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Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(In-Vitro Diagnostic Division)

This document serves as guidance for manufactures for submitting product licence applications to CDSCO through the “cdscomdonline” and “NSWS” portal. It outlines the specific details to be furnished in each section of the application, ensuring alignment with the corresponding sections of the checklist for completeness and accuracy for getting timely approval.

This document is now being placed in the public domain for comments/suggestions from relevant stakeholders. All stakeholders are requested to provide their comments/suggestions within 15 days from the date of publication of this document.

Google Form Link for providing comments on the Guidance document on
“Guidance for Manufacturing of In-Vitro Diagnostic Medical Device”

https://docs.google.com/forms/d/e/1FAIpQLSez2yrue7Vv58vf9FXq4vrKqK-kDs0BiZo68xBK7kSNiU3_-A/viewform?usp=publish-editor

Guidance document for Manufacturers for In-Vitro Diagnostic Medical Device

For submission of Manufacturing license applications on the Online System for Medical Devices



**Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India**

Notice: This Guidance document is aimed only for creating public awareness about In-Vitro Diagnostic Devices Regulation by CDSCO/SLA and is not meant to be used for legal or professional purposes. The readers are advised to refer to the statutory provisions of Medical Devices Rules, 2017 and subsequent amendments, guidance document, clarifications, FAQ's, and tool tip on CDSCO website.

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Abbreviation:

BARC	Bhabha Atomic Research Centre
CDSCO	Central Drugs Standard Control Organisation
CLA	Central Licensing Authority
CPE	Clinical Performance Evaluation
DMF	Device Master File
EDTA	Ethylene Diamine-tetraacetic Acid
EPC	Essential Principle Checklist
EU	European Union
FSC	Free Sale Certificate
FSCA	Field Safety Corrective Action
IFU	Instructions for Use
IVD	In-Vitro Diagnostics
ISO	International Organization for Standardization
IVDMD	In vitro Diagnostic Medical Device
MDR	Medical Device Rules
Min	Minute
NOC	No Objection Certificate
NRA	National Regulatory Authority
NSWS	National Single Window System
PER	Performance Evaluation Report
PMDs	Personalized Medical Devices
PMF	Plant Master File
PMS	Post Marketing Surveillance
POA	Power of Attorney
QC	Quality Control
QMS	Quality Management System
RIA	Radio Immuno Assay
SLA	State Licensing Authority
WHO	World Health Organization
LLP	Limited Liability Partnership
AOA	Articles of Association
MOA	Memorandum of Association
COI	Certificate of Incorporation

Scope

This guidance document aims to aid domestic manufacturers of In-Vitro Diagnostic (IVD) medical devices in understanding and complying with regulatory requirements by providing a step-by-step overview of the procedures, documentation, and regulatory obligations under the Medical Device Rules, 2017 (MDR 2017), and the Drugs and Cosmetics Act, 1940.

A key feature of this document is that it provides a quick outline of essential documents in a manufacturing licence application such as device risk classification, essential principles of safety and performance, grouping of IVDs in the application, substantial equivalence, evidence related to the predicate device, Notified Body audit, device verification and validation, performance evaluation, clinical performance evaluation, labelling, qualification & experience of personnel in manufacturing and testing, risk assessment & mitigation, quality management system (QMS) compliance, and post market surveillance.

In addition, this guidance underscores the importance of early regulatory engagement and proactive compliance planning, establishing good quality management system, enabling developers to align their innovations with both national and international best practices. It also highlights the necessity of robust verification and validation of test methodologies, ensuring that the extent of validation is appropriately proportionate to the potential risks posed by the IVD to users, patients, or public health.

By adhering to these structured guidelines, manufacturers can ensure that their devices comply with the minimum required safety, efficacy, and quality standards.

1. Introduction

An In-Vitro Diagnostic (IVD) medical device is a medical device used for in-vitro diagnosis of human or animal samples. IVD medical devices include reagents, calibrators, control materials, specimen receptacles, software, instruments, or analyzers or apparatus, and other related articles whether used alone or in combination, intended for the in-vitro examination of specimen derived from human or animal body solely used for diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, and determination of physiological status, to provide information for diagnostic, monitoring or compatibility purposes.

1.1 Purpose- This document aims to serve as guidance for Manufacturers of IVD while making manufacturing applications to Central Licensing Authority/State Licensing Authority, as the case may be, through the Online System for Medical Devices or the National Single Window System (NSWS) portal. It outlines the specific details to be provided in each section of the application, ensuring alignment with the corresponding checklist sections for completeness and accuracy, thereby facilitating timely approval.

1.2 Key definitions

1. **Accuracy:** Accuracy means the closeness of agreement between a measured value and the true or accepted reference value, where applicable.
2. **Analyte:** Analyte means the substance, constituent, microorganism, nucleic acid, antigen, antibody, metabolite, biomarker, or other measurable or detectable target intended to be detected or measured by an IVD.
3. **Analytical Performance:** Analytical performance means the ability of an IVD to correctly detect or measure an analyte under specified conditions, including characteristics such as accuracy/trueness, precision, analytical sensitivity, analytical specificity, measuring range, and related performance characteristics.
4. **Analytical Sensitivity:** Analytical sensitivity means the ability of an IVD to detect or measure an analyte at low concentrations.
5. **Analytical Specificity:** Analytical specificity means the ability of an IVD to detect or measure the intended analyte without being significantly affected by other substances, analytes, or conditions that may be present in the specimen.
6. **Assay Cut-off:** Assay cut-off” means the predetermined value of a measurable assay response or test result that serves as the decision threshold for interpreting a diagnostic test result as positive, negative, reactive, non-reactive, detected, or

not detected, as applicable to the intended purpose of the in vitro diagnostic medical device.

7. **Clinical Evidence:** Clinical evidence means information demonstrating the clinical safety, performance, and conformity of an IVD medical device with applicable essential principles, including relevant clinical performance data and supporting scientific evidence. The document identifies analytical and clinical performance as elements of clinical evidence.
8. **Clinical Performance:** Clinical performance means the ability of an IVD to yield results that are correlated with a particular clinical condition, physiological or pathological process, or clinical state, consistent with its intended purpose.
9. **Corrective and Preventive Action (CAPA):** Corrective and Preventive Action (CAPA) means a systematic process for identifying and investigating non-conformities or potential problems, determining their root causes, implementing corrective and preventive measures, and verifying their effectiveness.
10. **Cross-Reactivity:** Cross-reactivity means the ability of an assay to react with substances or analytes other than the intended target, potentially resulting in an incorrect or misleading test result.
11. **Device Master File (DMF):** Device Master File (DMF) means the technical documentation containing information necessary to provide a general understanding of the IVD medical device, including its intended use, design, specifications, manufacturing information, risk management, verification and validation, analytical and clinical performance, stability, labelling, and other applicable information.
12. **Endorsement:** Endorsement means the regulatory process for adding an IVD medical device to an existing manufacturing licence, where the device is proposed to be manufactured at an already licensed manufacturing site.
13. **Essential Principles:** Essential Principles means the fundamental requirements relating to the safety and performance of an IVD medical device with which the device is required to conform, as applicable under the Medical Devices Rules, 2017.
14. **Essential Principles Checklist (EPC):** Essential Principles Checklist means a structured document identifying each applicable Essential Principle, its applicability, the method used to demonstrate conformity, relevant standards or

specifications, controlled documents providing evidence, and justification or comments.

15. **Field Safety Corrective Action (FSCA):** Field Safety Corrective Action (FSCA) means an action taken by a manufacturer to reduce the risk of death or serious deterioration in health associated with an IVD medical device that has already been placed on the market.
16. **Instructions for Use (IFU):** Instructions for Use (IFU) means the information supplied by the manufacturer describing the intended use and instructions necessary for the proper, safe, and effective use of the IVD medical device.
17. **Intended Use:** Intended use means the objective purpose of an IVD medical device as specified by the manufacturer and reflected in the label, IFU, product/package insert, product manual, or related technical documentation, including the intended clinical purpose, analyte, specimen type, intended user, target population, and applicable testing environment.
18. **Intended User:** Intended user means the person or category of persons for whom the IVD medical device is designed or intended to be used by, such as a trained laboratory professional, healthcare professional, point-of-care user, or layperson for self-testing.
19. **Interference:** Interference means the effect of an endogenous or exogenous substance or condition present in a specimen that causes a clinically or analytically significant deviation in the measurement or interpretation of an IVD result.
20. **In-use Stability:** In-use stability means the ability of an IVD to maintain its specified quality and performance characteristics for the defined period after opening, reconstitution, activation, or commencement of use, under specified conditions.
21. **IVD System:** IVD System means a combination of IVD components, including applicable instruments, reagents, calibrators, controls, software, or accessories, designed to work together to perform a specified IVD function or testing process.
22. **IVD Test Kit:** IVD Test Kit means a set of components, reagents, or articles intended to be used together to perform a specified IVD test and meeting the applicable criteria for grouping as a test kit.
23. **Labelling:** Labelling means information provided on the IVD medical device, packaging, product insert, or associated documentation that identifies the device

and communicates information necessary for its safe and intended use. The document includes device identification, manufacturer details, intended use, warnings, storage conditions, and expiry/shelf-life information within its labelling requirements.

24. **Limit of Blank (LoB):** Limit of Blank (LoB) means the highest apparent analyte concentration expected to be observed in a defined proportion of measurements of a sample containing no analyte.
25. **Limit of Detection (LoD):** Limit of Detection (LoD) means the lowest amount or concentration of an analyte that can be reliably distinguished from the absence of the analyte under specified conditions.
26. **Limit of Quantitation (LoQ):** Limit of Quantitation (LoQ) means the lowest concentration of an analyte that can be quantitatively measured with specified requirements for accuracy/trueness and precision.
27. **Loan Licence:** Loan Licence means a licence granted to a person who intends to manufacture a medical device by utilizing the manufacturing site of another licensee for manufacturing the same medical device manufactured by that licensee at that site.
28. **Lot / Batch:** Lot or Batch means a defined quantity of an IVD or its components manufactured under essentially the same conditions and identified by a unique number or designation to enable traceability.
29. **Manufacturer:** Manufacturer means a person or entity responsible for the design, manufacture, packaging, labelling, and/or processing of an IVD medical device before it is placed on the market under its name or ownership, whether or not such operations are carried out by that person or entity itself.
30. **Manufacturing Licence:** Manufacturing Licence means the licence granted by the applicable Licensing Authority permitting manufacture of IVD medical devices for sale or distribution in accordance with the Medical Devices Rules, 2017.
31. **Manufacturing Site:** Manufacturing site means the premises or facility at which one or more activities related to the manufacture, processing, assembly, testing, packaging, labelling, storage, or release of an IVD medical device are carried out.
32. **Measuring Range:** Measuring range means the range of analyte concentrations over which an IVD provides results that meet predefined performance requirements under specified conditions.

33. **New IVD Medical Device:** New IVD medical device means an IVD medical device which do not have a similar device (in terms of detectable parameter, technology, sample/specimen type, etc.) approved by central licensing authority to market in India.
34. **Non-conforming IVD:** Non-conforming IVD means an IVD medical device that does not meet one or more specified requirements, specifications, acceptance criteria, regulatory requirements, or applicable quality standards.
35. **Performance Evaluation Report (PER):** Performance Evaluation Report (PER) means a documented report containing the relevant performance evaluation data and conclusions demonstrating the performance of an IVD medical device and tested by a laboratory/ hospital as per the provision of Clause (h), Paragraph (ii), part II of Fourth Schedule of Medical Devices Rules 2017.
36. **Performance Evaluation:** Performance evaluation means the systematic process of assessing and demonstrating the analytical and, where applicable, clinical performance of an IVD medical device to establish conformity with applicable requirements.
37. **Plant Master File (PMF):** Plant Master File (PMF) means a document providing a comprehensive description of the manufacturing site, including premises, layout, personnel, equipment, manufacturing activities, quality systems, storage, testing facilities, sanitation, documentation, and other site-related information relevant to regulatory assessment.
38. **Post-Market Surveillance (PMS):** Post-Market Surveillance (PMS) means the systematic collection, review, evaluation, and assessment of information relating to the safety, quality, and performance of an IVD after it has been placed on the market. The document includes complaints, vigilance reporting, and CAPA within PMS-related documentation.
39. **Precision:** Precision means the closeness of agreement among independent measurement results obtained under specified conditions and is generally associated with random error.
40. **Predicate Device:** Predicate device" means a device, first time and first of its kind, approved for manufacture for sale or for import by the Central Licensing Authority and has the similar intended use, material of construction, and design characteristics as the device which is proposed for licence in India.

