**No.CDSCO/IVD/GD/DRAFT/IMP/01/2026**
**Government of India**
**Directorate General of Health Services**
**Central Drugs Standard Control Organization**
**(In-Vitro Diagnostic Division)**

This document serves as guidance for Importers 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 Import of In-Vitro Diagnostic Medical Device”**

https://docs.google.com/forms/d/e/1FAIpQLScSdkOzgsr6I1ybgS992nk3465tbH3pAuLfi8gmbcrZ7y29Gg/viewform?usp=publish-editor

# Guidance for Import of In-Vitro Diagnostic Medical Device

# For submission of Import licence applications to online portal

**Central Drugs Standard Control Organization**
**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 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 and clarifications, FAQ's, tool tip in portal issued by CDSCO time to time for all their professional needs.

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## Abbreviations:

| | |
|---|---|
| **BARC** | **Bhabha Atomic Research Centre** |
| **CDSCO** | Central Drugs Standard Control Organisation |
| **EU** | European Union |
| **FSC** | Free Sale Certificate |
| **IFU** | Instructions for Use |
| **IVD** | In-Vitro Diagnostics |
| **MD** | Medical Device |
| **MDR** | Medical Devices Rules |
| **NOC** | No Objection Certificate |
| **NRA** | National Regulatory Authority |
| **NSWS** | National Single Window System |
| **PER** | Performance Evaluation Report |
| **POA** | Power of Attorney |
| **RIA** | Radio Immuno Assay |

## 1. Introduction

1.1 **Purpose**- This document serves as guidance for Importers 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.

1.2 **Scope**- This document applies to import of In-vitro Diagnostics Medical Device (IVDs).It is a consolidated reference document made available for importers about the standards, regulatory and other requirements for IVD medical devices in India. The document outlines the applicable regulatory framework, procedural steps, documentation requirements, and compliance obligations that must be fulfilled in accordance with the Medical Devices Rules, 2017 (MDR-2017).

## 2. Licensing Authority

The Central Licensing Authority, Central Drugs Standard Control Organization (CDSCO), under the Directorate General of Health Services shall be the competent authority for issuing of the Import Licence for all classes of IVD.

## 3. Online Portal

Application for grant of registration/permission/licence for IVD Medical Device shall be submitted in the online system for Medical Devices (MD Online Portal; **www.cdscomdonline.gov.in**) for MD-14 and NSWS portal (**https://www.nsws.gov.in/**) for MD-16.

## 4. Classification of IVDs

IVD shall be classified on the basis of parameters specified in Part II of the First Schedule by the Central Licensing Authority, in the following classes which includes kit/reagent, instrument, analyzers and software-

**Low risk**- Class A
**Low moderate risk**- Class B
**Moderate high risk**- Class C
**High risk**- Class D

Kindly refer to "**Classification of In-vitro Diagnostic Medical Devices under the provisions of Medical Devices Rules, 2017**" published on CDSCO website (https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/IVD_classifiction25oc23.pdf).

(https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Classificationg1.pdf).

## 5. Types of Import Application

**Test Licence=** Test Licence application in Form MD-16 is an application to obtain permission to import medical devices in limited quantities for purposes other than commercial sale e.g., for testing, evaluation, demonstration, training or clinical investigation. In Form MD-17 the actual Test Licence is granted upon approval of Form

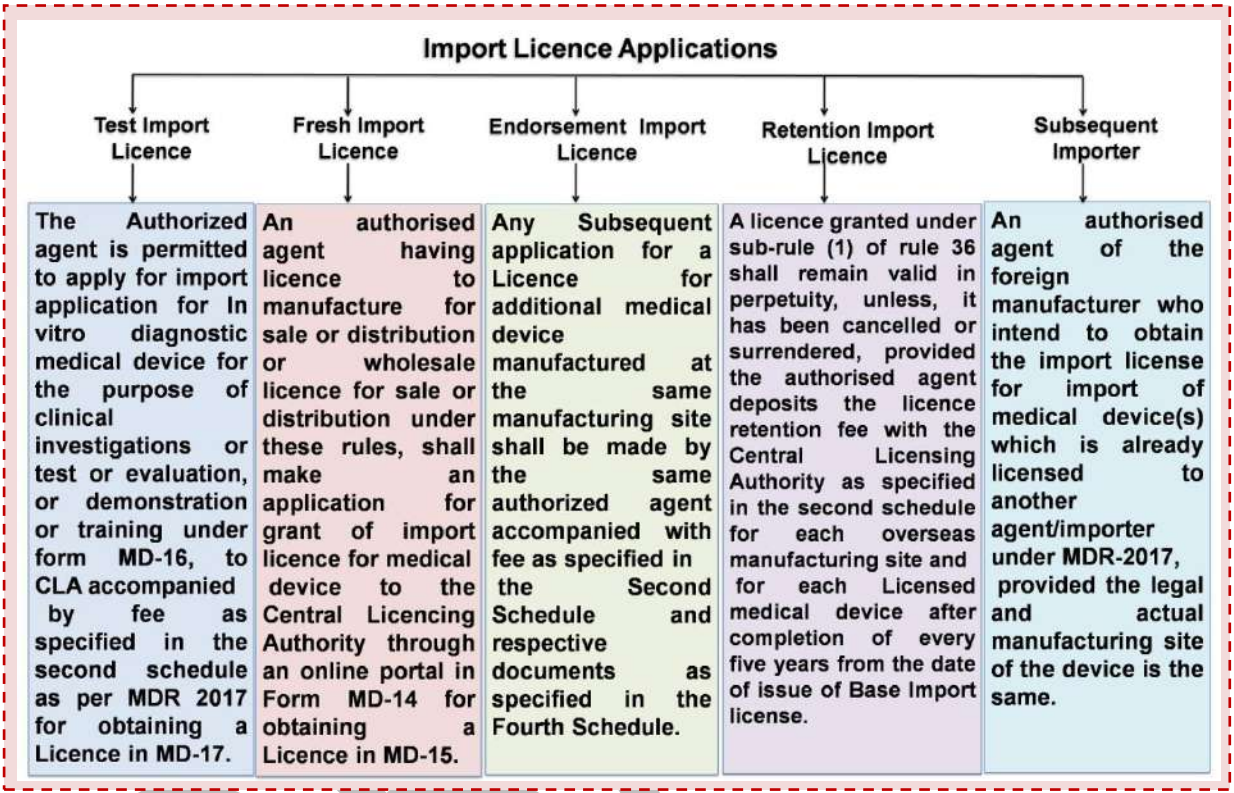
MD-16. This is the licence document that allows import of the specified device(s) under defined purpose and quantity restrictions.

**Fresh** = First time licence

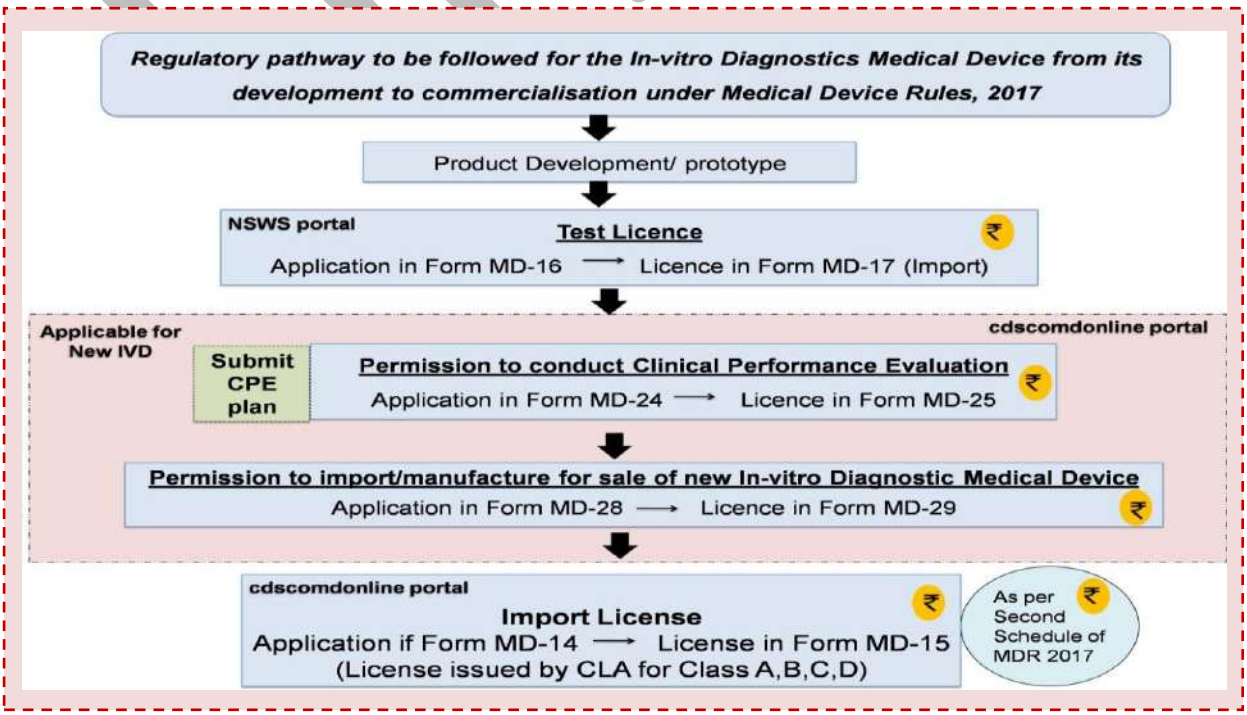
**Endorsement** = Adding new products/variants to an existing licence.

