva would be included for evaluation of the take-home case study.

9.6.4 Interview evaluation methodology

a) Evaluation for the interview is to be done by a panel of 3 examiners
b) The maximum time for interview evaluation would be 1 hour per candidate.
c) The interview shall cover competence standards, evidence review, as well as the take-home case studies.

### 9.7 Mandatory Evaluation Methods by Level

| Level | Mandatory Methods |
|---|---|
| Consultant | Written assessment, Take-home Case Study, Interview |
| Senior Consultant | Written assessment, Take-home Case study, Interview, Evidence review |
| Principal Consultant | Take-home Case study, Interview, Evidence review |

**These are mandatory methods for first-time applications. But in case of renewal and renewal at an upgraded level, the following would be applicable:**

| Level | Mandatory Methods |
|---|---|
| Consultant | Written assessment, Take-home Case Study, Interview |
| Senior Consultant | Take-home Case study, Interview, Evidence review |
| Principal Consultant | Interview, Evidence review |



## 10. Examiner Guidance – Scoring & Judgment

### 10.1 Examiner Guide for Unbiased and Evidence-Based Judgment

Examiner shall:

a) Use the approved **10-point scoring scale** consistently

b) Base scores on **demonstrated evidence**, not assumptions

c) **Record clear justifications** for each domain score

d) **Avoid bias** related to employer, qualification, or background in the context of education, religion, region, and culture

e) Each evaluation methodology shall have **equal weightage**

### 10.2 Scoring Scale

| Score | Interpretation |
|---|---|
| 0–5 | Inadequate or limited competence |
| 5–7 | Adequate / working-level competence |
| 7–9 | Strong/independent competence |
| 9–10 | Expert / leadership-level competence |

### 10.3 Level-wise Minimum Qualification Criteria

| Sl. No. | Criterion | Requirement for Level 1- Consultant | Requirement for Level 2- Senior Consultant | Requirement for Level 3- Principal Consultant |
|---|---|---|---|---|
| **1** | Overall Score | ≥ 49 / 70 (70%) | ≥ 72 / 90 (80%) | ≥ 81/90 (90%) |
| **2** | Minimum Score per Domain | ≥ 5 / 10 | ≥ 6 / 10 | ≥ 7 / 10 |
| **3** | Mandatory Domains | A, B, C, D, E, F, G | All (A–I) | All (A–I) |
| **4** | Experience Expectation | Foundational consulting exposure | ~10 completed consulting projects | ~25 completed consulting projects |
| **5** | Independence Level | Works under guidance | Independently manages engagements | Strategic leadership & mentoring |
| **6** | Competence Intent | Working-level competence sufficient to support regulatory and QMS activities | Independent consultant capable of leading projects and audits | Expert-level consultant with strategic, mentoring, and policy interpretation capability |

## 11.Certification Decision

11.1 Decision on certification shall be taken based on evaluation of the objective evidence collected during the Assessment process.

11.2 Records of the evaluation and decision shall be maintained.

11.3 Candidates will be informed about their right to appeal against the decision and procedure that for without request beforehand.

11.4 Evaluation results shall be reviewed by an independent certification decision-maker(s) who has not been involved in the evaluation process

11.5 Certification decisions shall be based solely on evaluation evidence

11.6 Certification level awarded shall be documented

11.7 Candidates meeting all applicable criteria shall be granted certification at the applied level.

11.8 Where the overall score is achieved, but one or more domain minimums are not met, the candidate will be given an option:

- 11.8.1 To undergo the full re-evaluation within a period of 6 months
- 11.8.2 To opt for a grant of certification at a lower level, provided the criteria for the lower level are met.
- 11.8.3 In case the candidate fails to appear in the re-evaluation within the period of 6 months or has failed in the re-evaluation, the candidate shall be required to reapply for certification.

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## 12. Certification Validity:

12.1. Certification validity would be for 3 years from the date of issuance, provided there are no changes notified by the Scheme Owner and PrCBs for the competence standard prescribed under the Scheme [document no. LSSSDC/MDCCS/CS/D/V0.2].