41. **Qualitative Test:** Qualitative test means an IVD test that provides a categorical result, such as positive/negative, reactive/non-reactive, or detected/not detected.
42. **Quality Management System (QMS):** Quality Management System (QMS) means the structured system of policies, procedures, processes, responsibilities, resources, and controls established by a manufacturer to consistently ensure that IVD medical devices meet applicable quality, safety, performance, and regulatory requirements.
43. **Quantitative Test:** Quantitative test means an IVD test that provides a numerical measurement of the concentration or quantity of a specified analyte.
44. **Repeatability:** Repeatability means precision under repeatability conditions, such as the same method, operator, equipment, location, and short time interval, as applicable.
45. **Reproducibility / Intermediate Precision:** Reproducibility or intermediate precision means the consistency of assay results when measurements are performed under varying conditions, such as different days, runs, operators, sites, instruments, or lots, as applicable.
46. **Retention:** Retention means the regulatory process by which the validity of a manufacturing licence is continued by payment of the applicable retention fee and submission of required information/documents within the prescribed period. The document states that the manufacturing licence remains valid in perpetuity, subject to payment of the retention fee before completion of five years from the date of issue.
47. **Risk Classification:** Risk classification means the categorization of an IVD medical device according to its intended use, potential risk to the individual, user, or public health, as determined in accordance with the applicable classification parameters under the Medical Devices Rules, 2017.
48. **Risk Management:** Risk management means the systematic process of identifying, analysing, evaluating, controlling, and monitoring risks associated with an IVD medical device throughout its applicable lifecycle. The document refers to ISO 14971 as a recognized framework for risk analysis and control.
49. **Semi-quantitative Test:** A semi-quantitative test means an IVD test that provides results within defined categories, ranges, grades, or approximate concentrations rather than an exact quantitative measurement.

50. **Shelf Life:** Shelf life means the period during which an IVD medical device, when stored under specified conditions, is expected to remain within its established specifications and performance requirements.
51. **Shipping Stability:** Shipping stability means the ability of an IVD to maintain its specified quality and performance characteristics during transportation under defined real or simulated shipping conditions, including relevant temperature and environmental extremes.
52. **State Licensing Authority (SLA):** State Licensing Authority (SLA) means the authority designated under the Medical Devices Rules, 2017, responsible for regulatory functions, including the grant of manufacturing licenses for Class A and Class B IVD medical devices.
53. **Test Licence:** Test Licence means the licence permitting manufacture of a limited quantity of IVD medical devices for purposes such as clinical investigation, testing, evaluation, examination, demonstration, or training, as applicable under the Medical Devices Rules, 2017.
54. **Trueness:** Trueness means the closeness of agreement between the average of an infinite number of replicate measured values and a reference value, generally expressed in terms of bias.
55. **Validation:** Validation means the process of providing objective evidence that an IVD medical device or process is capable of consistently achieving its intended purpose and specified requirements under defined conditions.
56. **Verification:** Verification means the process of providing objective evidence that specified design or technical requirements of an IVD medical device have been fulfilled.
57. **Vigilance Reporting:** Vigilance reporting means the process of identifying, documenting, evaluating, and reporting safety-related information, incidents, complaints, and corrective actions associated with an IVD medical device after placing it on the market.

2. Licensing Authority

Under the Medical Devices Rules, 2017, the Central Licensing Authority (CLA), functioning through the Central Drugs Standard Control Organization (CDSCO) under the Directorate General of Health Services (DGHS), is the competent authority for granting manufacturing licences for Class C and Class D in vitro diagnostic (IVD)

medical devices. The State Licensing Authority (SLA) is the competent authority for granting manufacturing licences for Class A and Class B IVD medical devices.

3. Online portal for submission of applications

Application for grant of Manufacturing Licence for IVD Medical Device shall be submitted in the Online System for Medical Devices (www.cdscomdonline.gov.in) for Form MD-3/4/7/8, risk classification, condition fulfilment and licence surrender, and NSWs portal (www.nsws.gov.in) for Form MD-12.

4. Risk Classification of IVDs

IVD shall be classified on the basis of parameters specified in Part II of the First Schedule of MDR 2017 by the Central Licensing Authority, in the following classes:

Low risk- Class A

Low moderate risk- Class B

Moderate high risk- Class C

High risk- Class D

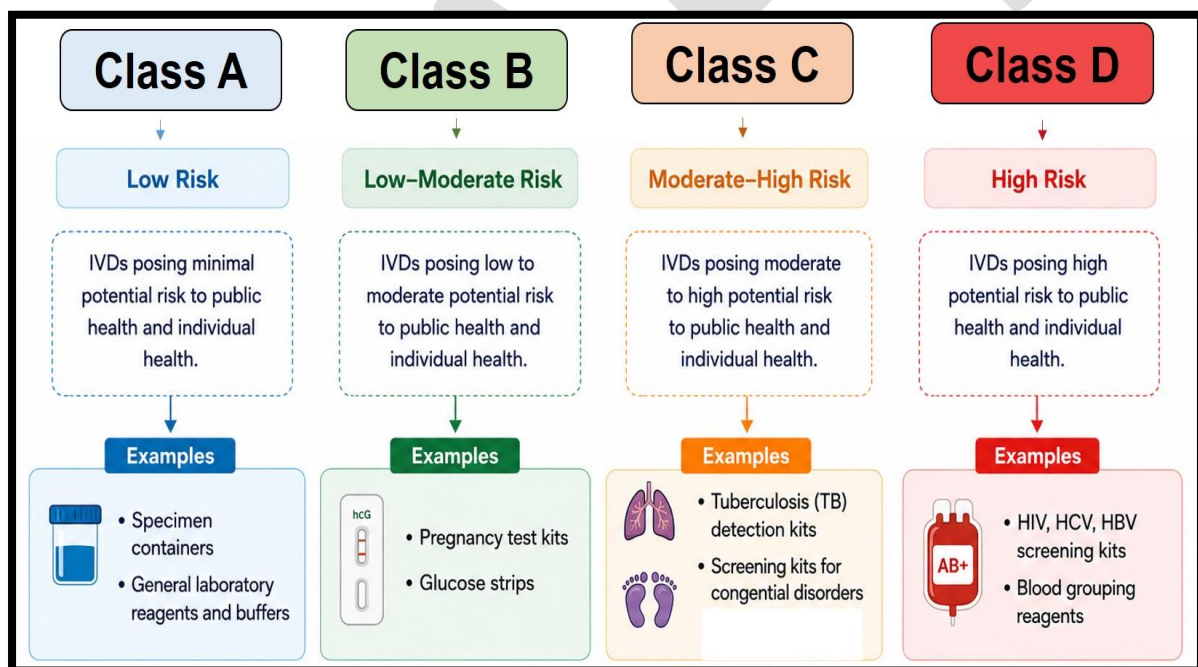


Figure 1: Risk classification of in vitro diagnostic medical devices (IVDs) under Medical Devices Rules 2017.

The risk classification list is dynamic in nature and updated from time to time. Manufacturers are highly encouraged to refer to notices on the subject “Classification of In-vitro Diagnostic Medical Devices under the provisions of Medical Devices Rules,

2017” published on www.cdsco.gov.in and auto-populated risk classification information in www.cdscomonline.gov.in.

5. Types of Manufacturing Licence Applications:

Test Licence to manufacture for test, evaluation, clinical investigations, etc.-

Small quantity of Class A or Class B or Class C or Class D of IVD medical devices may be manufactured for the purpose of clinical investigations, test, evaluation, examination, demonstration or training for which an application shall be made in Form MD-12 to the Central Licensing Authority and shall be accompanied with a fee as specified in the Second Schedule of MDR, 2017.

Manufacturing Licence for Sale and Distribution of IVDs - A fresh manufacturing licence is required when a new manufacturing facility is established, when a firm or company starts manufacturing IVDs for the first time, or when an application is submitted following a change in the constitution of the existing manufacturer.

Endorsement of IVDs to the Manufacturing Licence for Sale and Distribution- Refers to the addition of IVDs to an already approved licence. This includes incorporating a new in vitro diagnostic (IVD) device under the existing licence.

Loan licence- A licence issued for manufacturing a medical device by the State Licensing Authority or the Central Licensing Authority, as the case may be, to a person who intends to utilise the manufacturing site of another licensee for manufacturing the same medical device as manufactured by the licensee at that site.

Validity of manufacturing licence- A licence remains valid in perpetuity, provided the manufacturer pays the retention fee before completion of the period of five years from the date of issue of the licence. Retention fee includes both manufacturing site fee and device (included in licence and endorsement) fees as per the Second Schedule of the MDR, 2017. A retention application, including the fee and documents as per the checklist, needs to be submitted to CLA or SLA, as the case may be.

Table 1: Types of Manufacturing Licences and their Issuing authority

Licence Type	Device Class	Application Form	Licence Form	Issuing Authority
Manufacturing Licence	Class A & B	MD-3	MD-5	SLA

Loan Licence	Class A & B	MD-4	MD-6	SLA
Manufacturing Licence	Class C & D	MD-7	MD-9	CLA
Loan Licence	Class C & D	MD-8	MD-10	CLA
Test Licence	All Classes	MD-12	MD-13	CLA

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6. Regulatory pathway of IVD MD

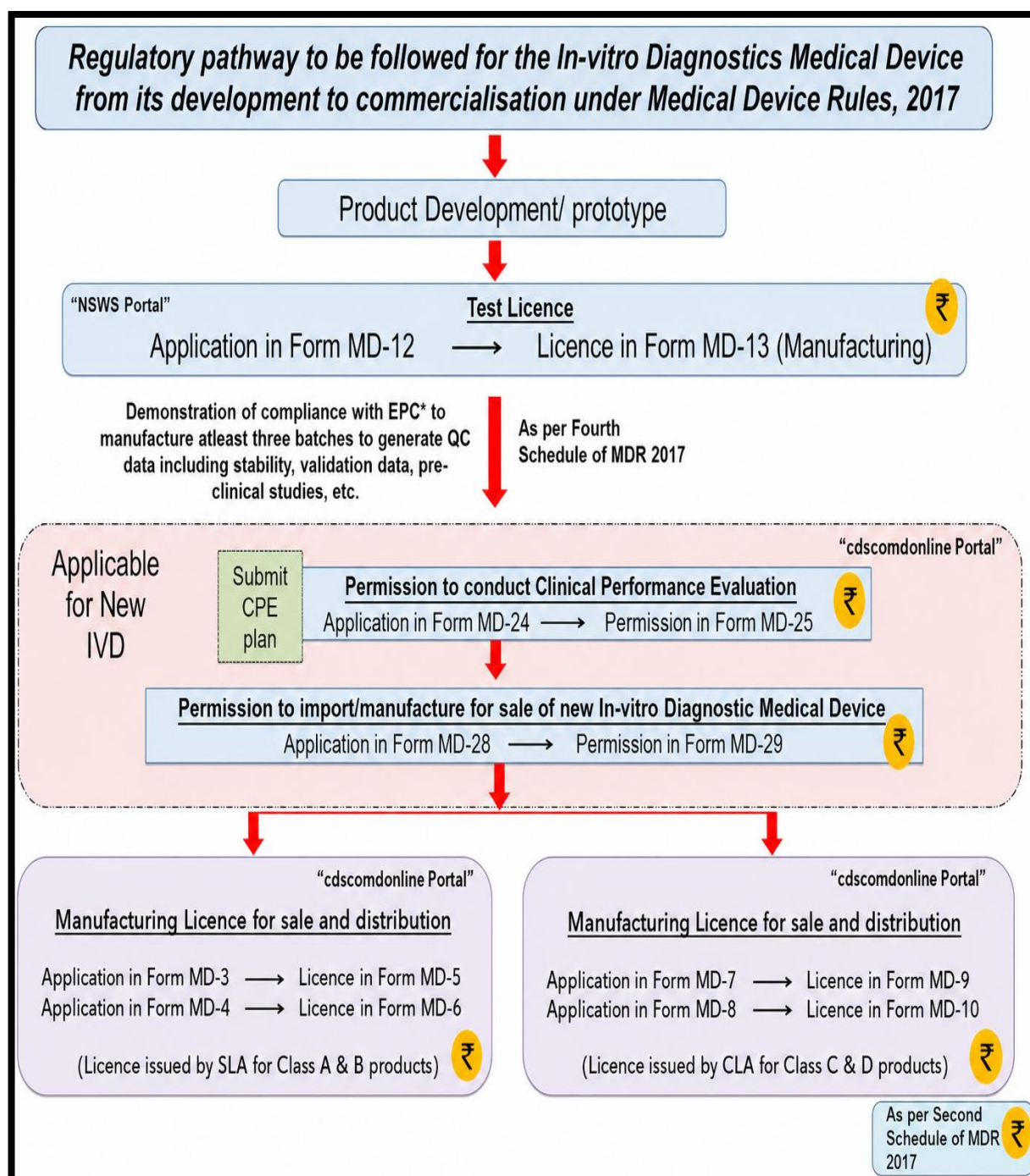


Figure 2: Schematic representation of the regulatory pathway for IVD Medical Devices Rules 2017