**Retention** = Renewal/extension of an existing licence to maintain validity.

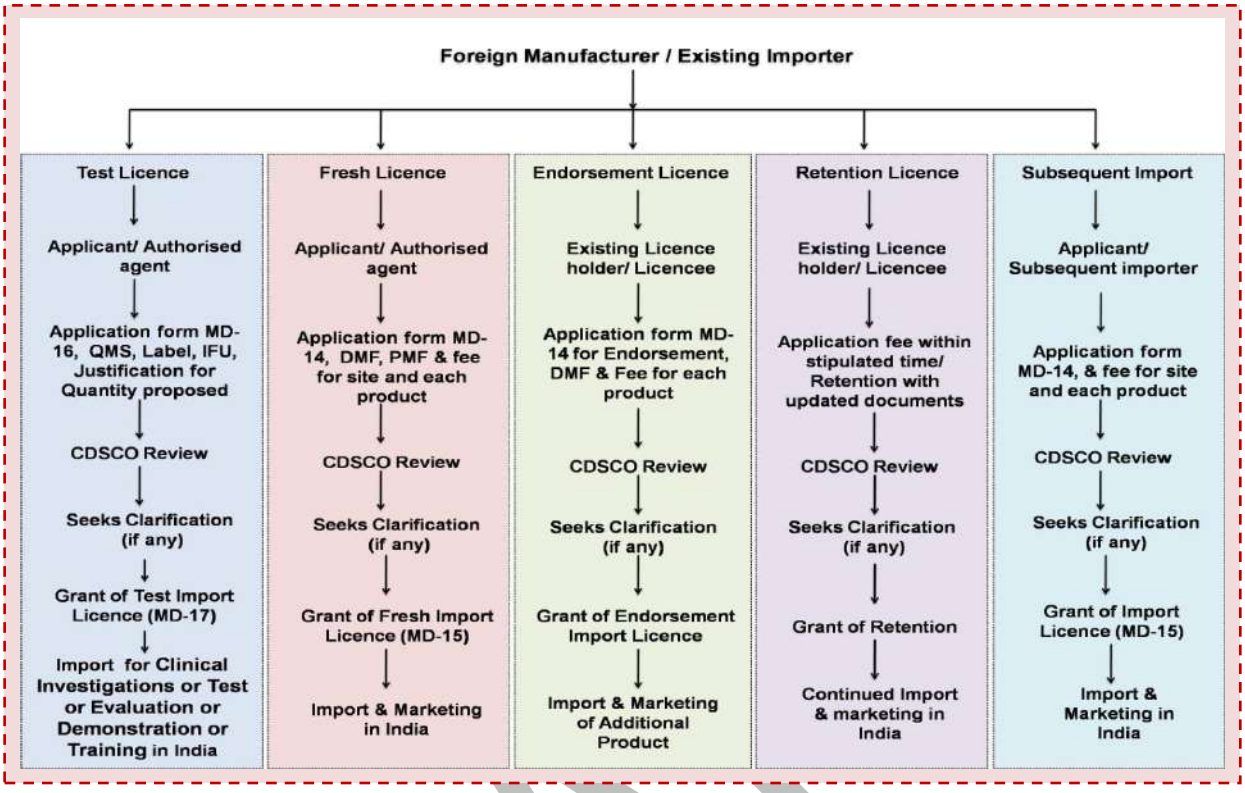
**Subsequent Importer**=Importer of In-Vitro Diagnostics Medical Device, already approved by the Central Licensing Authority.




## 6. Regulatory Pathways for Import Licences



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




## 8. Checklist

### 8.1 For Import Test Licence (MD-16)

| 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** | Justification of quantity proposed to be imported | **Yes** |
| **4.0** | Test protocol/Approved clinical investigation plan if any | **Yes** |
| **5.0** | Quality certificates like QMS etc., of the manufacturer, if any | **Yes** |
| **6.0** | Labels and IFU, if any | **Yes** |
| **7.0** | Other document, if any | **No** |
| **8.0** | An undertaking stating that the medical device proposed to be imported to be used exclusively for purpose specified at serial Number 7 of Form-16 and shall not be used for commercial purpose. | **Yes** |
| **9.0** | An undertaking from the testing laboratory, Stating that required facilities including equipment, instrument and personnel will be provided to test or evaluate medical device. | **Yes** |
| **10.0** | Fee Chalan | **Yes** |
| **11.0** | **Legal Form** | **Yes** |

## 8.2 For Import License (MD-14)

| Section no. | Checklist Name | Fresh | Endorsement | Retention | Subsequent Importer |
|---|---|---|---|---|---|
| **1.0** | Covering Letter, | Yes | Yes | Yes | Yes |
| **2.0** | Power of Attorney (Original) authenticated in India either by a Magistrate of First Class or by Indian Embassy in the country of origin or by an equivalent authority through apostilled along with undertaking from the authorized agent as specified in Part I of Forth Schedule, | Yes | Yes | Yes, If any changes | Yes |
| **3.0** | Self-attested copy of valid Whole sale licence or manufacturing licence if any, | Yes | Yes | No | Yes |
| **4.0** | Regulatory Certificates along with previous import licence.(if any) | - | - | - | - |
| **4.1** | Notarized copy of overseas manufacturing Site or establishment or plant registration, by whatever name called, in the country of origin issued by the competent authority, | Yes | Yes | No | No |
| **4.2** | Notarized and valid copy of Free Sale Certificate issued by the National Regulatory Authority or equivalent competent authority of the country of origin.(if any) | Yes | Yes | Yes | Yes |
| **4.3** | Notarized and valid copy of Free Sale Certificate issued by the National Regulatory Authority or equivalent competent authority of the any of the countries namely United States of America, Australia, Canada, Japan, and European Union Countries. | Yes | Yes | Yes | Yes |
| **4.4** | 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. | Yes | Yes | No | No |
| **4.5** | Copy of NOC from Department of Animal Husbandry, Ministry of Agriculture, In Case of Veterinary IVD Kits, | Yes | Yes | No | No |
| **4.6** | Copy of NOC from Bhabha Atomic Research Centre (BARC), Mumbai, In case Radio Immuno Assay Kits | Yes | Yes | No | No |
| **5.0** | Quality Management System certificate in respect of legal and actual manufacturing sites(s) (Wherever applicable), | - - | - | - | - |
| **5.1** | Notarized and valid copy of Quality Management System certificate (ISO13485) certificate issued by the competent authority, | Yes | Yes | No | Yes |
| **5.2** | Notarized and valid copy of Production Quality Assurance certificate or Full quality Assurance certificate issued by the competent authority.(if any) | If applicable | Yes | No | Yes |
| **5.3** | Notarized and valid copy of CE design certificate issued by the competent authority.(if any), | If applica | Yes | No | Yes |