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## 13. Certification Agreement:

13.1. Every candidate shall sign an agreement, inclusive of the code of conduct and ethical practices, with PrCB prior to the issuance of the certificate.

13.2. As a reference to PrCBs, a model code of conduct and ethical practices is provided in **Annexure II**

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## 14. Surveillance

14.1. Surveillance in case of a change in the Competence Standard

In the event of any significant change in the competence requirement, the certified candidates may have to undergo a special evaluation with a limited scope specific to the change.

14.2. Regular Surveillance

14.2.1. Surveillance to be conducted between 15 and 18 months from the date of certification.

14.2.2. For the certified Medical Devices consultants who have been working consistently in the field of Medical Devices & In Vitro Diagnostics (IVD) Industry/regulatory body after being certified, for them, there will be no surveillance assessment on the production of evidence that the professional has been productively employed/delivered services as a consultant in a similar capacity.

14.2.3. For surveillance purposes, the certified consultant shall be required to submit the details of consulting projects undertaken in the last 15 months.

14.2.4. Possible evidence shall be

a. Number of projects delivered over the period, including the issues identified during the CDSCO /Notified Body audits.
b. Feedback from the client
c. Credits provided by LSSSDC for any recognized programs/ activities. A table of credits would be provided by LSSSDC in the public domain.

14.2.5. For those who are unable to provide any evidence of working as a Medical Devices consultant or professional, or if client feedback is negative, and the consultant wishes to continue with their certified status, they will have to undergo re-evaluation through an interview as surveillance.

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## 15. Recertification

15.1. Recertification shall be undertaken before the expiry of the certificate and any time after 2.5 years.

15.2. The recertification will be through the same assessment process as the initial certification for all certified professionals and completed before expiry.

15.3. The PrCB shall send the Renewal notice to the certified Medical Devices Consultant at least 6 months before the expiry of the certificate validity period to the registered email ID and/or to the registered address.

15.4. The certified Medical Devices Consultant shall apply for renewal in the prescribed format along with a fee as prescribed at least 4 months before the expiry of certification.

15.5. The PrCB shall review the performance of the certified Medical Devices Consultants seeking recertification (renewal of the Certificate), with regard to compliance with certification criteria during the entire certification cycle. The performance of the certified **Medical Devices Consultants** shall be reviewed based on the recertification assessment:

15.5.1. The surveillance assessment report(s);
15.5.2. Corrective actions are taken on any feedback given during surveillance;
15.5.3. Any suspension of the certificate during the previous validity period;
15.5.4. Complaints received, if any;
15.5.5. Feedback on his professional services to be obtained by the PrCB;
15.5.6. Feedback reports from the institution where the consultant was employed, if applicable, to be obtained by the PrCB;
15.5.7. Adverse information, if any.

15.6. Recertification of the certified Medical Device Consultants shall be based on their satisfactory performance during the previous certification period and shall be done before the expiry of the certification.

15.7. The PrCB shall not recertify Medical Device Consultants with conditions for compliance to be verified subsequently. There shall be no conditional recertification of Medical Devices Consultants.

15.8. The PrCB shall not recertify any certified Medical Device Consultants whose certification is under suspension till conditions for revocation are met.

15.9. When the performance of the certified Medical Device Consultant is not satisfactory, the PrCB shall withhold the recertification of the Medical Device Consultant, clearly state the reasons, and give time to effect corrective actions. The verification and decision on recertification shall be taken within 6 months of the expiry date

15.10. The PrCB shall verify corrective actions.

15.11. The recertification shall be effective from the date of the expiry of the previous certificate, and the intervening period shall be treated as a period of suspension. The certified Medical Device Consultants shall not claim certification during this period.

15.12. If the certified Medical Device consultant does not satisfactorily complete the actions within 3 months, a 15-day show-cause notice shall be served, with an opportunity to respond / personal hearing, prior to any adverse decision. After 15 days, the certificate shall stand expired from the date of expiry of the previous validity.

15.13. When a certificate is not renewed, it expires at the end of the validity period.

## 16. Change Of Level Of Certification

16.1. A change to a higher level of certification, if prescribed, on application by a Medical Device Consultant, shall be made after ascertaining competence through the prescribed means of assessment for that level of certification.