7. Pathway for various applications (Test, Fresh, Endorsement, Retention)

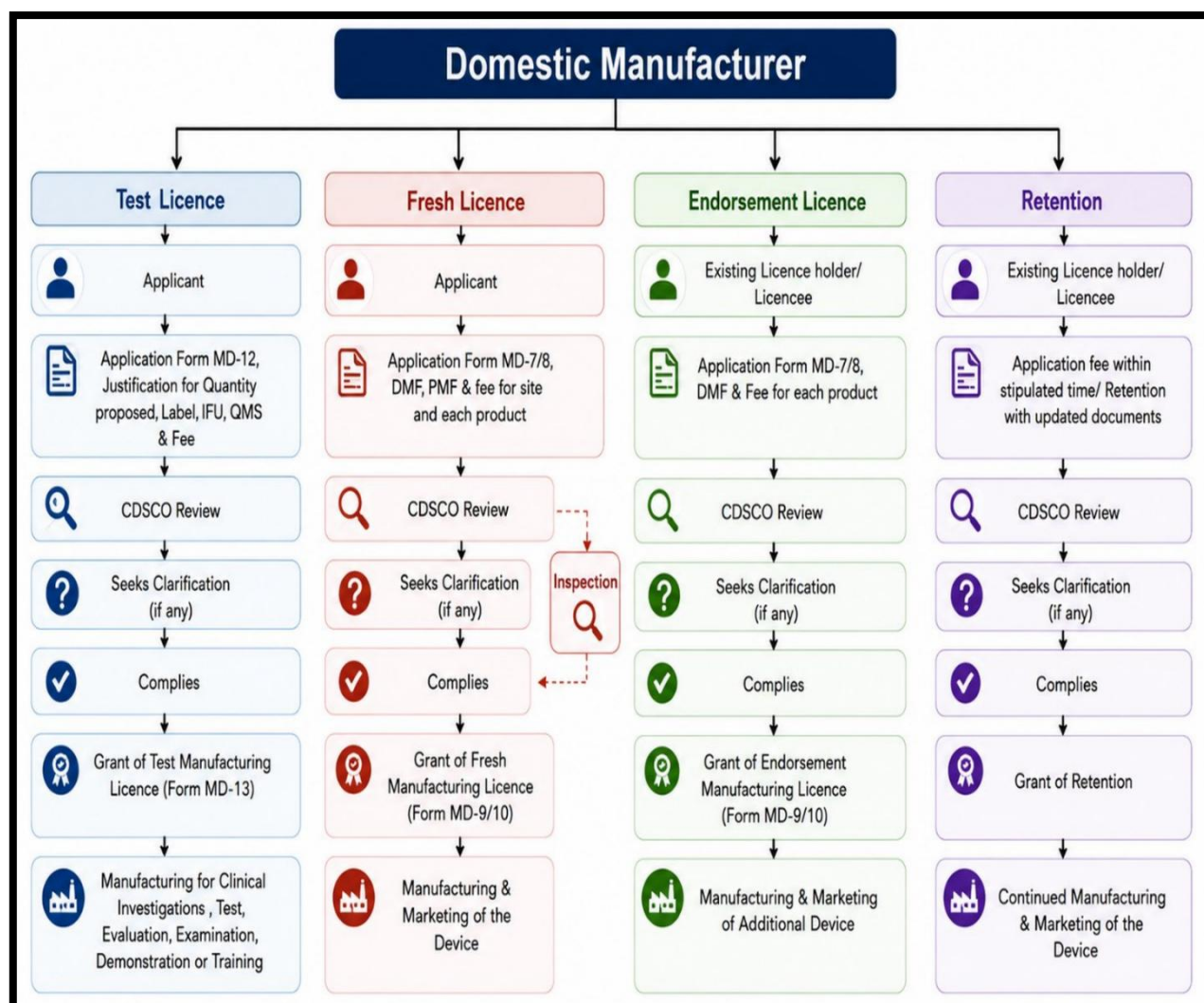


Figure 3: Regulatory pathway for test, fresh, endorsement and retention application for IVD medical devices under Medical Devices Rules 2017

8. Documents required

8.1 For application in Form MD-12

1. Covering letter: The cover letter should be on the company's official letterhead, mentioning the full address, and must be duly signed and stamped by the authorized signatory, whose signature is present on the Form MD12. It should clearly state the purpose of the application (purpose of manufacturing like clinical investigations, test, performance evaluation, examination, demonstration or training). The cover letter should include an index of enclosed documents with page numbers, relevant supporting information, and a detailed breakup of the prescribed fee, specifying the product class, number of products, and internal and external testing sites and manufacturing site details like name, address, email, phone number etc.

2. Brief description of the medical device, including intended use, material of construction, and design: The IVD medical device that is to be manufactured shall be intended for the purpose of examination, testing, performance evaluation, demonstration, or training, and is not meant for commercial sale or routine clinical use. The intended use should clearly describe the specific functions and context in which the device is used, e.g.,

- (1) Clinical purpose (options including but not limited to -screening, monitoring, staging, prognosis, diagnosis, or aid to diagnosis)
- (2) Type of output - Define whether the test is qualitative (positive/negative), quantitative (numerical values), or semi-quantitative.
- (3) Specimen Matrix: Detail the acceptable human body or animal samples (e.g., whole blood, serum, plasma, urine, sputum, body fluids, breath gases) and any required additives like anticoagulants
- (4) Intended User: Differentiate between a laboratory professional, a healthcare professional at the point of care/ near patient testing, or a layperson (for self-testing)
- (5) Target user: Define the specific patient demographic (e.g., adults, pediatric populations, symptomatic individuals, or pregnant women),
- (6) Age (if relevant to devices),
- (7) Target species: define the target species, such as human or animal species.
- (8) System Instruments: Mention if the test is manual, automated, or if it must be run on specific platforms (e.g., for use with the (Brand Name) Analyzer).

A structured template is given below for an indicative purpose,

The (Product Name) is an (automated/manual), (qualitative/quantitative) (in vitro diagnostic test/immunoassay/molecular assay) intended for the (detection/measurement) of (Analyte/Biomarker) in (human or animal species) (Specimen Matrix, e.g., serum or EDTA plasma).

This device is intended for use as an aid to diagnosis/screening/monitoring/prognosis of (Disease/Condition/Clinical State) in (Target Population, e.g., adult patients with signs and symptoms of infection).

It is designed for use by (Intended User, e.g., trained laboratory professionals) within a (Use Environment, e.g., clinical laboratory environment) on the (Instrument Name, if applicable). The device design, safety, performance, principle of operation, and material of construction shall be briefly described in the application.

Labelling medical device or a new in vitro diagnostic medical device for purpose of test, evaluation, clinical investigations, etc.: Any new in vitro diagnostic medical device manufactured, for the purpose of clinical performance evaluation, test, evaluation, demonstration and training, shall be kept in containers bearing labels, indicating the name of the product or code number, batch or lot number, serial number wherever applicable, date of manufacture, use before date, storage conditions, name and address of the manufacturer, and the purpose for which it has been manufactured.

3. Quality certificates like QMS etc., of the manufacturer from where the raw material is procured, if any: In case of test licence application for the purpose of testing and performance evaluation, the site from where raw materials are sourced for such IVD manufacturing facilities, are expected to have a quality management system. Any documentary evidence supporting the implementation of a quality management system may be submitted

4. Undertaking stating that the required facilities including equipment, instruments, and personnel have been provided to manufacture such medical devices: The firm/company needs to provide an undertaking stating that the “**Firm/Company Name**” having manufacturing premises address at “_____” hereby undertakes that the required facilities including equipment, instruments, and personnel have been provided to manufacture such medical devices. We assure you that all guidelines and conditions prescribed by the CDSCO or Medical Devices Rules, will be strictly adhered to.

5. List of equipment, instruments: The firm shall provide a complete list of equipment/instruments available/in use at the manufacturing facility for manufacturing of IVDs for the purpose of carrying out test or evaluation.

6. List of qualified personnel: The firm shall provide a list of qualified personnel associated with the manufacturing facility, along with their responsibility/allocated duties. The list needs to contain information on the educational qualification of qualified personnel, the number of years of experience in the manufacturing of IVD, and experience in testing of IVD (if planned to carry out in-house testing of IVD). The firm may submit mentioned details in below format:

Name of qualified personnel	Educational Qualification, and Designation	Brief summary on the experience in manufacturing of IVD and number of years of experience in manufacturing of IVD	Brief summary on the experience in testing of IVD and number of years of experience in testing of IVD (if planned for in house testing of IVD)	Summary of any other experience (if any)

A competent technical staff under whose direction and supervision the manufacturing activity of a medical device shall be undertaken, and such staff shall possess the following educational qualifications and experience:

(a) degree in engineering in a relevant branch or in pharmacy or in science in an appropriate subject from a recognized University and shall have experience of not less than two years in manufacturing or testing of medical devices; or

(b) diploma in engineering (in a relevant branch) or in pharmacy from a recognized institute, and shall have the experience of not less than four years in manufacturing or testing of medical devices;

For testing of medical devices (incl. IVD), appoint competent technical staff with degree or diploma in engineering (in relevant branch) or in pharmacy or in science in relevant subject and having experience of not less than two years in testing of medical devices under whose direction and supervision, the testing activity of a medical device shall be undertaken.

However, in Form MD-12 application for the purpose of demonstration, training, or examination, the applicant may submit details of qualified personnel handling demonstration, training, or examination of IVD.

7. Justification of quantity proposed to be manufactured: The quantity proposed to be manufactured should be limited to the minimum number of units required solely for the intended purpose of testing, evaluation, demonstration, or training under Form MD-13. The proposed quantity shall be justified, taking into account the tests mentioned in the testing protocol for performance evaluation, clinical performance evaluation or other device verification and validation tests. The firm needs to submit the complete utilization breakdown of the quantity (in appropriate international system of units (SI unit)) manufactured. Further, if testing is planned to be carried out at an external site, the quantity breaks up needs to indicate the quantity for internal and external test site clearly. Additionally, where the external site is a Medical Device Testing Laboratory (MDTL) registered under Form MD-40, the MDTL registration number should also be mentioned.

In case of manufacturing for the purpose of clinical performance evaluation of new IVD the approved clinical performance evaluation permission may be submitted. The quantity manufactured shall not be intended for commercial sale.

Further, in the MD-12 application for the purpose of demonstration, training, or examination, the applicant needs to submit a quantity (in SI units) along with a proper correlation with the number of demonstration or training sites.

8. Test Protocol, if any: The applicant needs to submit details of the test protocol proposed for conducting the testing and performance evaluation. The protocol should include the standards adopted and the statistical considerations used to determine the sample size/quantity for conducting various tests, such as stability studies, performance studies, verification, validation, etc. However, for an MD-12 application submitted for the purposes of demonstration, training, or examination, the applicant need not to submit test protocol.

9. Copy of Manufacturing licence issued under these rules, if any: The firm/company shall provide details of already issued manufacturing Licence for the mentioned facility/site, if any. If the site is not licenced for manufacturing, statement clearly indicating the same needs to be submitted. However, for an MD-12 application

submitted for the purposes of demonstration, training, or examination, the applicant need not to submit the manufacturing license copy.

10. Approval letter authorizing to undertake research and development activities issued by any government organization, if any: For manufactures that intended to carry out R&D of IVD and has already obtained certificates from any recognized body (like DSIR), a copy for the same may be submitted.

11. Other documents, if any: The firm shall submit other supporting documents, if any related to the applied device.

12. Fee Challan: The applicant shall pay the applicable fee prescribed under the Second Schedule of the Medical Devices Rules, 2017 (MDR, 2017) for an application in Form MD-12. The fee shall be paid through the payment facility available on the National Single Window System (NSWS) portal, wherever enabled for the application. The applicant shall ensure that the complete applicable fee is paid and that the payment is made against the respective MD-12 application.

13. Legal Form/MD- 12 application: The firm shall submit the MD-12 form, which should be digitally signed using digital signature certificate, system-generated, and should have all essential details filled. It should be signed by an authorized signatory who has signed the cover letter.

Table 2: Legal form and application requirement for Form MD-12

Form MD-12 See sub-rule (1) of Rule 31	
Application for licence to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration or training	
1. Name of Applicant	The name of the Firm/Company/Organization as per the records of MOA/ AOA/ Registrar of Companies (ROC) or registrar of partnership or firms shall be mentioned.
2. Nature and constitution of manufacturer: (i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified)	The constitutional nature of the Firm/Company/Organization i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, or other needs to be specified.
3. (i) Corporate/ registered office address including telephone number, mobile number, fax number and e-mail id	The name of the Firm with address of the corporate or registered office of the firm as per the records of Registrar of Companies or registrar of partnership or firms, including telephone number, mobile number, fax number and e-mail id shall be mentioned.
(ii) Testing or evaluation site address including telephone number, mobile number, fax number and e-mail id	In case of testing/ evaluation/ examination, the applicant shall mention the name and address of the testing centre(s) (in house or external site) where the proposed manufacturing test is to be carried out.