| | | | | | |
|---|---|---|---|---|---|
| | | ble | | | |
| **6.0** | Site or plant master file as specified in Appendix I of Fourth Schedule of MDR-2017. | - | - | Yes if there is some changes in PMF/ If No submit Undertaking | Yes if there is some changes in PMF/ If No submit Undertaking |
| **6.1** | Part 1, | Yes | - | No | No |
| **6.2** | Part 2, | Yes | - | No | No |
| **6.3** | Part 3, | Yes | - | No | No |
| **6.4** | Part 4, | Yes | - | No | No |
| **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 | Yes | Yes | Yes if there is some changes in DMF/ If No submit Undertaking | Yes if there is some changes in DMF/ If No submit Undertaking |
| **7.1** | Part-1 Executive Summary, Description and specification, including variants and accessories and Design & manufacturing<br>Information of the in-vitro diagnostic medical device | Yes | Yes | No | No |
| **7.2** | Part-2 Regulatory status of the similar device in India (approved or new in vitro diagnostic medical device). | Yes | Yes | No | No |
| **7.3** | Part–3 Essential principles checklist | Yes | Yes | No | No |
| **7.4** | Part–4 Risk analysis and control summary, Product validation and verification and Clinical Evidences | Yes | Yes | No | No |
| **7.5** | Part-5 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 | No | No |
| **7.6** | Part-6 Claimed Shelf life stability study report for at least 3 lots including the protocol, acceptance criteria, testing intervals and conclusion, In use stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion & Shipping stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion. | Yes | Yes | No | No |
| **7.7** | Part-7 Product Insert, Pack size, Label | Yes | Yes | No | No |
| **7.8** | Part-8 Specimen batch test report for at least consecutive 3 batches showing specification of each testing parameter | Yes | Yes | No | No |
| **7.9** | Part-9 Copy of performance evaluation Report | Yes | Yes | No | No |

| | | | | | |
|---|---|---|---|---|---|
| | 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/ Specific evaluation report, if done by any laboratory in India, showing the sensitivity and specificity of the in-vitro diagnostic medical device | | | | |
| **7.10** | Part-10 Post Market Surveillance Data and any other information of the product | Yes | Yes | Yes | Yes |
| **8** | Correlation chart with respect to products list mentioned in MD-14 and FSC submitted, | Yes | Yes | No | No |
| **9** | Testing method preferably in Video (if available), | If applicable | If applicable | No | No |
| **10** | Fee Chalan | Yes | Yes | Yes | Yes |
| **11** | Legal Form | Yes | Yes | Yes | Yes |

## 9. Stakeholders & Their Roles

**9.1 Foreign Manufacturer-**The process of importing and marketing in-vitro diagnostic (IVD) devices in India involves multiple stakeholders, each with clearly defined roles and responsibilities to ensure regulatory compliance and safeguard public health. The Foreign Manufacturer is the primary holder of product approvals in the country of origin and carries the overall responsibility for ensuring the safety, quality, and performance of the device throughout its life cycle. It is their obligation to manufacture the product in accordance with internationally recognized standards and quality management systems, and to provide all necessary regulatory documents, certifications, and declarations required for submission to the Indian authorities.

**9.2 Authorized Indian Agent (Applicant)** -The Authorized Indian Agent (Importer) acts as the legal representative of the foreign manufacturer in India and plays a pivotal role in regulatory interactions with the Central Drugs Standard Control Organization (CDSCO). The Indian Agent must hold a valid licence under the Medical Devices Rules (MDR), 2017, and is responsible for submitting applications, maintaining regulatory approvals, and ensuring post-market compliance, including reporting of adverse events, product recalls, or field safety corrective actions, as applicable. They serve as the key link between the foreign manufacturer and Indian regulatory authorities, ensuring transparency and accountability.

## 10. Documents required

### 10.1 As per Checklist MD-16

### i) 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 legal form. It should clearly state the purpose of the application (test license and purpose of import). 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 manufacturing site details.

**ii) Brief description of the medical device including intended use, material of construction, design**

The medical device which is to be imported shall be intended for the purpose of examination, testing, evaluation, demonstration, or training and is not meant for commercial sale or routine clinical use. The intended use should clearly describe the specific function of the device, target user, and the context in which it will be used during testing or evaluation. The device design and material of construction shall be mentioned in brief in the application (if applicable to the device).

**iii) Justification of quantity proposed to be imported**

The quantity proposed to be imported should be limited to the minimum number of units required solely for the intended purpose of testing, evaluation, demonstration, or training under MD-16. The proposed quantity shall be justified taking into account the requirement for clinical investigation, approved clinical investigation plan and information and documents submitted by the applicant. The quantity imported shall not be intended for commercial sale. The firm shall submit the complete utilization breakup of the quantity imported.

**iv) Test protocol/Approved clinical investigation plan if any**

The test protocol or approved clinical investigation plan **if applicable** shall outline the objective, methodology, and scope of testing to be conducted using the imported medical device. The study plan shall include details of the study design, sample size, inclusion and exclusion criteria, test procedures, performance parameters to be evaluated, data collection and analysis methods, and acceptance criteria. The protocol also specifies the study sites, roles and responsibilities, ethical considerations, and compliance with applicable regulatory requirements. This ensures that the testing or investigation is conducted in a systematic, controlled, and scientifically valid manner.

**v) Quality certificates like QMS etc., of the manufacturer, if any**

**If applicable,** the ISO 13485certificates shall be submitted which must be valid and notarized. The ISO 13485 should be submitted for both legal and actual manufacturer (where applicable). The certificate should mention the Name of the issuing body, ISO 13485 certification number, manufacturer or legal entity, Scope of the certification, Date of issue and expiry &Signature and seal of the issuing authority.

**vi) Labels and IFU, if any**

**If applicable**, the firm shall submit label which mentions product name and description, manufacturer information, Lot no. & expiration date, storage instructions, warning/ precautions and complete Information for Use (IFU).

**vii) Other document, if any**

**viii) An undertaking stating that the medical device proposed to be imported to be used exclusively for purpose specified at serial Number 7 of Form-16 and shall not be used for commercial purpose.**

The firm shall provide undertaking mentioning that the "**Firm Name** having registered address at _____hereby undertake that the medical device proposed to be imported will be used exclusively for the purpose specified at serial number 7 of Form-16. We further confirm that the device shall not be used for any commercial purposes. We assure you that all guidelines and conditions prescribed by the CDSCO will be strictly adhered to".

**ix) An undertaking from the testing laboratory, stating that required facilities including equipment, instrument and personnel will be provided to test or evaluate medical device.**

The firm shall provide undertaking from testing lab stating that "We, **Testing Lab Name** having our registered offices at **office address** hereby undertake that all required facilities, including equipment, instruments, and personnel, will be provided to test or evaluate medical device".

**x) Fee Chalan**

Bharat Kosh receipt should be submitted as per Second Schedule of MDR 2017. Chalan should be linked to the application and complete fee should be paid (Second Schedule, MDR 2017).

**xi) Legal Form**

The firm shall submit the legal form which should be digitally signed, system generated and should have all essential details filled. It should be signed by authorized signatory who has signed the cover letter.

| **Form MD-16** | |
|---|---|
| [See sub-rule (2) of rule 40] | |
| **Application for Licence to Import Medical Devices for the Purpose of Clinical Investigations or Test or Evaluation or 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) shall be mentioned.** |
| 2. Address of applicant | • **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.** |
| 3. Name and Address of device Manufacturer | • **The name and address of the actual Manufacturing site for the applied product shall be mentioned including telephone number, mobile number, fax number and e-mail id.** |
| 4. Name and Address of site(s) where test or evaluation is proposed to be conducted | • **The Registered office/ site address including telephone number, mobile number, fax number and e-mail address where the test or evaluation of the product will be carried out.** |
| 5. Details of medical device(s) to be Imported | |
| 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 any) | • **The Trade name or Brand name (if registered under Trade Marks Act1999) of the applied products shall be mentioned.**<br>• **Same shall be matched with the Labels and IFU.** |
| 3. Model No. (if any) | • **The firm shall mention Model/Catalogue Number of the applied products shall be mentioned in accordance with the product Brochure or Catalogue.** |
| 4. 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)** |
| 5. 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 https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Guidelines_Grouping_of_MDandIVD.pdf.** |
| 6. Proposed 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 in the CDSCO website.**<br>• **For classification of IVD Analyzers, instruments and software's: - https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/IVD_classifiction25oc23.pdf**<br>• **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==**<br>• **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** |
| 7. Shelf life (if applicable) | • **The claimed Shelf life of the product shall be mentioned as per the real time stability study report submitted with the application.**<br>• **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<br>• **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 |
| 8. Whether Sterile or Non-sterile | • **The Sterile or Non-sterile status of the product shall be mentioned as per the label and IFU claim.** |