16.2. The candidate shall be issued a fresh certificate as an initial certification instead of the current certificate after returning the lower-level certificate.

## 17. Suspensions And Withdrawal

17.1. The PrCB shall issue instructions to the certified person for suspension of certification, with due notice of 15 days after giving a chance to respond and a personal hearing, if desired by the professional, when:

17.1.1. The surveillance shows unsatisfactory performance;

17.1.2. Any serious complaint/feedback which is found to be valid;

17.1.3. Any administrative requirement like payment of a fee or timely provision of information;

17.1.4. Any violation of the terms and conditions of certification.

17.1.5. any action of a certified professional that brings the certification scheme or LSSSDC into disrepute

17.2. On receipt of instructions for suspension of certification, the certified Medical Device Consultants shall, with immediate effect, remove any reference to certification in all of their communications.

17.3. The certified Medical Devices Consultant shall be advised to undertake a root cause analysis and identify and initiate necessary corrective actions for resolving the same.

17.4. Suspension shall not exceed six months, and provided it is still within the validity period of the certificate. The Certified Medical Device Consultant's inability to resolve issues relating to suspension within this period shall lead to cancellation of certification.

## 18. Withdrawal Of Certification

18.1. **PrCB** shall withdraw the certificate when:

18.1.1. Certified **Medical Device Consultants** contravene the terms and conditions of certification and provisions of this certification scheme, like claiming or displaying the scope of certification other than that granted;

18.1.2. If any evidence of any fraudulent behaviour, or submitting false information, or concealment of information is established;

18.1.3. The corrective actions taken are not ensuring compliance, or the proposed plan for corrective actions will take a considerable time beyond 3 months for implementation;

18.1.4. Any administrative requirement, like payment of a fee or timely provision of information;

18.1.5. Any action of a certified medical device consultant that brings the certification scheme or LSSSDC into disrepute.

18.2. PrCB/LSSSDC shall withdraw the certificate at the request of the certified Medical Devices Consultant if the certified Medical Device Consultant is no longer interested.

18.3. In the event of withdrawal, the PrCB shall advise the certified Medical Device Consultant to return the certificate issued by the PrCB.

18.4. Any suspension or withdrawal of certification shall be publicly available on the Scheme Owner's and PrCB's website.

## 19. Complaints

19.1. The complaints-handling process is an essential control mechanism within the personnel certification system. PrCB and LSSSDC shall establish, implement, and maintain a documented process for receiving, evaluating, and making decisions on complaints received from any stakeholder with public accessibility.

19.2. The complaint procedure shall be designed to treat all parties — complainants, applicants, certified persons, and other affected stakeholders — fairly and equitably.

19.3. Complaints shall be evaluated objectively, without bias or conflicts of interest, and by personnel who are independent of the subject matter where required.

19.4. Where a complaint about a certified person is substantiated, the body in receipt of the complaint, i.e., PrCB/ LSSSDC, shall refer the complaint to the certified person concerned at an appropriate time, and confidentiality shall be maintained.

19.5. Timeliness is critical for maintaining confidence in the certification process and preventing undue harm to any party involved. The entire complaint-handling and decision-making process shall be **completed within 30 calendar days** by the body in receipt of the complaint, i.e., PrCB/ LSSSDC.

## 20. Appeals

20.1. The appeal-handling process is a critical element of the certification system to support transparency and confidence in the decisions taken by the PrCB/LSSSDC. The appeals-handling process shall be publicly accessible, and any aggrieved candidate may appeal.

20.2. LSSSDC/PrCB shall retain full responsibility for all decisions taken at every level of the appeals-handling process and shall not delegate this responsibility externally.

20.3. The appeal decision-making shall be made by the LSSSDC, or a notified panel by LSSSDC/ PrCB, who is not involved in the original examination, evaluation, or certification decision that is under appeal. The notified panel by LSSSDC/PrCB may constitute an appeal panel comprising medical device and personnel certification experts who are not involved in evaluation and decision-making.