	- In case of demonstration/ training, the applicant shall mention the name and address of the site(s) where the demonstration/ training is to be performed. - In case of Clinical evaluation, the applicant shall mention the name and address of each site(s) where the clinical study is to be carried out. Note: Multiple site (name and address) can be mentioned in the same row. But separate each site with serial number to distinguish each other.
(iii) Address for correspondence: (corporate office/ testing site)	The Corporate or Registered office, or manufacturing site, or testing site address including telephone number, mobile number, fax number and e-mail address of the firm shall be specified for correspondence.
4. Details of medical device(s) to be manufactured	
4.1 Generic Name	- Only the Generic name of the IVD product/ technology (e.g., ELISA, CLIA, RAPID, PCR etc.) shall be mentioned and not a trademark or product brand name. All acronyms in the Form MD- 12 application must be expanded. - Generic Name of an IVD may include any information necessary for the user to identify the device and to distinguish it from similar devices, without using trademarks
4.2 Brand Name	- The Trade name or Brand name (if registered under Trade Marks Act 1999) of the applied products shall be mentioned. - Same shall be matched with the Labels and IFU.
4.3 Model No. (if any)	- The firm shall mention model/catalogue number of the applied products in accordance with the product Brochure or Catalogue. - It shall be matched with Model/Catalogue No. Specified in labels, pack size, and Instruction for Use (IFU)/Package/Product Insert.
4.4 Proposed Class of medical device	- The Risk Class of the applied product shall be specified as per the published risk classification of In-vitro diagnostics (from time to time) and Frequently Asked Questions that are available on the CDSCO website. - For classification of IVD Analyzers, instruments and software's- https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/IVD_classification25oc23.pdf - For classification of IVD reagents and kits- https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDM5Ng== - Firm can refer the Parameters for classification for IVD Medical Devices under Part II, First Schedule of MDR, 2017- https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules.%202017.pdf - Risk classification are also updated time to time on the website www.cdscomdonline.gov.in
4.5 Proposed Intended use	The intended use of the applied IVD product shall be mentioned as per the claims specified in the Instruction for

	Use (IFU)/Package/Product Insert/ product manual/ product brochure. Type of specimen/ user/human/animal, testing population shall also be mentioned (Rule 3(v) of MDR, 2017) https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/Medical-Devices-Rules/ - In the Form MD-12 application, do not use the “&” symbol, special character/ Greek letter, but can mention as a term. Special characters will not be captured properly in Form MD-12/MD-13. - All acronyms in the Form MD-12 application must be expanded.
4.6 Sterile or non-sterile	The Sterile or Non-sterile status of the product shall be mentioned as per the label and IFU claim.
4.7 Quantity proposed to be manufactured	The proposed quantity (in SI units, or any applicable units) shall be mentioned in line with the test protocol submitted.
5. Fee paid on _____ Rs _____ receipt/ challan/transaction id _____.	Bharatkosh Payment receipt/challan/transaction id details will be captured by the system.
6. I hereby state and undertake that, I shall comply with all applicable provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.	
Place: _____ Date: _____	Signature Name and designation To be Signed Digitally

*Any information which is not relevant for the subject device may be stated as ‘Not Applicable’ in the relevant Sections/Columns of the above format, and reasons for non-applicability should be provided.

8.2 For application in Form MD- 7/8

1. Covering letter: The cover letter must be prepared on the company’s official letterhead and should clearly mention the full address of the firm. It must be duly signed and stamped by the authorized signatory, and it is essential that the same authorized person signs both the legal form and the covering letter to maintain consistency and authenticity. The covering letter should explicitly specify the purpose and intent of the application, whether it is being submitted as a fresh application, an endorsement, or a retention. In case of endorsement, the firm shall provide the base Licence number and date and indicate the retention status of the base Licence, particularly where the base Licence is more than five years old.

In addition to this, the cover letter should include a properly prepared index of all documents enclosed with the application, along with their respective page numbers, for ease of review by the authorities. Any other important and relevant information supporting the application may also be included in the cover letter. Furthermore, the firm must provide a complete breakup of the prescribed fee in the covering letter, indicating the risk class of the product applied for, the number of products included in the application, and the details of the manufacturing site, like name, address, email, phone number, etc. This ensures clarity, transparency, and completeness in the submission, thereby facilitating smooth processing of the application.

2. Constitution Details of Manufacturer: The applicant shall clearly specify the constitutional nature of the Firm/Company/Organization. This includes indicating whether the entity is a proprietorship, partnership (including Limited Liability Partnership), private limited company, public limited company, society, trust, or any other legally recognized structure, which should be duly specified, along with supporting documents i.e. for company AoA, Col, MoA with respect to the constitutional nature claimed, for LLP firm LLP registration certificate and document indicating partners, for partnership firm registration document indicating partners, for sole proprietorship indicating the firm registration as a proprietary firm etc.

3. Site or plant master file as specified in Appendix I of Fourth Schedule of MDR 2017: A brief description of the manufacturing site shall be provided, including the official name and complete address along with contact details such as telephone number, fax number, website URL, and e-mail address. The information should explain the site's relationship with any other associated or subsidiary sites and highlight details in accordance to the fourth schedule of MDR 2017 followed at the facility. A clear outline of the manufacturing activities authorized by the Competent Authorities must be included, along with any additional operations conducted at the location. The description should mention the type of diagnostic kit(s) handled at the site and provide details of any toxic or hazardous substances, including their safe handling methods and precautions taken.

A concise overview of the site covering its size, location, surrounding environment, and any other co-located activities should be added. The number of personnel involved in production, quality control, warehousing, and distribution operations must be mentioned. If the firm utilizes external scientific, analytical, or technical services for product design, manufacturing, or testing, such arrangements should be described. A short summary of the company's Quality Management System (QMS) should be provided, and details of the devices that are registered or approved in foreign countries must also be included.

3.1 Part-1 Plant Layout of premises with an indication of scale: The firm should submit a detailed manufacturing plant layout that clearly illustrates the movement of personnel and materials, along with the clean room classifications for each relevant area. The submission must also include a description of the control measures implemented to prevent unauthorized access. Additionally, a simple, scaled plan of each area should be provided, with all sections clearly labeled and annotated for easy identification, preferably prepared by a civil engineer/architect. All plans must be neat, clear, and fully legible to facilitate proper review and understanding. Further, the firm needs to provide information on the points below:

- short description of the site (size, location, and immediate environment, and other activities on the site);
- number of employees engaged in production, quality control, warehousing, and distribution;

- use of outside scientific, analytical or other technical assistance in relation to the design, manufacture, and testing;
- short description of the quality management system of the company;
- devices details registered with foreign countries;
- brief description of testing facility

3.2 Part-2 Organization chart showing the arrangements for key personnel: The firm shall provide an organogram identifying the key personnel involved in Quality Assurance, Production, and Quality Control. The organogram should include only senior managers and supervisory-level staff, clearly depicting their roles, reporting hierarchy, and functional responsibilities within the organization.

3.3 Part-3 Qualification, Experience, and Responsibilities of key Technical Persons: The firm shall provide brief details of the educational qualifications and the number of years of relevant experience held by each key personnel since obtaining their qualifications. Additionally, the submission should include clearly defined job descriptions for all key personnel, outlining their primary roles, responsibilities, and functions within the organization.

A competent technical staff under whose direction and supervision the manufacturing activity of a medical device shall be undertaken and such staff shall possess the following educational qualification and experience-

(a) degree in engineering in relevant branch or in pharmacy or in science in appropriate subject from a recognised University and shall have experience of not less than two years in manufacturing or testing of medical devices; or

(b) diploma in engineering (in a relevant branch) or in pharmacy from a recognised institute and shall have the experience of not less than four years in manufacturing or testing of medical devices;

For testing of Medical device (incl. IVD), appoint competent technical staff with degree or diploma in engineering (in relevant branch) or in pharmacy or in science in relevant subject and having experience of not less than two years in testing of medical devices under whose direction and supervision, the testing activity of a medical device shall be undertaken. However, in MD 12 application for purpose of demonstration, training or examination, the applicant may submit details of qualified personnel handling demonstration, training or examination of IVD.

3.4 Part-4 List of Equipment and Instruments: The firm shall provide details of the equipment and machinery used for manufacturing and quality control, including their make, model, and intended use. The firm shall also ensure that the equipment is made of suitable and non-reactive materials, particularly for product-contact parts, and is designed for easy and effective cleaning. Where materials such as stainless steel, polypropylene, PVC, or other suitable materials are used, their suitability for the intended purpose shall be ensured. A brief description of each major equipment item,

including any accessories or attachments, shall be provided. The firm shall also provide details of any computerized, automated, or microprocessor-based systems used in manufacturing, testing, or quality control activities. Further, the firm shall provide the below mentioned information as part of PMF:

- Sanitation: Written specifications and procedures for cleaning of manufacturing areas and equipment.
- Production: Brief description of production operations, process flow, material handling, reprocessing/rework, rejected materials handling, process validation, and sterilization facilities, where applicable.
- Quality Assurance and Storage: Description of the quality assurance system, quality assurance activities, finished product release procedures, and storage policy.
- Documentation and Internal Audit: Description of the documentation control system, including preparation, revision, distribution, storage of master documents, and the internal audit system.

3.5 Part-5 Contract Activities, if any: The firm shall provide a brief description of the technical contract established between the contract giver and the contract acceptor, outlining the nature and scope of responsibilities assigned to each party. The explanation should include the method by which compliance with the Quality Management System (QMS), or any other applicable standards, is evaluated to ensure adherence throughout the contracted activities. The firm should also justify the suitability of the selected standards for the operations being performed. Additionally, the type of activities undertaken by the contract acceptor such as manufacturing steps, testing services, storage, or distribution must be clearly specified.

4. Quality Management System: A structured framework of policies, procedures, processes, and resources shall be submitted to demonstrate that the manufacturing facility consistently produces in vitro diagnostic (IVD) devices in compliance with quality, safety, and regulatory requirements. This framework should clearly outline the systems in place to ensure continuous conformity to applicable standards.

4.1 Part-1 Quality Management System as per Fifth Schedule of Medical Devices

Rules, 2017: The firm shall provide a detailed description of the activities carried out under the quality management system (QMS), including specifications, test methods, analytical testing procedures, packaging material testing, component testing, microbiological testing, and any other relevant quality-related data collection processes. Additionally, the firm should outline its role in the preparation, review, revision, and controlled distribution of documents, particularly those related to specification sheets, test methods, batch manufacturing records, and release criteria. This should clearly reflect how the QMS system ensures consistency, traceability, and compliance with regulatory requirements.

4.2 Part-2 Quality Manual: The firm shall provide a clear description of the scope of its Quality Management System (QMS), including any exclusions or non-applications, along with a justification for each. The submission should also include the documented procedures established under the QMS, or appropriate references to where these procedures are maintained. In addition, the firm must describe how the various QMS processes interact with one another, demonstrating the overall integration and functionality of the system in ensuring consistent product quality and regulatory compliance.

4.3 Part-3 Quality Policy: The firm shall clearly state the overall intention and direction of the organization with respect to quality, as defined and endorsed by the management with executive responsibility. The statement should reflect the company's commitment to maintaining high standards of product quality, regulatory compliance, and continuous improvement across all operations.

4.4 Part-4 Control of Documents: The firm shall submit documents that have been duly approved, signed, and dated by the appropriate and authorized personnel. These documents must clearly demonstrate formal authorization, accountability, and adherence to established procedures within the organization.

Refer to section 4.2.3 Control of documents in MDR 2017.
https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf

4.5 Part-5 Control of Records: The firm shall describe the proper documentation system to be maintained, including the procedures established to define the controls required for the identification, storage, protection, retrieval, retention period, and final disposition of records. These controls should ensure that all records remain accurate, accessible, and traceable.

Refer to section 4.2.4 Control of records in MDR 2017.
https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf

4.6 Part-6 Management Responsibility: The firm shall describe how the top management of the manufacturer ensures that responsibilities and authorities are clearly defined, documented, and communicated throughout the organization. This includes ensuring that all processes required for the Quality Management System (QMS) are properly established, implemented, and maintained. The firm should also explain how QMS performance is reported to top management, and identify any areas requiring improvement. Furthermore, the submission must detail how top management promotes awareness of regulatory and customer requirements across all levels of the manufacturing organization.

Human resources: The manufacturer shall determine, provide, and maintain the personnel performing activities affecting product quality who are competent, based on

appropriate education, training, skills, and experience, with adequate staffing according to workload. Employees shall undergo pre-employment and annual medical examinations, and corresponding records shall be maintained. The manufacturer shall identify competency requirements, provide and evaluate training, ensure personnel are aware of their quality responsibilities, and maintain training records. Adequate infrastructure, including buildings, utilities, equipment, software, transport, and communication systems, shall be provided and maintained in accordance with documented maintenance procedures. A suitable work environment shall be established and controlled through documented health, hygiene, clothing, and environmental requirements to ensure product quality, prevent contamination, and prohibit smoking, eating, or drinking in production, laboratory, and storage areas.

4.7 Part-7 Internal Audit System: The firm shall provide details addressing the following points. First, it should describe how the internal audit system is used to verify that all activities influencing the quality of diagnostic kits are conducted in accordance with the established and planned arrangements. The firm must also confirm the existence of documented procedures governing the internal audit process, including the execution of audits and any required follow-up actions. Additionally, the firm should indicate whether the results of internal audits are properly recorded and communicated to the personnel responsible for the areas and activities evaluated. Finally, the description should explain how the system ensures that individuals accountable for the relevant areas take timely and effective corrective actions to address any deficiencies identified during the audit process.

4.8 Part-8 Preventive and Corrective Action: The firm shall provide a detailed description of the Corrective and Preventive Action (CAPA) processes implemented to ensure the safety, quality, and compliance of their products. This should include procedures for identifying deviations or non-conformities, investigating root causes, implementing corrective measures, monitoring effectiveness, and taking preventive actions to avoid recurrence. The CAPA system must demonstrate a structured approach to maintaining consistent product quality and adherence to regulatory and safety standards.

4.9 Part-9 Procedure for identifying training needs and ensuring that all persons are trained to adequately perform their assigned responsibilities: The firm shall provide a brief overview of its training program, encompassing both induction and ongoing continuous training. The description should include how training needs are identified and by whom, ensuring that all relevant staff receive appropriate instruction. The firm must state the procedure/type of training conducted, such as in-house sessions or external programs, and explain how practical experience is integrated, including which categories of staff are involved. Training evaluation procedures should be outlined to demonstrate how effectiveness is assessed, along with the process for identifying the need for retraining. Finally, the firm shall provide brief details of the training records maintained, ensuring documentation of all training activities.