| | |
|---|---|
| 9. Quantity to be imported | • **Firm shall mention the quantity of kits/tests to be imported along with unit and pack size.** |
| 6. Brief description of medical device | • **The product description as per the label and Instruction for Use(IFU)/Package/Product Insert shall be mentioned** |
| 7. Purpose of Import | • **The firm shall mention the objective/aim/purpose justifying the import of the mentioned product.** |
| 8. Justification for quantity to be imported | • **The firm shall provide a brief justification about the proposed quantity to be imported.** |
| 9. An undertaking stating that required facilities including equipment, instrument and personnel have been provided to test or evaluate medical device | |
| 10. An undertaking stating that the medical device proposed to be imported to be used exclusively for purpose specified above and shall not be used for commercial purpose | |
| 11. Fee paid on _____ Rs. _____ receipt/chalan/transaction id ____ | • **Bharat Kosh Payment receipt/chalan/transaction id details will be captured by the system.** |
| 12. I hereby state and undertake that, I shall comply with all applicable provisions of the Drugs and Cosmetic Act, 1940 (23 of 1940) and the Medical Devices Rules, 2017. | |

**Place:** _____

**Date:** _____

**Signature**
**(Name and designation)**
**(To be signed digitally)**

### 10.2 As per Checklist MD-14

#### 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 renewal. In the case of endorsement, the firm must provide details of the base licence number and also indicate the retention status of the base licence; if the base licence is older than five years, this fact should be clearly highlighted.
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 class of product applied for, the number of products included in the application, and the details of the manufacturing site. This ensures clarity, transparency, and completeness in the submission, thereby facilitating smooth processing of the application.

#### 2. Power of Attorney (POA)

All pages of the Power of Attorney (POA) must be duly authenticated with the signature and stamp of the apostilling authority to ensure its validity. The POA should be prepared strictly in accordance with Part I of the Fourth Schedule, and it must include both the "POA signed

and stamped by the manufacturer" as well as the "Undertaking signed and stamped by the Indian Agent," clearly indicating the name and designation of the respective authorized signatories. It is essential that the POA is co-jointly signed and stamped by both the manufacturer and the Indian Agent, and it must also specify the name and address of the firm along with the signatory details. The document should clearly outline critical product details, including the Generic Name, Brand Name, Model Number, Dimensions, Intended Use, Shelf Life, Sterile or Non-Sterile status, and the Class of Medical Device as defined in the legal form and Free Sale Certificate (FSC).

Furthermore, the names of the proposed devices mentioned in the POA must exactly correlate with those stated in the Legal Form as well as the FSC being submitted. Similarly, the names and addresses of both the legal or actual manufacturer and the Indian Agent as stated in the POA must match with the details provided in the Legal Form, FSC, and the Wholesale Licence/ MD-42 to avoid discrepancies during review. To facilitate quick and efficient examination, the firm should highlight the applied products in the POA by assigning serial numbers corresponding to the entries in the legal form. This consistency across documents ensures clarity, compliance with regulatory requirements, and streamlines the evaluation process.

**3. Self-attested copy of valid Whole sale licence or manufacturing licence**

The firm is required to submit a self-attested copy, duly signed and stamped by the Indian Agent, of a valid Wholesale Licence issued under the Drugs and Cosmetics Rules. This licence should authorize the sale or distribution of drugs in Form 20B and 21B, or alternatively, a valid Wholesale Licence permitting the sale and distribution of medical devices in Form MD-42. In cases where the original licence has already been renewed, the firm may submit the valid renewal copy of Form 20B and 21B or Form MD-42 as issued by the respective State Licensing Authority. If the renewed licence is under process and the final copy has not yet been issued, the firm may provide a copy of the acknowledged receipt of the licence renewal fee issued by the State Licensing Authority as supporting evidence of the application being under renewal. These documents must be valid and current, and their submission is critical to demonstrate that the firm and its Indian Agent are duly authorized for the lawful sale, stocking, and distribution of drugs or medical devices in India, in compliance with the applicable regulatory framework.

**4. Regulatory Certificates along with previous import licence**

**Note:** Relevant information should be put in each section.

**4.1 Notarized copy of overseas manufacturing, Site or establishment or plant registration, by whatever name called, in the country of origin issued by the competent authority**

The Firm should submit valid copy of actual Manufacturing Site/Plant Valid Registration certificate; the registration must be issued by the relevant regulatory or competent authority in the country of origin. The document must be notarized for authenticity.

**4.2 Notarized and valid copy of Free Sale Certificate issued by the National Regulatory Authority or equivalent competent authority of the country of origin (if any)**

The Firm should submit duly notarized/Apostilled/Attested (by apostilling/notarizing officer in the country of origin) and valid copy of Free Sale Certificate/Certificate to Foreign Government/ Certificate of Marketability for each device issued by National Regulatory

Authority or equivalent competent authority of the country of origin. Free Sale Certificate should state that the proposed device is freely sold in Country of Origin and can be legally exported. It should also specify name and address of both the legal and actual manufacturing site along with applied product name(s) in generic and Model name, if any. The certificate should also clearly display the date of issue and the date of expiry to confirm the validity period of the certification at the time of submission.

**4.3 Notarized and valid copy of Free Sale Certificate issued by the National Regulatory Authority or equivalent competent authority of the any of the countries namely United States of America, Australia, Canada, Japan, and European Union Countries**

The Free Sale Certificate (FSC) submitted by the firm must be valid and issued by the National Regulatory Authority (NRA) or an equivalent competent authority from one of the countries, namely the USA, Australia, Canada, Japan, the United Kingdom, or any of the European Union (EU) member states. The FSC shall be duly notarized to ensure authenticity. While submitting the FSC, the firm shall clearly indicate the applied products in a tabulated manner with corresponding Serial Numbers (Sl. No.), aligned with the details provided in the legal form (MD-14). This will facilitate efficient verification and quick examination of the documents by the reviewing authority. The certificate should also clearly display the date of issue and the date of expiry to confirm the validity period of the certification at the time of submission.

**4.4 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)**

Copy of latest Inspection/Audit Report along with compliance verification report carried out by Notified bodies/National Regulatory Authority/Competent Authority dated within the last 3 years. Report must include official stamp and signatures.

**4.5 Copy of NOC from Department of Animal Husbandry, Ministry of Agriculture, In Case of Veterinary IVD Kits (if any)**

The No Objection Certificate (NOC) must be current and issued by the Department of Animal Husbandry, Ministry of Agriculture. The firm shall submit the NOC in the correct official format as issued by the Department of Animal Husbandry, that it includes the department's official letterhead, stamp, and signatories. The NOC issued should include Name of the product, manufacturer details, approval status, and date of issuance.

**4.6 Copy of NOC from Bhabha Atomic Research Centre (BARC), Mumbai, In case Radio Immuno Assay Kits (if any)**

The No Objection Certificate (NOC) should be current and issued by the Bhabha Atomic Research Centre (BARC), Mumbai, indicating that the Radio Immuno Assay (RIA) kits comply with the necessary regulatory and safety standards. The NOC should include The name and description of the Radio Immuno Assay (RIA) kit, Details of the manufacturer or distributor, Approval status, Date of issuance and signature of the authorized signatory at BARC.

**5. Quality Management System certificate in respect of legal and actual manufacturing sites(s) (Wherever applicable),**

**Note: Relevant information should be put in each section.**

**5.1 Notarized and valid copy of Quality, Management System certificate (ISO13485) certificate issued by the competent authority**

The ISO 13485 certificate submitted by the firm must be valid, current, and duly notarized to establish its authenticity. It is mandatory that the ISO 13485 certification is provided for both the legal manufacturer as well as the actual manufacturer, wherever applicable, in order to ensure full compliance with regulatory requirements. The certificate must clearly state the name of the issuing certification body along with the unique ISO 13485 certification number, thereby confirming traceability and authenticity. In addition, the certificate should include the name of the manufacturer or legal entity to which the certification is granted, along with a precise description of the scope of certification, specifying the types of medical devices, processes, or activities that are covered under the quality management system.