20.4. Throughout the appeals process, PrCB/LSSSDC shall keep the appellant informed by providing timely progress updates. This includes acknowledgment of receipt of the appeal, information on the status of the review, and notification of any delays or additional steps required. Once a decision is reached, PrCB/LSSSDC shall clearly communicate the outcome, including the rationale for the decision where appropriate.

20.5. The entire appeal handling and decision-making shall be **completed within 30 calendar days**.

## 21. Records And Confidentiality

21.1. All records shall be:

21.1.1. Maintained securely

21.1.2. Treated as confidential

21.1.3. Retained as per PrCB /LSSSDC procedures

21.1.4. As per any regulatory or professional requirement

21.2. In the absence of any regulatory or professional requirement, the retention of the records shall be maintained for the current and previous cycles.

## 22. Fee

22.1. A fee will be charged to the person seeking certification without any discrimination.

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

22.3. The PrCB shall notify and obtain consent to its fee structure at the application stage from the candidate before granting of certification.

22.4. As and when the fee changes, the same shall be communicated to all, including applicants, and their consent shall be obtained at the renewal application stage.

## Annexure-I: Medical Device Consultant Certification Scheme

### Application Form

| Applicant Information | | | |
|---|---|---|---|
| First Name | | | |
| Last Name | | | |
| Address | | | |
| City/State/Pin | | | |
| Phone | | Alt Phone | |
| Email | | | |
| Date of Birth | | | |
| **Educational Background** | | | |
| Highest Degree | | | |
| Field of Study | | | |
| Institution | | | |
| Year of Graduation | | | |
| **Professional Background** | | | |
| Total Work Experience | | | |
| Current Role | | | |
| Job Title | | | |
| Organization | | | |
| Years in Current Role | | | |
| Brief Description of Current Responsibilities: | | | |

| Relevant Experience in Medical Devices/ Healthcare | |
|---|---|

| **Domain Expertise (Check if applicable)** | |
|---|---|
| ☐ Regulatory Affairs | ☐ Manufacturing Post-Market |
| ☐ Quality Assurance / QMS | ☐ Surveillance |
| ☐ Clinical Affairs | ☐ Healthcare Practice |
| ☐ Product Development | ☐ Consulting |
| Others: (Please specify): | |

| **Knowledge of Standards & Regulations** |
|---|
| *Regulatory Knowledge (Indian MDR 2017, CDSCO process and International Regulations (EU MDR, US FDA, UKMHRA, TGA, etc.))* |
| ISO 13485: |
| ISO 14971: |
| Clinical Evaluation: |

| **Key Projects / Assignments handled** | |
|---|---|
| Project 1: | |
| Your Title: | |
| Organization/ Client: | |
| Your Role: | |
| Outcome Impact | |
| *Note: Add additional sheets to describe additional projects* | |

| **Statement of Purpose** |
|---|
| (Why do you want to become a certified Medical Devices Consultant? Indicate what you believe is your core competence) |

| **Intended Certification Level** | | |
|---|---|---|
| ☐ Level 1 Consultant | ☐ Level 2 – Senior Consultant | ☐ Level 3 – Principal consultant |

| **Supporting Documents (Check and Attach the following)** |
|---|
| ☐ Resume/CV |
| ☐ Details of educational achievements |
| ☐ Details of Professional Qualifications and/or courses attended |

☐ Details of Work Experience
☐ Details of any special/significant achievement
☐ ID Proof (Aadhar card or any other government issued Identification

## Professional References

**Reference 1**

| | |
|---|---|
| Name: _____ | Email: _____ |
| Designation: _____ | Contact no: _____ |
| Organization: _____ | Relationship: _____ |

**Reference 2**

| | |
|---|---|
| Name: _____ | Email: _____ |
| Designation: _____ | Contact no: _____ |
| Organization: _____ | Relationship: _____ |

## Self-Assessment (Briefly assess yourself in the disciplines below)

Regulatory Knowledge:

QMS Understanding:

Risk Management:

Consulting Skills:

## Declaration

I hereby declare that the information provided is true and accurate.