4.10 Part-10 Table showing the areas and environmental requirements for Medical Devices as per Annexure A of Fifth Schedule of Medical Devices Rules, 2017: The firm shall provide comprehensive details regarding the cleanliness and hygiene practices maintained within the manufacturing facility, including regular cleaning schedules and sanitation procedures. Information on storage conditions for raw materials, in-process items, and finished products should be included, specifying temperature, humidity, and other relevant controls. The firm must also describe waste management practices, including segregation, handling, and disposal of hazardous and non-hazardous waste. Additionally, details of environmental monitoring programs, such as monitoring of air quality, surfaces, and critical areas, should be provided to demonstrate compliance with regulatory and quality requirements.

The firm also needs to provide details as per below mentioned points:

- **Purchasing:** Establish documented procedures for supplier qualification, evaluation, re-evaluation, purchasing controls, and verification of purchased materials/services to ensure they meet specified requirements.
- **Production and Service Provision:** Document procedures to ensure controlled manufacturing and servicing activities, including process controls, identification, traceability, handling, packaging, storage, and release of IVDs.
- **Control of Monitoring and Measuring Devices:** Implement procedures for calibration, verification, maintenance, identification, and record keeping of monitoring and measuring equipment to ensure accuracy and reliability.
- **Measurement, Analysis and Improvement:** Establish procedures for monitoring product conformity, conducting internal audits, analyzing quality data, handling customer feedback, and implementing continual improvement activities.
- **Control of Non-conforming IVD:** Document procedures for identification, segregation, evaluation, disposition, and recording of non-conforming IVDs to prevent unintended use or distribution.
- **Improvement (CAPA):** Establish a documented Corrective and Preventive Action (CAPA) system for investigation of non-conformities, root cause analysis, implementation of corrective/preventive actions, verification of effectiveness, and maintenance of CAPA records.

Note: Refer to Annexure A of Fifth Schedule of Medical Devices Rules, 2017

5. Undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule of MDR 2017: The firm shall provide comprehensive details regarding the implementation of the Quality Management System (QMS), and any other relevant procedures to ensure that in-vitro diagnostic (IVD) medical devices products are manufactured safely and effectively, in accordance with the requirements outlined in the Fifth Schedule of the Medical Devices Rules (MDR) 2017. This undertaking must be formally signed and stamped by the authorized person to confirm accountability and compliance.

6. Regulatory Certificates

6.1 Copy of the latest inspection or audit report carried out by Notified Bodies:

The firm needs to include the most recent inspection/audit report conducted by a Notified Body for Class A & B product/device. The report must include the official stamp and signatures of the inspecting or auditing authority to verify authenticity and compliance. For class C & D product, the inspection shall be conducted by a team comprising at least two Medical Device Officers, which may include a senior officer, and may also include an expert or a Notified Body as per Rule 13(4).

6.2 Copy of NOC from Department of Animal Husbandry, Ministry of Agriculture, In case of New Veterinary IVD Kits (if available):

The firm shall submit a No Objection Certificate (NOC) issued by the Department of Animal Husbandry, Ministry of Agriculture, for the products specifically for veterinary use. The NOC must be provided in the official format as issued by the department and should include the official letterhead, stamp, and signatures of the authorized signatories. Additionally, the NOC must clearly specify the product name, the manufacturer's details, the approval status, and the date of issuance.

Refer to Addendum to Doc No. CDSCO. IVD. FAQ. 04. 2022 dated 13.03.2026:

https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/Addendum-Doc-No-CDSCOIVDFAQ-042022dated-13032026.pdf

6.3 Copy of NOC from Atomic energy regulatory board (AERB)/Bhabha Atomic Research Centre (BARC), Mumbai, in case Radio Immuno Assay Kits (if available):

The firm shall submit a recent No Objection Certificate (NOC) issued by the AERB or BARC, Mumbai, confirming that the Radio Immuno Assay (RIA) kits comply with the required regulatory and safety standards. The NOC must include the name and description of the RIA kit, details of the manufacturer or distributor, approval status, date of issuance, and the signature of the authorized signatory at BARC.

6.4 Valid copy of the Quality Management System (ISO 13485) certificate issued by the competent authority (if any):

The firm shall submit a Quality Management System (QMS) certificate issued by a recognized certification body. The ISO 13485 certificate must be valid. It should include the name of the issuing body, ISO 13485 certification number, manufacturer or legal entity, scope of certification, date of issue and expiry, and possess the signature and seal of the authorized issuing authority.

6.5 Copy of Test licence obtained for testing and generation of quality control data (for domestic manufacturers only), if any:

The firm needs to obtain a Test Licence in Form MD-13 to manufacture medical devices for purposes such as testing, evaluation, or related activities. A small quantity of Class A, B, C, or D medical devices may be manufactured specifically for clinical investigations, testing, or evaluation. For this, an application must be submitted in Form MD-12 to the Central Licensing Authority and accompanied by the applicable fee as specified in the Second Schedule of the Medical Devices Rules.

Product verification and validation data studies undertaken to demonstrate conformity of the in vitro diagnostic medical device with the essential principles that apply to it. Product standards for medical devices: The medical device needs to conform to the standards laid down by the Bureau of Indian Standards or as may be notified by the Ministry of Health and Family Welfare in the Central Government, from time to time.

Where no relevant standard for a medical device has been laid down as stated above, for such a device needs to conform to the standard laid down by the International Organisation for Standardisation (ISO) or the International Electro Technical Commission (IEC), or by any other pharmacopoeial standards.

Further, where standards have not been specified as mentioned above, the device shall conform to the validated manufacturer's standards.

6.6 Self-attested copy of valid Wholesale licence or manufacturing licence (if any): The firm shall submit a duly attested or notarized (within India) and valid copy of the Wholesale Licence for the sale or distribution of drugs under the Drugs and Cosmetics Rules in Form 20B & 21B, or its renewal in Form 21C, or Form MD-42, or retention, or Form MD-4/5/9/10 as issued by the State Licensing Authority or CLA as the case may be.

7. Device Master File for In-vitro Diagnostic Medical Devices as per Appendix–III of Part III of Fourth Schedule of Medical Devices Rules, 2017

7.1 Part-1 Executive Summary: The firm shall submit introductory descriptive information on the IVD medical device, including its intended use and indications for use, the Class of the device, any novel features, shelf life, and a concise synopsis of the dossier content. Details regarding the sterilization status of the device must be provided, specifying whether it is sterile or non-sterile, and if sterile, the mode of sterilization should be mentioned. The submission should include the regulatory status of similar devices in India (approved or not approved), the domestic price of the device.

7.2 Part-2 Regulatory status of the similar device in India (approved or new in vitro diagnostic medical device): The response may be selected as "Yes" if a similar IVD which is substantial equivalent to a CLA approved IVD in terms of - specimen type, technology, principle, composition, specific intended use or other characteristics applicable (Refer IVD Approved Devices details available in <https://cdscomdonline.gov.in>).

The response shall be selected as "No" if no substantially equivalent predicate IVD is approved by the CLA. In such cases, the firm must obtain the necessary permissions in Form MD-25 and MD-29 before applying for a manufacturing Licence in Form MD-7. The approval status must be verified with respect to the new IVD definition under Rule 3(zh) of MDR, 2017.

(https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf).

Substantial equivalence with a predicate IVD may be established based on the following principles:

1. Intended Use Evaluation- The manufacturer must demonstrate that the subject IVD has the same intended use as the predicate. Document this in a direct comparative table assessing:

- a. Target Analyte: What the test detects or measures (e.g., specific antibodies, nucleic acids, metabolites).
- b. Clinical Indications: The clinical condition, disease state, or patient population being evaluated.
- c. Intended User & Environment: Whether it is for professional laboratory use, point-of-care (POC), or over-the-counter (OTC) self-testing

2. Analyze Technological Characteristics- Map out the principles of operation to confirm technological similarities. Manufacturer must track and evaluate:

- a. Assay Methodology: The reaction platform (e.g., ELISA, Real-Time PCR, Lateral Flow).
- b. Specimen Type: The validated matrix (e.g., whole blood, serum, plasma, urine, saliva).
- c. Detection Mechanism: The readout technology (e.g., fluorescence, colorimetry, chemiluminescence).
- d. Components: Reagents, calibrators, controls, and integrated software

3. Generate Analytical Performance Data- To validate your claim of equivalence, you must conduct comparative non-clinical studies between your subject IVD and the predicate:

- a. Analytical Sensitivity: Establish and compare the Limit of Detection (LoD) or Limit of Quantitation (LoQ).
- b. Analytical Specificity: Provide cross-reactivity and interference data to show both tests behave similarly under stress.
- c. Precision and Accuracy: Document the repeatability and reproducibility of results.
- d. Method Comparison (Correlation): Test split-sample patient specimens simultaneously across both the subject and predicate devices to calculate the bias, slope, and intercept (R^2 correlation).

4. Comparative deviation- The manufacturer needs to find rationale for difference in terms of analytical justification for any technical or material deviations from the predicate IVD.

7.3 Part-3 Description and specification, including variants and accessories of the in vitro diagnostic medical device: The firm shall provide the product description as per the label and the Instruction for Use (IFU), Package Insert/Product Insert. A complete list of accessories or components intended to be used in combination with the applied IVDs must be included, and these accessories should be clearly reflected in the IFU, Package Insert, or Product Insert. Accessories are classified separately in

their own right, independent of the device with which they are used, as per Part II 1(b) of the First Schedule of the Medical Devices Rules, 2017.

If the firm intends to manufacture and sell the accessories or components (critical components) separately from the main system, a separate endorsement application to licence for such items must be submitted for each individual product, along with the requisite fee and supporting documents for the main device system.

In pursuance of rule 5 of the Medical Devices Rules, 2017, the Central Government notifies guidelines for grouping Medical Devices for a person who applies for a licence to import or manufacture for sale or distribution of medical devices.

The applicant may group medical devices having the same or similar intended uses or commonality of technology and submitted in a single application. The grouping of medical devices is for the purpose of submitting a single application for licence to manufacture in the following manner:

In Vitro Diagnostic (IVD) Grouping

- Single IVD
- IVD Family
- IVD Test Kit
- IVD System
- IVD Cluster

Refer: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Guidelines_Grouping_of_MDandIVD.pdf

7.4 Part-4 Essential principles checklist for demonstrating conformity to the essential principles of safety and performance of the in vitro medical device:

The firm shall submit an Essential Principles checklist that includes the following details:

- (a) The Essential Principles
- (b) An indication of whether each Essential Principle applies to the device, and if not, a justification for its non-applicability
- (c) The method(s) used to demonstrate conformity with each applicable Essential Principle
- (d) References for the method(s) employed, such as recognized standards
- (e) The precise identity of the controlled document(s) that provide evidence of conformity for each method used
- (f) A clear explanation of how conformity is demonstrated, including standard references and the corresponding controlled documents serving as evidence

Essential Principle	Relevant Yes/No	Specification/standard Sub-clause/reference	Complies Yes/No	Document Reference Justification and/or comments

General principles				
Principles about design and construction....				

Refer:

https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf

7.5 Part-5 Risk analysis and control summary: The firm needs to submit a detailed document outlining the potential risks associated with the IVD device, including the steps taken to identify, analyse, and mitigate these risks. The risk analysis must be conducted in accordance with recognized standards, such as ISO 14971, and should form part of the manufacturer's comprehensive risk management plan based on complexity and risk class of the device, demonstrating a systematic approach to ensuring safety and effectiveness. For veterinary IVD and software based IVD, manufactures are expected to conduct risk management and control to the extent possible under said standards.

Refer to Appendix III, point 4-6

https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf

7.6 Part-6 Device Design and Manufacturing Information: The firm shall submit the Device Master File (DMF), which provides comprehensive information enabling a reviewer to gain a general understanding of the design of the IVD medical device. The DMF should include a description of the critical ingredients of the assay, such as antibodies, antigens, enzymes, and nucleic acid primers, whether provided or recommended for use with the device. Additionally, the DMF should present an overview of the production process, including the technologies employed, assembly procedures, in-process and final product testing, and the packaging of the finished IVD medical device.

Device design for instruments, would include a description of major subsystems, analytical technology (e.g. operating principles, control mechanisms), dedicated computer hardware and software.

For instruments and software, an overview of the entire system would be required, including an Architecture Design Chart which is typically a flowchart of the relationships among the major functional units in the software, including relationships to hardware and to data flows such as networking.

For standalone software, this would typically include a description of the data interpretation methodology (i.e. Algorithms, Artificial Intelligence Model Architecture (the structural framework) and Trained Artificial Intelligence Model).

For self-testing devices the design should include a description of the design aspects that make it suitable for lay person use.

Planning of Product Realization- The firm shall provide documented evidence of the manufacturer's product realization planning process. The plan should define product quality objectives, applicable regulatory and product requirements, required manufacturing and quality processes, supporting documents and resources, verification, validation, monitoring, inspection, testing activities, product acceptance criteria, and records demonstrating conformity. The planning process shall be aligned with the Quality Management System (QMS) and include documented risk management activities throughout the product realization lifecycle in accordance with IS/ISO 14971, with all associated risk management records maintained.

Customer-Related Processes: The firm shall provide documented procedures demonstrating how customer and regulatory requirements are identified, reviewed, and communicated. The documentation should include processes for determining customer-specified and intended-use requirements, applicable statutory and additional manufacturer requirements, reviewing contracts or orders before acceptance, resolving requirement changes, maintaining review records, and ensuring effective customer communication regarding product information, inquiries, orders, amendments, feedback, complaints, and advisory notices.