The certificate should also clearly display the date of issue and the date of expiry to confirm the validity period of the certification at the time of submission. Furthermore, it must carry the official signature and seal of the issuing certification authority as evidence of its validity and approval. Ensuring that all these details are explicitly mentioned on the certificate is essential for the regulatory authorities to verify the adequacy of the manufacturer's quality management system in line with ISO 13485 requirements.

**5.2 Notarized and valid copy of Production Quality Assurance certificate or Full Quality Assurance certificate issued by the competent authority (if any)**

The Production Quality Assurance or Full Quality Assurance certificate must be notarized, valid and issued by a recognized competent authority.

**5.3 Notarized and valid copy of CE design certificate issued by the competent authority (if any)**

The CE Design Certificate must be current, notarized and issued by a competent authority or Notified Body recognized within the European Union (EU).The certificated should include the name of the manufacturer, legal and actual manufacturing site (s),and the product name, certificate number, Scope of certification, Details of the Notified Body, Date of issuance and expiry date and signature and stamp of authorized person.

**6.0 Site or plant master file as specified in Appendix I of Fourth Schedule of MDR-2017.**
**Note: Relevant information should be put in each section.**

**6.1 Part 1** - Should submit Site or plant master file as specified as per Part III, Appendix I of MDR-2017.Should submit all annexure/attachments if specified in PMF

6.2 Part 2
6.3 Part 3
6.4 Part 4

**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, Description and specification, including variants and accessories and Design & manufacturing Information of the in-vitro diagnostic medical device**

The Firm should submit introductory descriptive information on the IVD/medical device, the intended use and indication for use, Class of Device, novel features of the device (if any), Shelf Life of the Device and a synopsis on the content of the dossier (not more than 500 words). Information regarding Sterilization of the Device (whether it is sterile or Non-sterile; if sterile, mode of sterilization).Regulatory status of the similar device in India (Approved or Not Approved in India).Domestic price of the device in the currency followed in the Country of origin. Marketing History of the device from the date of introducing the device in the market. List of regulatory approvals or marketing clearance obtained (Submit respective copies of Approval Certificates).

### 7.2 Part-2 Regulatory status of the similar device in India (approved or new in vitro diagnostic medical device)

The Firm shall provide a list of all products of the same type, class, intended use, or function that have already been approved, along with the licence details of any similar approved products, if available. In cases where the applied device differs from existing approved devices (e.g., due to new technology or intended use), the similarity and differences should be clearly highlighted.

### 7.3 Part–3 Essential principles checklist

The Firm shall submit essential principles checklist including:
a) The Essential Principles
b) Whether each Essential Principle applies to the device and if not, why not.
c) The method(s) used to demonstrate conformity with each Essential Principle that applies.
d) A reference for the method(s) employed (e.g., standard).
e) The precise identity of the controlled document(s) that offers evidence of conformity with each method used.
f) The method used to demonstrate conformity, a standard reference for the method employed, and the precise identity of the controlled document that offers evidence of conformity with each method used.
(**Refer: to the document on "Essential principles for safety and performance of medical device guidelines**"
https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Essentialprinciples.pdf).

### 7.4 Part-4 Risk analysis and control summary, Product validation and verification and Clinical Evidences

The Firm need to submit detailed document outlining the potential risk associated with IVD and steps taken to identify, analyze, and mitigate associated risk. The risk analysis should be based on recognized standards e.g. ISO 14971 and be part of the manufacturer's risk management plan based on complexity and risk class of the device.
**(Refer to Medical Devices Rules 2017, Appendix III, and point 4-6:**
https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf).

### 7.5 Part-5 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

The Firm shall refer to **Medical Devices Rules 2017, Appendix III, MDR-2017 Point 7-14** (https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf). **The Firm shall submit 03 lots Analytical Performance Validation report.**

**7.6 Part-6 Claimed Shelf life – stability study report for at least 3 lots including the protocol, acceptance criteria, testing intervals and conclusion, In use stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion & Shipping stability study report for 1 lot including the protocol, acceptance criteria, testing intervals and conclusion**

The firm shall submit the shelf life stability study report should include data from at least three lots of the product. The firm shall mention methodology for the study, including storage conditions, testing intervals, and procedures along with defined time points at which testing is conducted (e.g., 0, 3, 6, 12 months) to assess stability over the claimed shelf life should be mentioned. For In use stability the study report including the protocol, acceptance criteria and testing intervals along with conclusions and claimed in use stability should be reported. Shipping studies can be done under real and/or simulated conditions and should include variable shipping conditions such as extreme heat or cold.

The Firm should mention

(a) The study report (including the protocol, acceptance criteria)
(b) Method used for simulated conditions, conclusion and recommended shipping conditions.

(Refer to the "**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)).

**7.7 Part-7 Product Insert, Pack size, Label**

The firm shall ensure that the draft India-specific labels submitted along with the application are complete, accurate, and in compliance with the applicable regulatory requirements. The labels must clearly specify the intended use of the device, along with the indications and indications for use, so that the scope and purpose of the product are unambiguously communicated. They should also include any warnings and precautions necessary for the safe handling and usage of the device, ensuring that users are well informed of any potential risks or limitations. In addition, the storage conditions must be stated in precise terms to safeguard product stability, and the expiration date or shelf life should be prominently displayed to guide safe utilization within the recommended timeframe. The labels should also provide complete and accurate contact information of the manufacturer or authorized agent to enable users to seek clarifications or report issues when required.

Accordingly, the pack size should be clearly indicated, specifying the number of test kits, reagents, or devices contained within each unit of packaging, to avoid any ambiguity regarding product quantity. The label must also display the product name and description along with manufacturer's details, including the name and full address of the legal and actual manufacturer, wherever applicable. Additional critical information such as the lot/batch number, expiry date, and storage instructions must be prominently presented to ensure product traceability and safe usage. The inclusion of all relevant warnings, precautions, and reference to the Instructions for Use (IFU) on the label is essential to ensure that users can operate the device safely and effectively. These requirements collectively ensure that the

labelling is comprehensive, user-friendly, and compliant with Indian regulatory standards, thereby facilitating safe distribution and use of the medical device in the Indian market.

**7.8 Part-8 Specimen batch test report for at least consecutive 3 batches showing specification of each testing parameter**

The Firm should mention batch size & selection, test protocol, acceptance criteria, test interval for at least consecutive 3 batches.

**7.9 Part-9 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/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 performance evaluation reports (PER) for three independent batches of IVDs listed below, from the list of laboratories mentioned in guidance document issued by CDSCO, time to time on PER. PER is subjected to current regulatory practice, If PER submitted from NABL accredited laboratory, firm needs to submit 03 lots report with valid NABL certificate along with scope reflecting the applied product details. The firm may also refer to the following document published on CDSCO website for performance evaluation data-

(i) **Guidance on Performance Evaluation of In-vitro Diagnostic Medical devices** (https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/GuidanceonPER-updated13-Feb2020-Final.pdf)

(ii) **Overview on Performance Evaluation /External Evaluation of In vitro Diagnostic Medical Device (IVDMD)**(https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODc2Ng==)

(iii) **CDSCO updated list of Laboratories for conducting Performance Evaluation of In-Vitro Diagnostic Medical Device** (https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/Guidance-on-PER-updated-04-June-2025.pdf).

**- Performance Evaluation Report is required for the In-Vitro Diagnostic Medical Devices intended for:-**

1. HIV
2. HBV
3. HCV
4. Blood Grouping reagent
5. Cancer
6. Tuberculosis
7. Malaria
8. Dengue
9. Chikungunia
10. Syphlis
11. Typhoid
12. Influenza
13. ToRCH (*Toxoplasma gondii*, Rubella virus, Cytomegalovirus, Herpes simplex virus)

14. Chlamydia
15. Pneumonia
16. Methicilline-Resistant *Staphylococcus aureus*
17. Entero virus
18. Marker for congenital disorder e.g. Screen test for Down's syndrome
19. Sexually transmitted agent i.e. *Treponema pallidum*, *Neisseria gonorrhoeae*, Human Papilloma Virus, Herpes Virus
20. Other life threatening Infections / agent.