Signature:

Date:

## Annexure-II: Model code of conduct and ethical practices for Medical Device Consultant

### CODE OF ETHICS

The **LSSSDC** as the **Scheme Owner** has the responsibility of verifying the quality and integrity of the assessment services provided by its approved Personnel Certification Bodies (PrCBs).

LSSSDC is committed to maintaining the trust and respect of the members of its various committees, office bearers, clients, stakeholders, **certified consultants** and the public at large through unquestionable integrity, honesty, independence and ethical business conduct.

All personnel engaged in LSSSDC's **Medical Device Consultant Certification Scheme (MDSCS)** – staff, committee members, assessors, technical experts, certified MD Consultants - are expected to uphold the basic ethics. In addition to the requirements of the code of ethics and conflict of interest disclosure prescribed herein, they shall also comply with applicable national and state laws and regulations.

The personnel involved with the Scheme shall abide by the following to maintain integrity:

1. Act impartially ensuring that he/she is independent in judgment and actions and take all reasonable steps to be satisfied as to the soundness of all decisions taken.
2. Act honestly, in good faith, in the true spirit, be ethical, have adaptability, able to think critically and in the best interest as per the procedures and instructions of LSSSDC and not engage in conduct likely to bring discredit upon LSSSDC.
3. Apply due care and diligence in fulfilling the functions of assessment and exercising any powers attached therewith.
4. Submit the assessment report/inputs complete in all respects for the assessments carried out as per the timelines prescribed.
5. Not disclose to a third party any information of proprietary nature about the certification and the assessment findings/outcome that would be gathered as part of the assessment process and remain bound by confidentiality even after opting out/retiring from LSSSDC related activities.
6. The assessment report and the notes on the assessment will be the property of LSSSD and not be disclosed to any third party.
7. Updated copy of the procedures, documents, rules, and regulations of LSSSDC, as available on its website, or any specific information provided by the LSSSDC secretariat from time to time shall be abided by.
8. LSSSDC secretariat to be contacted by anyone who is in doubt with regard to a specific business conduct question or would like to report an infraction.
9. Report to the LSSSDC secretariat of any conflicts, or potential conflicts of interest, arising out of the fulfillment of his/her duties and the responsibilities as a staff member/committee member/assessor/technical expert.
10. Each person involved in a specific case shall disclose his/her past and present associations with the entity to be assessed and/or the group of companies to which it belongs or any entity engaged in assessment.

11. The assessor and technical expert shall not witness assessments of those organizations where he/she has been engaged as consultant/employee/in any other role which may affect impartiality for at least 2 years since separation from it that can be or perceived to adversely affect the impartiality of the process. Any association with the organization to be witnessed shall be brought to the notice of the LSSSDC secretariat. The same applies to members of decision-making and appeals panels.
12. LSSSDC shall be informed of any requests from any competing organization for any service received to enable LSSSDC to take a view before accepting such a request.
13. Any committee member or assessor or technical expert shall not market himself/herself as LSSSDC Scheme committee member/assessor/technical expert for gaining work or misuse his/her position.
14. The organization to be assessed for LSSSDC certification shall book accommodation and provide local transport for assessors and technical experts.
15. The assessor and technical expert shall avoid consumption of alcohol during LSSSDC assessment visits and in any case not consume alcohol during the assessment or charge it to the organization seeking approval/accreditation. No personal expenses or laundry bills etc. shall be charged by the assessor and technical expert, except for the food expenses.
16. The assessor/technical expert shall refrain from using his/her mobile phone during assessments except during breaks.
17. No gifts to be accepted by the assessment team.
18. None of the Committee members involved in decision/appeals panels or assessor or technical expert shall have any financial dealing with organizations assessed/accredited/approved by LSSSDC. Any expenses incurred shall be claimed from LSSSDC.
19. For any complaints received against the assessment team for non-compliance of the code of ethics, LSSSDC shall investigate, in accordance with the LSSSDC's Scheme Complaint's Procedure.

Signed by

Name

Address

District State Pin Code

Contact No

Email ID



**End of Certification Scheme Manual – Version 0.2**