7.7 Part-7 Product validation and verification: The device master file should summarize the results of validation and verification studies undertaken to demonstrate conformity of the in vitro diagnostic medical device with the essential principles that apply to it. Where appropriate, such information might come from literature. The firm shall provide validation and verification information in the Device Master File (DMF). The information may be provided in the form of a summary or detailed information, as applicable:

The information should include a comprehensive description of the study protocol, method of data analysis, study results and study conclusion, sufficient for the regulatory authority to assess the validity of the study. Where a recognized standard is available, a declaration or certificate of conformity to the standard may be provided along with a summary of the data, particularly where the standard does not specify acceptance criteria. If no recognized standard is available, a published non-recognized standard, professional guideline, industry method or in-house method may be used with a suitable justification, description of the method, summary of data and conclusion. Relevant published literature on the applied device, analyte or similar IVDs may also be considered. Where applicable, the actual test results and their acceptance criteria should be provided rather than only stating "pass" or "fail."

7.8 Part-8 Analytical studies, Specimen type, Analytical performance characteristics, Analytical sensitivity, Analytical Specificity, Metrological

traceability of calibrator and control material values, measuring range of assay, Technical documentation for IVD medical devices requires comprehensive analytical studies, including detailed specimen stability data and precise measures of analytical performance like trueness and precision. Documentation must establish analytical sensitivity through LoB, LoD, and LoQ; prove specificity against exogenous and endogenous interferences; and ensure metrological traceability for calibrators. Furthermore, files must define the assay's measuring range, including dilution procedures to address hook effects, and outline the statistical methods, such as ROC curves, used to determine the assay cut-off and gray-zone results

i. Specimen Type: This section details how patient samples must be collected, handled, and evaluated.

- **Sample Descriptions:** Explicitly identify all valid specimen types, matrices, and required anticoagulants.
- **Stability and Logistics:** Define explicit limits for specimen storage duration, temperature boundaries, transportation conditions, and allowable freeze/thaw cycles.
- **Accuracy Comparison:** Outline the exact measurement procedures, sample sizes, target concentrations (using spiked samples if necessary), statistical formulas, and conclusions used to verify accuracy across different matrices.

ii. Analytical Performance Characteristics: This section measures the core functionality, consistency, and errors associated with the assay.

a) Accuracy of Measurement

- **Total Error:** Total accuracy is defined by a combination of random and systematic errors.
- **Trueness:** Evaluates systemic error, which is formally expressed and calculated as bias.
- **Precision:** Evaluates random error, which is formally expressed and measured as standard deviation.

b) Trueness of measurement

- This section should provide information on the trueness of the measurement procedure and summarize the data in sufficient detail to allow assessment of the adequacy of the means selected to establish the trueness. Trueness measures apply to both quantitative and qualitative assays only when a reference standard or method is available.

c) Precision of measurement

- This section should describe repeatability and reproducibility studies.

Repeatability

- This section should include repeatability estimates and information about the studies used to estimate, as appropriate, within-run-variability. Repeatability data is obtained for instrumentation in conjunction with an appropriate assay.

Reproducibility (Intermediate Precision)

- **Variability Testing:** Summarizes the assay's performance consistency by calculating variability across multiple days, runs, testing sites, manufacturing lots, operators, and instruments.
- **Instrumentation Rule:** For hardware platforms, reproducibility data must be generated in tandem with an appropriate assay.
- **Analyte Range:** Studies must utilize samples that span the full expected measuring range claimed by the manufacturer.

iii. Analytical Sensitivity: This section defines the lowest thresholds of analyte detection using detailed study designs and replicate numbers. It establishes three distinct metrics:

- **Limit of Blank (LoB):** The calculated number of standard deviations above the average value of a sample completely lacking the target analyte.
- **Limit of Detection (LoD):** The absolute lowest concentration of an analyte that can be reliably distinguished from zero.
- **Limit of Quantitation (LoQ):** The lowest concentration where the analyte can be measured while maintaining strictly specified accuracy criteria (trueness and precision).

iv. Analytical Specificity: This section proves the assay's capability to detect *only* the targeted analyte in the presence of external or internal confounding factors.

- **Interference Testing:** Evaluates exogenous or endogenous substances by spiking them into the sample to measure any resulting bias against an unspiked control.
- **Cross-Reactivity:** Tests the assay against structurally similar analytes or samples from unrelated medical conditions that mimic the target condition (e.g., testing a Hepatitis B positive sample on a Hepatitis A assay).
- **Confounding Variables:** Evaluates common risk sources including therapeutic drugs, food/alcohol, preservatives, sample prep additives, and natural blood elements (hemoglobin, lipids, bilirubin, proteins).

v. Metrological Traceability of Calibrator and Control Materials

- **Value Assignment:** Summarizes the formal methods, validation processes, and acceptance criteria used to link calibrators and trueness controls back to recognized reference materials or reference measurement procedures.
- **Precision Controls Exception:** Standard precision control materials used purely to establish assay reproducibility do not require metrological traceability verification.

vi. Measuring Range of the Assay

- **System Boundaries:** Defines the upper and lower limits for linear and non-linear measuring systems, inclusive of the LoD.
- **Study Design Details:** Details the specimen types, sample sizes, replicate counts, and matrix preparation procedures used to confirm the range.
- **Hook Effect Mitigation:** If applicable, manufacturers must document data regarding the "high-dose hook effect" and detail corresponding mitigation protocols (such as automated dilution steps).

vii. Definition of Assay Cut-off

- **Boundary Generation:** Summarizes the analytical data and study designs utilized to establish the clinical cut-off point of the assay.

- **Demographics:** Documents the exact population metrics, including selection mechanics, inclusion/exclusion criteria, and the total number of individuals evaluated.
- **Statistical Methods:** Employs mathematical models, such as Receiver Operator Characteristic (ROC) curves, to define clean boundaries and establish gray-zone or equivocal boundaries where testing results are uncertain.
- **Where relevant,** the device master file should contain data on the clinical performance of the IVD medical device. This clinical performance data is one of the elements of clinical evidence that demonstrates the conformity of the IVD medical device to the Essential Principles that apply to it.

Note: Analytical performance and clinical performance are elements of clinical evidence.

Refer to Appendix III, MDR 2017 Point 7-14

https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf

7.9 Part-9 Claimed Shelf life - Stability Study Report for at least 3 lots including the protocol, acceptance criteria, testing intervals and conclusion: The firm shall submit a stability study report that includes data from at least three independent lots of the product. The report must describe the study's methodology, including storage conditions, testing intervals, and testing procedures. It should also specify the defined time points at which testing is conducted (e.g., 0, 3, 6, and 12 months) to assess the product's stability over its claimed shelf life.

Accelerated studies or extrapolated data from real-time stability studies may be used to support the initial shelf-life claim. However, these studies shall be followed by real-time stability studies to confirm the claimed shelf life. The firm shall provide details of the stability study, including the study protocol, the number of lots tested, the acceptance criteria, the testing intervals, and the study report. Where accelerated studies have been conducted, the method used for the accelerated study shall also be provided. The firm shall also provide the study conclusion and the proposed shelf life.

The shelf life may be established based on the lot having the longest available real-time stability data, provided that the accelerated or extrapolated data from all three lots are comparable.

7.10 Part-10 In use stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion for: The firm shall submit the in-use stability study report, which includes the study protocol, defined acceptance criteria, and specified testing intervals. The report should also provide conclusions drawn from the study and clearly state the claimed in-use stability of the product.

7.11 Part-11 Shipping stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion for: The firm shall conduct shipping studies under real/simulated conditions, including variable factors such as extreme heat or cold, to assess the product's stability during transport. The submission

should include (a) the study report, detailing the study protocol and defined acceptance criteria, and (b) the methods used for simulated conditions, along with conclusions and recommended shipping conditions based on the study findings.

Software verification and validation

Where relevant, the device master file should contain evidence of the validation of the software, as used in the finished device. This information should typically include the summary results of all verification, validation and testing performed in-house and as applicable in an actual user environment prior to final release. It should also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.

7.12 Part-12 Clinical Evidence: The Firm shall submit Clinical Evidence Evaluation report that demonstrates conformity of the IVD medical device to the Essential Principles that apply to it.

7.13 Part-13 Product Insert, Pack size, Label: The particulars to be printed in indelible ink on the label, on the shelf pack of the medical device, or on the outer cover of the medical device, and on every outer covering in which the medical device is packed.

The firm shall provide labelling details that include the name of the medical device, the details necessary for the user to identify the device and its use the name of the manufacturer and address of manufacturing premises where the device has been manufactured, the correct statement about the net quantity in terms of weight, measure, volume, number of units, as the case may be, and the number of the devices contained in the package expressed in the metric system, to provide, wherever required, an indication that the device contains medicinal or biological substance, to indicate, wherever required, any special storage or handling conditions applicable to the device, to give, if considered relevant, warnings or precautions to draw the attention of the user of medical device intended use, indications for use, warnings and precautions, storage conditions and expiration date or shelf life.

The pack size should specify the number of test kits, reagents, or devices included. The label must refer to the Instruction for Use (IFU).

The label may use symbols recognized by BIS or ISO instead of text, provided that the meaning of the symbol is clear to the user or that not understanding the symbol does not affect the safe use of the device.

Refer: Chapter VI of MDR 2017 for the labelling of medical devices.

7.14 Part-14 Specimen batch test report form for at least three consecutive batches showing specification of each testing parameter: The firm shall provide details of batch size and selection before release to market, mentioning the test

parameters evaluated according to the defined acceptance criteria, and the testing intervals, covering at least three consecutive batches.

7.15 Part-15 Specific evaluation report, if done by any laboratory in India, showing the sensitivity and specificity of the in-vitro diagnostic medical device:

The firm shall submit a report mentioning the sensitivity and specificity of the device, including laboratory information, test protocols, and defined acceptance criteria.

7.16 Part-16 Copy of performance evaluation report issued by the central medical device testing laboratory or medical device testing Laboratory registered under sub-rule (3) of rule 83 of MDR 2017 for three batches: The firm shall submit performance evaluation reports (PER) for three independent batches of the IVD, each manufactured using three different lots of key raw materials. The applicant shall submit the report issued by the central medical devices testing laboratory or a medical device testing laboratory registered under rule 83 or by any laboratory accredited by the National Accreditation Board for Testing and Calibration Laboratories or by any hospital accredited by National Accreditation Board for Hospitals and Healthcare Providers or by any Central Government or State Government Laboratory of any hospital or of any institute, specified by the concerned State Licensing Authority or the Central Licensing Authority”.

Refer:

1. https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/GuidanceonPER-updated13-Feb2020-Final.pdf
2. https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/Revised-PER-list-dated-29.06.2026.pdf

7.17 Part-17 Post Market Surveillance Data: The dossier shall include the Post-Marketing Surveillance (PMS) or Vigilance Reporting procedures. This may encompass details of complaints received and the corresponding corrective and preventive actions (CAPA) implemented to address those issues, if any.

7.18 Part-18 Others: Any other relevant supporting document to be submitted.

8. Fee Challan: Bharatkosh receipt should be submitted as per Second Schedule of MDR-2017. Challan should be linked to the application and the complete fee should be paid (Second Schedule, MDR-2017).

Fee Challan on payment to CLA: Bharatkosh receipt should be submitted, and the challan should be linked to the application.

Mode of payment of fee to SLA: Where the specified fee is payable to the State Licensing Authority, the same shall be paid through a challan or by electronic mode as may be specified by the concerned State Government. The complete fee should be paid as per the Second Schedule of the MDR, 2017.

Table 3: Fee requirement as per various rules, MDR 2017

S. No.	Rule	Subject	In rupees (INR) except where specified in dollars (\$)
1	20(2)	Manufacturing Licence or Loan Licence for Class A or Class B In-vitro diagnostic medical device for	-
		(a) One site, and	500/-
		(b) Each distinct medical device	500/-
2	21(2)	Manufacturing Licence or Loan Licence to manufacture Class C or Class D In-vitro diagnostic medical device	-
		(c) One site	50000/-
		(d) Each distinct In-vitro diagnostic medical device	1000/-
3	29(1)	Manufacturing Licence or Loan Licence retention fee for	
		(a) one site of manufacturing Class A or Class B In-vitro diagnostic medical device	5000/-
		(b) one site of manufacturing Class C or Class D In-vitro diagnostic medical device	50000/-
		(c) Each distinct In-vitro diagnostic medical device of Class A or Class B	500/-
		(d) Each distinct In-vitro diagnostic medical device of Class C or Class D	1000/-
4	31(1)	Test Licence to manufacture for clinical investigations, test, evaluation, examination, demonstration or training for each distinct In-vitro diagnostic medical device	500/-

9. Legal form 7/8: The firm shall submit the MD- 7/8 form which should be digitally signed and system generated and possesses all essential details filled. The mentioned Intended use should be as per IFU/user manual. Refer to tool tip mentioned below for filling legal form (Form MD-7).