**7.10 Part-10 Post Market Surveillance Data and any other information of the product**

The dossier should contain the Post Marketing Surveillance or Vigilance Reporting procedures and data collected by the manufacturer encompassing the details of the complaints received and corrective and Preventive actions taken for the same. The firm may also refer to "Guidance **on Post-Market Surveillance of In-vitro Diagnostic Medical Device (IVDMD)**"

(https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODc2Nw==).

**Kindly refer to:**
chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj /https://www.ipc.gov.in/images / Guidance_Document_MvPI.pdf

**8.0 Correlation chart with respect to products list mentioned in MD-14 and FSC submitted**

The Firm needs to mention the details of page no. and serial no. in Free Sale Certificate, POA and legal form in tabular form with respect to each applied product.

**9.0 Testing method preferably in Video (if available),**

**10.0 Fee Chalan**

Bharat Kosh receipt should be submitted as per Second Schedule of MDR-2017. Chalan should be linked to the application and complete fee should be paid (Second Schedule, MDR-2017).

| S. No. | Rule | Subject | In rupees (INR) except where specified in dollars ($) |
|---|---|---|---|
| **1** | 34(2) | Import licence for Class A or Class B In-vitro diagnostic medical device | - |
| | | (a) One site | $1000 |
| | | (b) Each distinct In-vitro diagnostic medical device | $10 |
| **2** | 34(2) | Import licence for Class C or Class D In-vitro diagnostic medical device | - |
| | | (c) One site | $3000 |
| | | (d) Each distinct In-vitro diagnostic medical device | $500 |
| **3** | 35(2) | Inspection of the overseas manufacturing site | $6000 |

| | | | |
|---|---|---|---|
| **4** | 37 | Import licence retention fee | - |
| | | One overseas site manufacturing Class A or Class B In-vitro diagnostic medical device | $1000 |
| | | Each distinct In-vitro diagnostic medical device of Class A or Class B | $10 |
| | | One overseas site manufacturing Class C or Class D In-vitro diagnostic medical device | $3000 |
| | | Each distinct In-vitro diagnostic medical device of Class C or Class D | $500 |
| **5** | 40(2) | Fee for Import licence for test, evaluation or demonstration or training for each distinct medical device | $100 |
| **6** | 42(1) | Fee for Import of investigational medical device by Government hospital or statutory medical institution for treatment of patient of each distinct medical device | 500 |
| **7** | 59(2) | Permission to conduct clinical performance evaluation | 25000 |
| **8** | 64(1) | Permission to import or manufacture new In-vitro diagnostic medical device | 25000 |

**For reference purpose:**

1- What is the applicable fee for importing Class A and Class B medical devices, including the site registration fee?

A- For importing Class A and Class B IVD medical devices, the firm is required to pay the prescribed site registration fee along with the product registration fee as specified under the Medical Devices Rules, 2017. The total payable amount depends on the risk class and the number of products applied under the import licence.

**Example:**

| Subject | Fee | Total fee to be paid |
|---|---|---|
| **Site fee (for Class A & B products)** | $1000 | $1050 |
| **3 products are applied under Class A and 2 products under Class B** | 5 * $10 = $ 50 | |

2- What is the applicable fee for importing Class C/D product under to the already issued import licence for Class A and Class B IVD products?

A- For importing Class C/D IVD medical devices under endorsement if the firm already have import licence for Class A and Class B IVD products, the firm is required to pay the prescribed site registration fee for Class C/D products

along with the fee for the number of applied product as specified under the Medical Devices Rules, 2017.

**Example:**

| Subject | Fee | Total fee to be paid |
|---|---|---|
| **Site fee (for Class C/D products)** | $3000 | $4500 |
| **3 products are applied under Class C** | 3 * $500 = $ 1500 | |

## 11. Legal Form

The firm shall submit the legal form which should be digitally signed, system generated and should have all essential details filled. It should be signed by authorized signatory who signed the undertaking in POA checklist point. The authorized agent address should match with the address in wholesale licence or MD-42 registration form, and POA.

| **FORM MD-14** | | |
|---|---|---|
| [See sub-rule (1) of rule 34] | | |
| **Application for issue of import licence to import medical device** | | |
| **1.** | Name of Authorized agent | • **The Authorized agent is the Firm/Company/Organization appointed by an overseas manufacturer through a Power of Attorney to undertake import of IVD medical device in India. [Rule 3(f) of MDR-2017]**https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf<br>• **The name of the Firm/Company/Organization as per name mentioned in the wholesale licence/registration certificate shall be mentioned and name of the any individual name shall not be mentioned.** |
| **2.** | Nature and constitution of Authorized agent | • **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)Authorized Agent address: | • **The name and address of firm as per the wholesale licence or manufacturing licence or registration certificate including telephone number, mobile number, fax number and e-mail id, shall be specified.** |
| | (iv) Address for correspondence | • **The Corporate or Registered office/Authorized agent address including telephone number, mobile number, fax number and e-mail address of the firm shall be specified for correspondence.** |

<table>
<tr><td>4.</td><td>Particulars of overseas Manufacturer, Manufacturing site(s):<br><table><tr><th>Sr. No.</th><th>Name and Address of Manufacturer</th><th>Name and Address of Manufacturing Site</th></tr><tr><td>1</td><td>Legal Manufacturing Site:</td><td>Actual Manufacturing Site:</td></tr></table></td><td>• The name and address of the foreign manufacturer (Legal) and manufacturing site (Actual Manufacturing site) including telephone, fax, and email address shall be mentioned.<br>• Name and address of its legal and actual manufacturer shall match with FSC, POA and label and it shall be as per the overseas manufacturing site or establishment or plant registration issued by the competent authority in the country of origin and Free Sale Certificate issued by the National Regulatory Authority of the country concerned.<br>• The address mentioned in Power of Attorney shall be matched with addresses mentioned in this section.<br>• Firm shall have to specify only single legal manufacturer and single Manufacturing site in this section (from where the product is actually released will be considered as Actual Manufacturing site)</td></tr>
<tr><td>5.</td><td colspan="2">Details of medical device(s) to be imported</td></tr>
<tr><td></td><td>1. Generic Name</td><td>• 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.</td></tr>
<tr><td></td><td>2.BrandName(if registered under the Trade Marks Act, 1999)</td><td>• The Trade name or Brand name (if registered under Trade Marks Act1999) of the applied products shall be mentioned.<br>• Same shall be matched with FSC, POA and Labels.</td></tr>
<tr><td></td><td>3. Notified Category</td><td>• Refer to category specified in classification list of IVD</td></tr>
<tr><td></td><td>4. Class of Medical Device</td><td>• 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.<br>• For classification of IVD Analyzers, instruments and software’s: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/IVD_classifiction25oc23.pdf<br>• 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==<br>• 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</td></tr>
<tr><td></td><td>5. Shelf life</td><td>• The claimed Shelf life of the product shall be mentioned as per the real time stability study report submitted with the application.<br>• 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<br>• For Guidance on Stability Studies of In-vitro Diagnostic Medical Device (IVDMD):- https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-</td></tr>
</table>

| | | |
|---|---|---|
| | | 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 contain 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 on 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/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Guidelines_Grouping_of_MDandIVD.pdf. |
| | 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-2017** https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Guidelines_Grouping_of_MDandIVD.pdf. |
| | 14.Dimension | • **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. Pack Size | • **The net quantity in terms of weight, measure, volume, number of units/ no. of tests, as the case may be, and the number of the devices contained in the package expressed in metric system shall be mentioned (Rule 44(d), MDR-2017)** https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Guidelines_Grouping_of_MDandIVD.pdf. |

| | | |
|---|---|---|
| | | • **It shall be matched with the Pack size mentioned in label and Instruction for Use (IFU)/Package/Product Insert.** |
| | 17. Accessory/Components | • **The list of Accessories/Components which are intended to be used in combination with the applied IVDs shall be mentioned.**<br>• **Theses accessories shall reflect in the Instruction for Use (IFU)/Package/Product Insert**<br>• **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/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Guidelines_Grouping_of_MDandIVD.pdf.<br>• **If the firm intended to import 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.** |
| | 18. Model/Catalogue No./Name | • **The firm shall mention Model/Catalogue Number of the applied products shall be mentioned in accordance with the product Brochure or Catalogue.**<br>• **It shall be matched with Model/Catalogue/Article Numbers mentioned in Free Sale Certificate submitted.**<br>• **It shall be matched with Model/Catalogue No, specified in Labels, Pack size mentioned in label and Instruction for Use (IFU)/Package/Product Insert** |
| | 19. Equivalence to predicate device | • **It shall be selected Yes if the similar product wrt Specimen, technology, principal, composition, specific intended use is already approved by Central Licensing Authority (Refer IVD Approved Devices details available in https://cdscomdonline.gov.in)**<br>• **The approval status shall be verified wrt new IVD definition as per Rule 3(zh) of MDR-2017**https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/Guidelines_Grouping_of_MDandIVD.pdf.<br>• **It shall be selected NO if the similar product wrt Specimen, technology, principal, composition, specific intended use applied product is not approved by Central Licensing Authority. In this case firm shall obtain permissions in Form MD-25 & MD-29 before applying import licence in Form MD-14)** |
| **6.** | Fee paid on_____, **USD** _____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 for grant of licence to import medical device(s).** | |

## 11.0 Time Line

| S. No. | Application Type | Timeline (as per rule in days) |
|---|---|---|
| **1** | MD-14 | 270 |
| **2** | MD-16 | 30 |

## 12.0 List of Common Non-Compliance Observed

## 12.1 Non-Compliance in Import applications (MD-16)

| S. No. | Checklist Category | Non-Compliance Observed |
|---|---|---|
| **1.** | Covering letter | 1. It is observed that the submitted covering letter is not reflecting the purpose of the test licence applied for, details of list of documents are not enclosed.<br><br>2. It is observed that legal form is signed by one person and covering letter signed by another person.<br><br>3. It is observed that covering letter is addressed to other authority instead of CDSCO/DCG(I).<br><br>4. Firm has not mentioned testing site as per PER guidance document dated xx.xx.xxxx available on CDSCO website.<br><br>5. Firm has not mentioned proposed quantity with units (tests/strips etc.) and pack size.<br><br>6. Applied device is not of IVD category. |
| 2. | Brief description of the medical device including intended use, material of construction, design | 1. It is observed that description of the device has not been submitted.<br><br>2. It has been observed that the firm has submitted description for some other product.<br><br>3.The submitted description does not include the actual intended purpose or test/detection procedure/mechanism to work<br><br>4. Firm has not submitted details of similar/predicate device details. |
| 3. | Justification of quantity proposed to be imported | 1. It is observed that the justification for the quantity proposed to be imported, along with a detailed utilization break-up specifying the parameters to be tested using the applied product, has not been adequately provided.<br><br>2. It is observed that the firm has mentioned external lab details in the legal form. However, the quantity required for testing at the external lab is not mentioned in the utilization break up document.<br><br>3. Firm has not submitted details of disposal of analyzer/instrument after testing, whether they will do re-export of the product etc. |
| 4. | Test protocol/ approved clinical investigation plan if any | 1. It is being observed that the firm did not submit test protocol for the proposed product. |
| 5. | Quality certificates like QMS etc., of the manufacturer, if any | 1. It is being observed that the firm did not submit the QMS certificate of the manufacturer. |
| 6. | Labels and IFU, if any | 1. It is being observed that the firm did not submit IFU and labels.<br><br>2. Additional label stating "For Evaluation Purpose Only, Not for Commercial Use" is not submitted. |
| 7. | Other document, if any | NA |
| 8. | An undertaking stating that the medical device proposed to be imported to be used | 1. It is being observed that the firm did not submit the undertaking.<br><br>2. The undertaking has been submitted; however, the statement “shall not be used for commercial purpose” is not reflected in the undertaking. |

| | | |
|---|---|---|
| | exclusively for purpose specified at serial Number 7 of Form-16 and shall not be used for commercial purpose. | 3. The submitted undertaking is not signed, stamped and dated. |
| 9. | An undertaking from the testing laboratory, stating that required facilities including equipment, instrument and personnel will be provided to test or evaluate medical device. | 1. It is being observed that the undertaking is not submitted. |

## 12.2 Non- Compliance in Import applications (MD-14)

| S. No. | Checklist Category | Non-Compliance Observed |
|---|---|---|
| **1.** | Covering letter | 1. It is observed that legal form is signed by one person and covering letter signed by another person.<br><br>2. Firm has submitted a covering letter dated..... However, it is observed that the covering letter is not signed by the authorized agent (as per the legal form) and no company stamp/seal present.<br><br>3. It is observed that covering letter is addressed to other authority instead of CDSCO/DCG (I).<br><br>4. It is observed that firm has applied this application as fresh application; however, in covering letter firm is stating that they want to apply as an endorsement. |
| **2.** | Power of Attorney (POA) | 1. Apostilled POA is submitted. However, undertaking from the authorized agent is not submitted.<br><br>2. POA is submitted along with undertaking from the authorized agent. However, it is not apostilled/authenticated in India either by a Magistrate of First Class or by Indian Embassy in the country of origin.<br><br>3. POA and undertaking are submitted. However, in POA the name and designation are not reflected, further it is not signed and stamped.<br><br>4. Apostilled POA is submitted along with undertaking from the authorized agent. However, the manufacturing site address mentioned in POA and undertaking doesn't correlate with the one mentioned in legal form.<br><br>5. Firm has submitted copy of POA and undertaking from the authorized agent. However, it is observed that the format of POA is not as per that specified in Part I of Fourth Schedule of MDR-2017.<br><br>6. Firm has submitted notarized and apostilled copy of POA and undertaking from authorized agent. However, it is observed that the product name and model number mentioned in POA does not match with that mentioned in the legal form and FSC.<br><br>7. Firm has submitted notarized and apostilled copy of POA and undertaking from authorized agent. However, it is observed that the address of the authorized agent mentioned in POA and undertaking is different than the address mentioned in the legal form. |

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| | | 8. It is observed that product list in the POA is having more than the applied products and is not highlighted with serial number as per the legal form for matching the products with submitted legal form. |
| **3.** | Self attested copy of valid Whole sale licence or manufacturing licence | 1. Copy of wholesale licence in form 20B and 21B, valid upto xx.xx.xxxx is submitted. However, authorized agent address mentioned in legal form doesn't correlate with the one in wholesale licence.<br><br>2. Copy of wholesale licence in form 20B and 21B, valid upto xx.xx.xxxx is submitted. However, it is expired.<br><br>3. Firm has submitted valid copy of whole sale licence in Form.... valid upto ..... However, the document is not self attested by the applicant. |
| **4.** | Notarized copy of overseas manufacturing site or establishment or plant registration, by whatever name called, in the country of origin issued by the competent authority, | 1. NA is mentioned.<br><br>2. Site registration certificate is not notarized.<br><br>3. Firm has submitted notarized copy of plant registration of the overseas manufacturing site in the country of origin issued by the competent authority. However, it is observed that the document is in foreign language.<br><br>4. Firm has submitted plant registration certificate for contract manufacturer. |
| **5.** | Notarized and valid copy of Free Sale Certificate issued by the National Regulatory Authority or equivalent competent authority of the country of origin.(if any) | 1. It is observed that firm has not submitted Free Sale Certificate issued by the National Regulatory Authority or equivalent competent authority of the country of origin. |
| **6.** | Notarized and valid copy of Free Sale Certificate issued by the National Regulatory Authority or equivalent competent authority of the any of the countries namely United States of America, Australia, Canada, Japan, and European Union Countries. | 1. NA is mentioned.<br><br>2. The attached FSC is not notarized.<br><br>3. Model no. in FSC doesn't correlate with the one in legal form.<br><br>4. FSC of China is submitted.<br><br>5. Actual manufacturing site doesn't correlate with the one in legal form.<br><br>6. Firm has submitted notarized copy of FSC from EU (Netherlands). However, it is observed that the FSC contains only the legal manufacturer name and address, the name and address of the actual manufacturing site is not mentioned in this FSC.<br><br>7. Firm has submitted notarized copy of FSC from Singapore, country of origin. Firm has mentioned that the applied product (Class A) is not yet approved/registered in any other mentioned countries such as USA, UK, Australia, Canada, Japan and EU Countries.<br><br>8. Firm has submitted notarized copy of FSC from Singapore, country of origin. Firm has mentioned that the applied product (Class C) is not yet approved/registered in any other mentioned countries such as USA, UK, Australia, Canada, Japan and EU Countries. |
| **6.** | Copy of latest inspection or audit report carried out by Notified bodies or National Regulatory Authority or Competent Authority within last 3 | 1. Only first few pages of the audit report are submitted.<br><br>2. Firm has submitted audit report conducted by competent authority ... in the year 2019 |