Table 4: Legal form and application requirement for Form MD-7

Form MD-7	
Application for Grant of Licence to manufacture for Sale or for Distribution of Class C or Class D medical device	
1. Name of Applicant	The name of the Firm/Company/Organization as per the records of MOA/ AOA/ Registrar of Companies (ROC) or registrar of firms /partnership shall be mentioned.
2. Nature and constitution of manufacturer	The constitutional nature of the Firm/Company/Organization, i.e., proprietorship, partnership, including Limited Liability Partnership,

	private or public company, society, trust, or other to be specified.
3. (i) Corporate/registered office address	The name of the Firm with the address of the corporate or registered office of the firm as per the records of Registrar of Companies or firms or partnership, including telephone number, mobile number, fax number, and e-mail id, shall be mentioned.
(ii) Manufacturing site address/Sterilization site address	The name and address of the actual Manufacturing site proposed by the applicant for the applied product shall be mentioned, including telephone number, mobile number, fax number, and e-mail ID.
(iii) Address for correspondence	The Corporate or Registered office/Manufacturing site address, including telephone number, mobile number, fax number, and e-mail address of the firm, shall be specified for correspondence.
4. Details of medical device(s) to be manufactured	
1. Generic Name	Only the Generic name of the product/ technology, e.g., ELISA, CLIA, RAPID, PCR, etc., shall be mentioned and not a trademark or product brand name.
2. Brand Name (if registered under the Trade Marks Act, 1999)	- The Trade name or Brand name (if registered under the Trade Marks Act 1999) of the applied products shall be mentioned. - Same shall be matched with the Labels and IFU.
3. Notified Category	Refer to the category specified in the classification list of IVD.
4. Class of Medical Device	- The Risk Class of the applied product shall be specified as per the published classification of In-vitro diagnostics (from time to time) and Frequently Asked Questions that are available on the CDSCO website. - The firm can refer to the Parameters for classification for IVD Medical Devices under Part II, First Schedule of MDR, 2017.
5. Shelf life	- The claimed Shelf life of the product shall be mentioned as per the real-time stability study report submitted with the application. - It shall ordinarily not exceed sixty months from the date of manufacture, except in certain cases (Rule 47, MDR, 2017), or for IVD equipment, instruments, or apparatus, it may not be necessary (Rule 44 (e), MDR, 2017).
6. Sterile/Non-sterile	The Sterile or Non-sterile status of the product shall be mentioned as per the label and IFU claim.
7. Contains drugs	Firm shall specify whether the applied IVD products contain any drug components or not.
8. Medical Device Grouping Category	The firm shall refer to the grouping guidelines & grouping FAQs published under Rule 5 of the MDR, 2017 (available on the CDSCO website), which shall specify on which grouping Category (Single, Family, IVD Cluster, IVD Test Kit, System) the applied

	IVDs fall under.
9. Grouping Description	The firm shall refer to the grouping guidelines & grouping FAQs published under Rule 5 of the MDR, 2017 (available on the CDSCO website).
10. Intended Use	The intended use of the applied IVD product shall be mentioned as per the claims specified in the Instruction for Use (IFU)/Package/Product Insert/ product manual/ product brochure. Type of specimen/ user/human/animal, testing population shall also be mentioned (Rule 3(v) of MDR, 2017).
11. Product Description	The product description as per the label and Instruction for Use (IFU)/Package/Product Insert shall be mentioned.
12. Material of Construction	Description of the components (e.g., reagents, assay controls, and calibrators) and, where appropriate, a description of the reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers) where applicable shall be mentioned (2.1(e) of Appendix III of MDR, 2017).
13. Dimension (if any)	The Dimensions of the applied products as per the label & the label and Instruction for Use (IFU)/Package/Product Insert shall be mentioned or may be stated as Not Applicable if it is not relevant to the applied product.
14. Storage Condition	The Storage Conditions of the product mentioned in the label and Instruction for Use (IFU)/Package/Product Insert shall be provided, which shall be supported by the real-time stability at recommended storage conditions data provided with the application.
16. Accessory/Components	- The list of Accessories/Components that are intended to be used in combination with the applied IVDs shall be mentioned. - These accessories shall be reflected in the Instruction for Use (IFU)/Package/Product Insert. - Accessories are classified in their own right separately from the device with which they are used (Part II 1(b), First Schedule of MDR, 2017). - If the firm intends to sell the Accessories/Components separately from the system, the firm must apply for them as separate products, with the requisite fee and the main device system's documents.
17. Model No./Catalogue No.	- The firm shall mention the Model/Catalog Number of the applied products in accordance with the product Brochure or Catalog. - It shall be matched with the Model/Catalog No. specified in Labels, the pack size mentioned in the label, and the Instruction for Use (IFU)/Package/Product Insert.

18. Equivalence to predicate device	- It shall be selected Yes if the similar product w.r.t. Specimen, technology, principal, composition, and specific intended use are already approved by the Central Licensing Authority (Refer IVD Approved Devices details available in https://cdscomdonline.gov.in). - The approval status shall be verified w.r.t. new IVD definition as per Rule 3(zh) of MDR, 2017. - It shall be selected as "NO" if no similar product, based on specimen, technology, principle, composition, or specific intended use, has been approved by the Central Licensing Authority. In such cases, the firm shall obtain permission in Form MD-25 and MD-29 before applying for a manufacturing licence in Form MD-7.
5. Whether substantial equivalence to a predicate device is claimed	If yes, the firm shall submit the substantial equivalence to a similar/predicate device details
6. Fee paid on_____, INR _____ receipt/challan/transaction id _____.	Bharatkosh Payment receipt/challan/transaction id details will be captured by the system.
7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.	
8. I hereby state and undertake that:	
(i) The manufacturing site is ready for audit or shall be ready for audit on 0. _____in accordance with the requirements of Medical Devices Rules, 2017.	The firm shall provide the date on which the manufacturing site is ready for audit/ inspection by CDSCO officials.
(ii) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017.	

Table 5: Legal form and application requirement for Form MD-8

Form MD-8	
Application for Grant of Loan Licence to manufacture for Sale or for Distribution of Class C or Class D	
1. Name of Applicant	The name of the Firm/Company/Organization as per the records of MOA/ AOA/ Registrar of Companies (ROC) shall be mentioned.
2. Nature and constitution of manufacturer	The constitution nature of the Firm/Company/Organization i.e. proprietorship, partnership including Limited Liability Partnership, private or public company, society, trust, other to be specified.

3. (i) Corporate/registered office address	The name of the Firm with address of the corporate or registered office of the firm as per the records of Registrar of Companies, including telephone number, mobile number, fax number and e-mail id shall be mentioned.
(ii) Manufacturing site address/ Sterilization site address	The name and address of the actual Manufacturing site proposed by the applicant for the applied product shall be mentioned including telephone number, mobile number, fax number and e-mail id.
(iii) Address for correspondence	The Corporate or Registered office/Manufacturing site address including telephone number, mobile number, fax number and e-mail address of the firm shall be specified for correspondence.
4. Details of medical device(s) to be manufactured	
1. Generic Name	Only the Generic name of the product/ technology e.g. ELISA, CLIA, RAPID, PCR etc. shall be mentioned and not a trademark or product brand name.
2. Brand Name (if registered under the Trade Marks Act, 1999)	- The Trade name or Brand name (if registered under Trade Marks Act 1999) of the applied products shall be mentioned. - Same shall be matched with the Labels and IFU.
3. Notified Category	Refer to category specified in classification list of IVD.
4. Class of Medical Device	- The Risk Class of the applied product shall be specified as per the published the classification of In-vitro diagnostics (from time to time) and Frequently Asked Questions that are available in the CDSCO website. - For classification of IVD Analyzers, instruments and software's- https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/IVD_classification25oc23.pdf - For classification of IVD reagents and kits- https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NDM5Ng== - Firm can refer the Parameters for classification for IVD Medical Devices under Part II, First Schedule of MDR, 2017- https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf
5. Shelf life	- The claimed Shelf life of the product shall be mentioned as per the real time stability study report submitted with the application. - It shall ordinarily not exceed sixty months from the date of manufacturer except in certain cases (Rule 47, MDR 2017) or for IVD equipment or instruments or apparatus, may not be necessary (Rule 44 (e), MDR, 2017)- https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf - For Guidance on Stability Studies of In-vitro

	Diagnostic Medical Device (IVDMD)- https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/GuidanceIVDs-202.pdf
6. Sterile/Non-sterile	The Sterile or Non-sterile status of the product shall be mentioned as per the label and IFU claim.
7. Contains drugs	Firm shall specify whether the applied IVD products contains any Drugs components or not.
8. Medical Device Grouping Category	The firm shall refer to the grouping guidelines & grouping FAQs published under Rule 5 of the MDR, 2017 (available in CDSCO website) shall specify on which grouping Category (Single, Family, IVD Cluster, IVD Test Kit, System) the applied IVDs falls thereunder- https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Guidelines_Grouping_of_MDandIVD.pdf.
9. Grouping Description	The firm shall refer to the grouping guidelines & grouping FAQs published under Rule 5 of the MDR, 2017 (available in CDSCO website)- https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Guidelines_Grouping_of_MDandIVD.pdf.
10. Intended Use	The intended use of the applied IVD product shall be mentioned as per the claims specified in the Instruction for Use (IFU)/Package/Product Insert/ product manual/ product brochure. Type of specimen/ user/human/animal, testing population shall also be mentioned (Rule 3(v) of MDR, 2017)- https://cdsco.gov.in/opencms/opencms/en/Acts-and-rules/Medical-Devices-Rules/.
11. Product Description	The product description as per the label and Instruction for Use (IFU)/Package/Product Insert shall be mentioned.
12. Technology	ELISA/RAPID/CLIA/iCLIA/PCR or any other shall be mentioned.
13. Material of Construction	Description of the components (e.g. reagents, assay controls and calibrators) and where appropriate, a description of the reactive ingredients of relevant components (such as antibodies, antigens, nucleic acid primers) where applicable shall be mentioned (2.1(e) of Appendix III of MDR, 17- https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules.%202017.pdf
14. Dimension (if any)	The Dimensions of the applied products as per the label & the label and Instruction for Use (IFU)/ Package/Product Insert shall be mentioned or may be stated as Not Applicable if it is not relevant to the applied product.
15. Storage Condition	The Storage Conditions of the product mentioned in the label and Instruction for Use (IFU)/Package/Product Insert shall be provided which shall be supported by the real-time stability at recommended storage conditions data provided with application.
16. Accessory/Components	The list of Accessories/Components which are intended to be used in combination with the applied IVDs shall be mentioned.

	• These accessories shall reflect in the Instruction for Use (IFU)/Package/Product Insert. • Accessories are classified in their own right separately from the device with which they are used (Part II 1(b), First Schedule of MDR, 2017)- https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules.%202017.pdf. If the firm intended to sale the Accessories/Components separately apart from the system, the firm has to apply it as separate individual product with for requisite fee and requisite documents of the main device system.
17. Model No./Catalogue No.	• The firm shall mention Model/Catalogue Number of the applied products shall be mentioned in accordance with the product Brochure or Catalogue. • It shall be matched with Model/Catalogue No, specified in Labels, Pack size mentioned in label and Instruction for Use (IFU)/Package/Product Insert.
18. Equivalence to predicate device	• It shall be selected Yes if the similar product (Rule 3(zm) of MDR,17) w.r.t. Specimen, technology, principal, composition, specific intended use is already approved by Central Licensing Authority (Refer IVD Approved Devices details available in- https://cdscomonline.gov.in) • The approval status shall be verified w.r.t. new IVD definition as per Rule 3(zh) of MDR, 2017- https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules.%202017.pdf. • It shall be selected as "NO" if no similar product, based on specimen, technology, principle, composition, or specific intended use, has been approved by the Central Licensing Authority. In such cases, the firm shall obtain permission in Form MD-25 and MD-29 before applying for a manufacturing licence in Form MD-8.
5. Whether substantial equivalence to a predicate device is claimed	• If yes, the firm shall submit the substantial equivalence to a similar/predicate device details
6. Fee paid on ____, INR ____ receipt/challan/transaction id _____	• Bharat Kosh Payment receipt/challan/transaction id details will be captured by the system.
7. I have enclosed the documents as specified in the Fourth Schedule of Medical Devices Rules, 2017	
8. I hereby state and undertake that:	
(i) The manufacturing site is ready for audit or shall be ready for audit on __in accordance with the requirements of Medical Devices Rules, 2017	• The firm shall provide the date on which the manufacturing site is ready for audit/ inspection by CDSCO officials.
(ii) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940), and the Medical Devices Rules, 2017.	

9. Timeline:**Table 6: Timeline as per type of application under MDR 2017**

S. No.	Application Type	Timeline (as per rule in days)
1.	Form MD- 3/4	45
2.	Form MD- 7/8	105

10. Inspection Requirement:**10.1 For Class A & B Devices, where licences are granted under Rule 20:**

- No audit of the manufacturing site shall be necessary prior to grant of licence or loan licence to manufacture for sale or for distribution of Class A medical device. The required audit of such manufacturing site by the registered Notified Body in the manner as specified in the Third schedule shall be carried out within one hundred and twenty days from the date on which the licence was granted by the State Licensing Authority.
- In case of application for grant of licence or loan licence to manufacture for sale or for distribution of Class B medical devices, the audit of the manufacturing site shall be carried out within 90 days from the date of application by the registered Notified Body in the manner specified in the Third Schedule.

***Notified Body:** means a body corporate or other legal entity, registered under rule 13 as a body competent to carry out the audit of manufacturing site, assessment, and verification of specified category of medical devices for establishing conformity with standards.