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| | years. | |
| **7.** | Notarized and valid copy of Quality Management System certificate (ISO 13485) certificate issued by the competent authority | 1. QMS certificate is not notarized.<br><br>2. QMS certificate is expired.<br><br>3. Firm has submitted notarized copy of QMS certificate (ISO 13485 2016) issued by..... Valid upto..... However, it is observed that the products covered under the scope of this QMS certificate are different, the applied products are not covered under its scope.<br><br>4. Firm has submitted copy of notarized QMS certificate (ISO 13485 2016) issued by.... valid upto.... of the legal manufacturer. Firm has not submitted the notarized copy of QMS certificate (ISO 13485 2016) of the Actual manufacturer.<br><br>5. Firm has submitted copy of notarized QMS certificate (ISO 9001 2015) issued by..... Valid upto.... of legal and actual manufacturer. Since the product is IVD kit for veterinary diagnostic use, which does not cover under the scope of ISO 13485 2016 QMS certification, we may consider the same. |
| **8.** | Site or plant master file as specified in Appendix I of Fourth Schedule of MDR-2017 | 1. NA is mentioned.<br><br>2. Firm has submitted the SMF/PMF. However, firm has not submitted the annexure mentioned in the PMF.<br><br>3. Firm has submitted a document describing on the actual manufacturing site. However, the sections/contents of this document is not as per Appendix I of Fourth Schedule of MDR-2017.<br><br>4. Firm has submitted SMF of the legal manufacturer. Firm has not submitted the SMF of the actual manufacturing site. |
| **9.** | Claimed Shelf life – stability study report for at least 3 lots | 1. Accelerated shelf life stability data is submitted.<br><br>2. Storage condition doesn't correlate with legal form.<br><br>3. Shelf life doesn't correlate with legal form. |
| **10.** | Product Insert, Pack size, Label | 1. Storage condition doesn't correlate with legal form.<br>.<br>2. Only IFU is submitted.<br><br>3. Only label is submitted. |
| **11.** | Specimen batch test report for at least consecutive 3 batches showing specification of each testing parameter | 1. COA of only one lot is submitted. |
| **12.** | 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/ Specific evaluation report, if done by any laboratory in India, showing the | 1. The submitted PER report is not from the lab as specified in the PER guidance document available on CDSCO website.<br><br>2. PER report from NABL lab is submitted. However, the applied test is not in the scope of NABL accreditation.<br><br>3. PER report of only one/two lot is submitted. |

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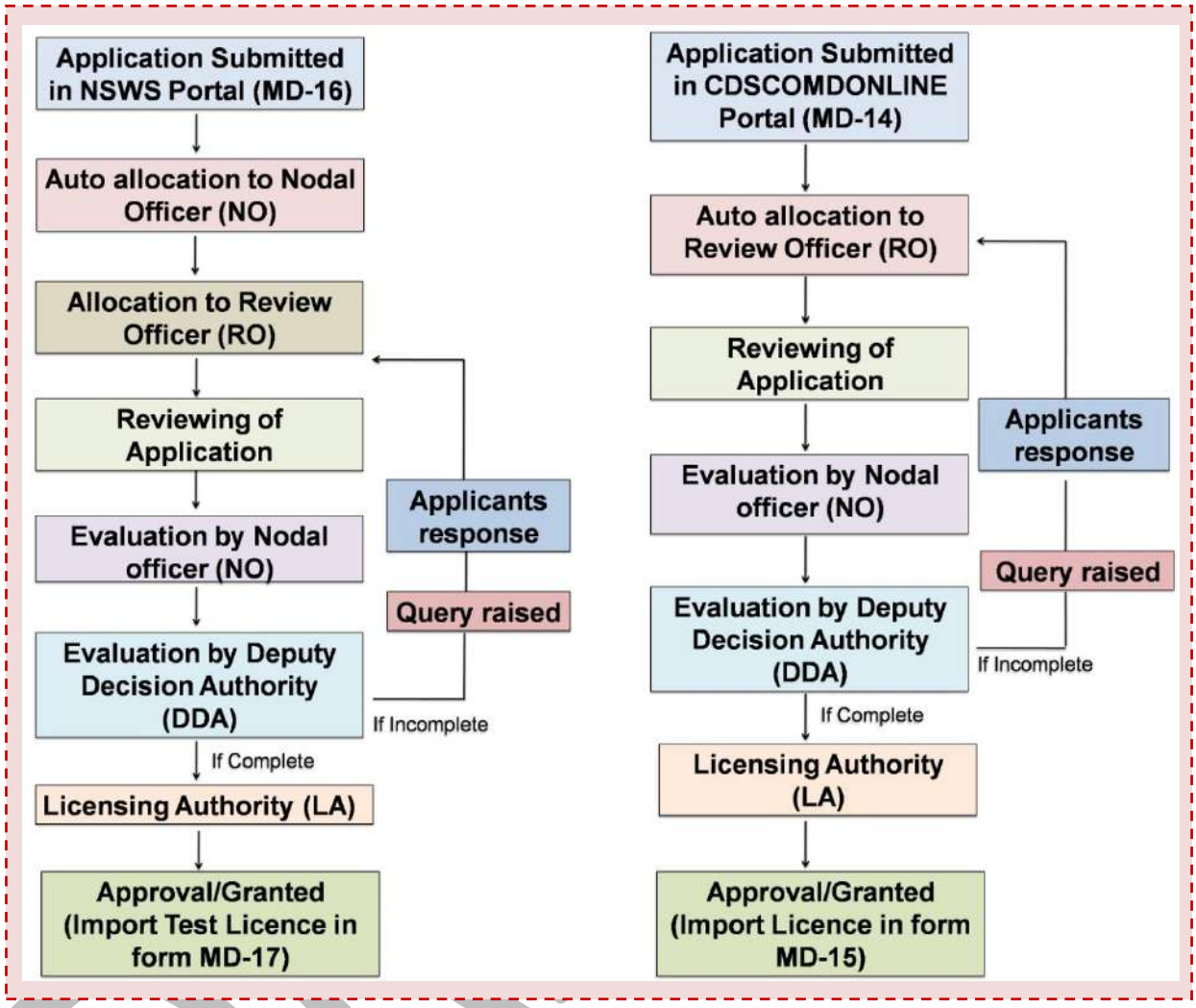
| | sensitivity and specificity of the in-vitro diagnostic medical device | |
| **13.** | Fee Chalan | 1. Site registration fee is not paid in case of fresh application.<br><br>2. Less fee is paid.<br><br>3. This is an endorsement application for Class C IVD products on base licence number. However, it is observed that the products approved under the base licence are Class A/B IVD products.<br><br>4. Firm has submitted NTRP chalan.<br><br>5. It is observed that the firm has mentioned different model numbers in the legal form for the applied product generic name. However, from the product technical details mentioned, it appears that the design, working mechanism/specifications including user manual are different for each of the model number. |
| **14.** | Legal Form | 1. The attached legal form is not digitally signed.<br><br>2. Authorized agent address is different from the one in base licence.<br><br>3. Class of device is wrong.<br><br>4. Digitally signed legal form is submitted. However, Model/Catalogue No./Name is not mentioned.<br><br>5. Firm has mentioned the shelf life of applied product as NIL in the legal form.<br><br>6. The intended use statement for the applied product mentioned in legal form is incomplete/not as per the IFU.<br><br>7. Firm has mentioned the product model/catalogue number as NA in the legal form.<br><br>8. As per the product details submitted by the firm, it appears that the predicate device to the applied product is not approved/available in Indian market.<br><br>9. It is observed that the applied product is a Medical Device and not intended for In-vitro Diagnostic Use/purpose.<br><br>10. It is observed that the firm has mentioned different model numbers in the legal form for the applied product generic name. However, from the product technical details mentioned, it appears that the design, working mechanism/specifications including user manual are different for each of the model number. |

## 13.0 Application process flow at CDSCO

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