10.2 Inspection for grant of licence or loan licence for Class C or Class D medical device:

- Before granting a licence to manufacture of Class C or Class D medical devices for sale or distribution, the manufacturing site shall undergo an inspection within 60 days from the date of application as per Rule 23, MDR 2017. The inspection shall be conducted by a team comprising at least two Medical Device Officers, which may include a senior officer, and may also include an expert or a Notified Body as per Rule 13(4).

10.3 Post-Licence Inspection Requirements for Manufacturing of IVD Medical Devices

Following the grant of a manufacturing licence, the licenced manufacturing site may be subjected to inspections by the Licensing Authority to verify continued compliance with the provisions of the Medical Devices Rules, 2017 and with the requirements of the Fifth Schedule. Such inspections are intended to ensure that the manufacturer continues to maintain an effective Quality Management System (QMS) and that the IVD medical devices manufactured consistently meet the prescribed standards of safety, quality, and performance.

Inspection on Grounds of Non-Compliance

Where the Central Licensing Authority (CLA) or the State Licensing Authority (SLA) has reason to believe, or it is alleged or suspected, that an IVD medical device:

- does not conform to the prescribed quality standards; or
- is not in compliance with the requirements of the Fifth Schedule,

the Licensing Authority may order an inspection of the licenced manufacturing site to verify compliance with the applicable regulatory requirements.

For Class A and Class B IVD medical devices, the State Licensing Authority (SLA) may direct an inspection of the licenced manufacturing site. However, the Central Licensing Authority (CLA) may order such an inspection for IVD medical devices of class (Class C, or D), wherever considered necessary. The inspection shall be carried out by a team of officers constituted in accordance with Rule 23 of the Medical Devices Rules, 2017.

During such inspections, the inspection team may examine the manufacturer's Quality Management System, manufacturing and quality control processes, production and testing records, calibration and maintenance records, complaint handling, vigilance reporting, recall procedures, CAPA implementation, control of non-conforming products, and other relevant records necessary to verify continued compliance with the Medical Devices Rules, 2017. Based on the inspection findings, the Licensing Authority may initiate appropriate regulatory actions in accordance with the Rules wherever non-compliance is observed.

References:

1. Drug and Cosmetic Act, 1940.
2. Medical Device Rules, 2017.
3. Regulation (EU) 2017/746 (IVDR) on in vitro diagnostic medical devices.

Annexure 1:**1A. Checklist****Table 1A.1 Checklist for manufacturing test licence (Form MD-12) for all Class of IVDs**

Section no.	Checklist Name	Is Mandatory
1.0	Covering Letter	Yes
2.0	Brief description of the medical device including intended use, material of construction, design	Yes
3.0	Quality certificates like QMS etc., of the manufacturer from where the raw material is procured, if any	No
4.0	Undertaking stating that the required facilities including equipment, instruments, and personnel have been provided to manufacture such medical devices	Yes
5.0	List of equipment, instruments	Yes
6.0	List of qualified personnel	Yes
7.0	Justification of quantity proposed to be manufactured	Yes
8.0	Test protocol, if any	No
9.0	Copy of Manufacturing licence issued under these rules, if any	No
10.0	Approval letter authorizing to undertake research and development activities issued by any government organization, if any	Yes
11.0	Other documents, if any	
12.0	Fee Challan	Yes
13.0	Legal Form	Yes

Table 1A.2 Checklist for manufacturing licence (Form MD-3/4, CLASS A/B IVD)

Section no.	Checklist Name	Fresh	Endorsement	Retention
1.0	Covering Letter	Yes	Yes	Yes
2.0	Constitution Details of Manufacturer	Yes	Yes	Undertaking for no change in the constitution
3.0	Site or plant master file as specified in Appendix I of Fourth Schedule of MDR 2017	-	-	Undertaking for no change in PMF or updated PMF
3.1	Part-1	Yes	Yes	No
3.2	Part-2	No	No	No
3.3	Part-3	No	No	No
3.4	Part-4	No	No	No
3.5	Part-5	No	No	No
4.0	Device master file as specified in Appendix III of Fourth Schedule of MDR 2017	-	-	No
4.1	Part-1	Yes	No	No
4.2	Part-2	No	No	No
4.3	Part-3	No	No	No
4.4	Part-4	No	No	No
4.5	Part-5	No	No	No
5.0	Essential principles checklist for demonstrating conformity to the essential principles of safety and performance of the in vitro medical device,	Yes	Yes	No
6.0	Undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule of MDR 2017,	Yes	Yes	No
7.0	Labelling and Pack Size,	Yes	Yes	No
8.0	Regulatory certificates	-	-	No
8.1	Copy of latest inspection or audit report carried out by Notified bodies or National Regulatory Authority or Competent Authority within last 3 years, if any.,	No	No	No
8.2	Valid copy of Quality Management System	No	No	No

	certificate (ISO:13485) certificate issued by the competent authority .(if any),			
8.3	Copy of NOC from Department of Animal Husbandry, Ministry of Agriculture, In Case of Veterinary IVD Kits (if available),	No	No	No
8.4	Copy of NOC from Bhabha Atomic Research Centre (BARC), Mumbai, In case Radio Immuno Assay Kits (if available),	No	No	No
8.5	Copy of Test licence obtained for testing and generation of quality control data, if any,	No	No	No
8.6	Self-attested copy of valid Whole sale licence or manufacturing licence if any,	No	No	No
9.0	Specific evaluation report, if done by any laboratory in India, showing the sensitivity and specificity of the in vitro diagnostic medical device (For class B medical devices) (if available)	-	-	Undertaking for no change or submit updated DMF
10.0	Specimen batch test report for at least consecutive 3 batches showing specification of each testing parameter (For class B medical devices),	No	No	No
11.0	Copy of performance evaluation report issued by the central medical device testing laboratory or medical device testing laboratory registered under sub-rule (3) of rule 83 of MDR 2017 for three batches (For class B medical devices)	No	No	No
12.0	A summary of analytical technology, relevant analytes and test procedure (For class A medical devices)	No	No	No
13.0	Working principle and use of a novel technology (For class A medical devices) (if any),	No	No	No
14.0	Stability (For class B medical devices),	No	No	No

14.1	Claimed Shelf life - stability study report for at least 3 lots including the protocol, acceptance criteria, testing intervals and conclusion.,	No	No	No
14.2	In use stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion	No	No	No
14.3	Shipping stability study report for 1 lot including the protocol, acceptance criteria, simulated conditions, conclusion and recommended shipping conditions,	No	No	No
15.0	Product Insert (For class B medical devices)	No	No	No
16.0	Fees Challan	Yes	Yes	Yes
17.0	Legal Form	Yes	Yes	Yes
18.0	Qualification, experience and responsibilities of current competent Technical staff	No	No	Yes
19.0	Post Marketing Surveillance data (Details of Sales, complaints, Recall, CAPA if any).	No	No	Yes
20.0	Any other additional documents	No	No	Yes
21.0	Copy of existing manufacturing Licence (MD5/MD-6/MD-9/MD-10) for which retention is applied.	No	No	Yes
22.0	Post Approval Change Applications (If Any)	No	No	No
23.0	Retention Fee Challan along with late fees (if any).	No	No	Yes
24.0	Duly Signed Retention Form	No	No	Yes

Table 1A.3 Checklist for manufacturing licence (Form MD-7/8, CLASS C/D IVD)

Section no.	Checklist Name	Fresh	Endorsement	Retention
1.0	Covering Letter	Yes	Yes	Yes
2.0	Constitution Details of Manufacturer	Yes	Yes	Undertaking for no change
3.0	Site or plant master file as specified in Appendix I of Fourth Schedule of MDR 2017	-	-	Undertaking for no change or submit updated PMF
3.1	Part-1 Plant Layout of premises with an indication of scale	Yes	Yes	-
3.2	Part-2 Organisation chart showing the arrangements for key personnel	Yes	Yes	-
3.3	Part-3 Qualification, Experience, and Responsibilities of key Technical Persons	Yes	Yes	-
3.4	Part-4 List of Equipment and Instruments	Yes	Yes	-
3.5	Part-5 Contract Activities, if any	Yes	Yes	-
4.0	Quality Management System	-	-	No
4.1	Part-1 Quality Management System as per Fifth Schedule of Medical devices Rules, 2017	Yes	Yes	No
4.2	Part-2 Quality Manual	Yes	Yes	No
4.3	Part-3 Quality Policy	Yes	Yes	No
4.4	Part-4 Control of Documents	Yes	Yes	No
4.5	Part-5 Control of Records	Yes	Yes	No
4.6	Part-6 Management Responsibility	Yes	Yes	No
4.7	Part-7 Internal Audit System	Yes	Yes	No
4.8	Part-8 Preventive and Corrective Action	Yes	Yes	No
4.9	Part-9 Procedure for identifying training needs and ensuring that all persons are trained to adequately perform their assigned responsibilities	Yes	Yes	No
4.10	Part-10 Table showing the areas and environmental	Yes	Yes	No

	requirements for Medical Devices as per Annexure A of Fifth Schedule of Medical devices Rules, 2017			
5.0	Undertaking signed by the manufacturer stating that the manufacturing site is in compliance with the provisions of the Fifth Schedule of MDR 2017	Yes	Yes	No
6.0	Regulatory certificates	-	-	No
6.1	Copy of the latest inspection or audit report carried out by Notified Bodies or National Regulatory Authority or Competent Authority within the last 3 years (if available)	No	No	No
6.2	Copy of NOC from Department of Animal Husbandry, Ministry of Agriculture, In case of Veterinary IVD Kits	Yes	Yes	No
6.3	Copy of NOC from Bhabha Atomic Research Centre (BARC), Mumbai, In case Radio Immuno Assay Kits	Yes	Yes	No
6.4	Valid copy of the Quality Management System (ISO 13485) certificate issued by the competent authority (if any)	No	No	No
6.5	Copy of Test licence obtained for testing and generation of quality control data, if any	Yes	Yes	No
6.6	Self-attested copy of valid manufacturing licence if any	No	No	Yes
7.0	Device Master File for In Vitro Diagnostic Medical Devices as per Appendix–III of Part III of Fourth Schedule of Medical devices Rules, 2017	-	-	Undertaking for no change or submit updated DMF
7.1	Part-1 Executive Summary	Yes	Yes	-
7.2	Part-2 Regulatory status of the similar device in India (approved or new in vitro diagnostic medical device)	Yes	Yes	-
7.3	Part-3 Description and specification, including variants and accessories of	Yes	Yes	-

	the in vitro diagnostic medical device			
7.4	Part-4 Essential principles checklist for demonstrating conformity to the essential principles of safety and performance of the in vitro medical device	Yes	Yes	-
7.5	Part-5 Risk analysis and control plan and report as per ISO 14971	Yes	Yes	-
7.6	Part-6 Device Design and Manufacturing Information with detailed composition of the in vitro diagnostic medical device and manufacturing flow chart process of the in vitro diagnostic medical device showing the specific flow diagram of individual components or source of the individual components and the details of source antigen or antibody as the case may be and characterization of the same. Process control of coating of antigen or antibody on the base material like Nitrocellulose paper, strips or cards or ELISA wells etc.	Yes	Yes	-
7.7	Part-7 Product validation and verification	Yes	Yes	-
7.8	Part-8 Analytical studies, Specimen type, Analytical performance characteristics, Analytical sensitivity, Analytical Specificity, Metrological traceability of calibrator and control material values, Measuring range of assay, Definition of assay	Yes	Yes	-
7.9	Part-9 Claimed Shelf life - stability study report for at least 3 lots including the protocol, acceptance criteria, testing intervals and conclusion	Yes	Yes	-
7.10	Part-10 In use stability study report for 1 lot including the protocol, acceptance criteria,	Yes	Yes	-

	testing intervals and conclusion			
7.11	Part-11 Shipping stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion	Yes	Yes	-
7.12	Part-12 Clinical Evidence	Yes	Yes	-
7.13	Part-13 Product Insert, Pack size, Label	Yes	Yes	-
7.14	Part-14 Specimen batch test report for at least consecutive 3 batches showing specification of each testing parameter along with test protocol of the in vitro diagnostic medical device	Yes	Yes	-
7.15	Part-15 Specific evaluation report, if done by any laboratory in India, showing the sensitivity and specificity of the in vitro diagnostic medical device	Yes	Yes	-
7.16	Part-16 Copy of performance evaluation report issued by the central medical device testing laboratory or medical device testing laboratory registered under sub-rule (3) of rule 83 of MDR 2017 for three batches (if applicable as per Guidance document dated 07/08/2018, on CDSCO website)	Yes	Yes	-
7.17	Part-17 Post Market Surveillance or Vigilance Reporting Procedures	Yes	Yes	Yes
7.18	Part-18-Others	No	No	No
8.0	Fee Challan (Fresh/Endorsement)	Yes	Yes	Yes
9.0	Legal Form (Fresh/Endorsement)	Yes	Yes	Yes
10.0	Post Marketing Surveillance data (Details of Sales, complaints, Recall, CAPA if any)	No	No	Yes
11.0	Copy of existing manufacturing Licence (Form	No	No	Yes

	MD-9/MD-10) along with cover letter			
12.0	Post Approval Change Applications (If Any)	No	No	Yes
13.0	Retention Fee Challan along with late fee (if applicable)	No	No	Yes
14.0	Duly signed Retention Form	No	No	Yes

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