Central Drugs Standard Control Organization

In-Vitro Diagnostic (IVD) Medical Devices Division

Frequently Asked Questions

Doc No.: CDSCO/IVD/FAQ/04/2022

Addendum No.:02, dated 13.03.2026

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION
DIRECTORATE GENERAL OF HEALTH SERVICES
MINISTRY OF HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA

Note:

The replies to the FAQs are aimed only for creating public awareness about In-Vitro Diagnostic Medical Devices Regulation by CDSCO and are not meant to be used for legal or professional purposes. The readers are advised to refer to the statutory provisions of Drugs and Cosmetics Act & Rules and respective Guidelines/Clarifications issued by CDSCO time to time for all their professional needs.

Addendum to FAQ on Medical Devices Rules, 2017

1. **How should the Licensee apply for retention of subsequently issued endorsements? Should these be submitted together with the base license retention, or only after the base license has been retained?**

   Ans: The retention application of subsequently issued each individual endorsement must be submitted together with the base license retention application. As endorsements are an integral part of the base license, both should be retained simultaneously.

2. **How to calculate the retention period of the base license and subsequent endorsement application?**

   Ans: Endorsements issued subsequently under the base license, even on different dates, remain valid as long as five years have not elapsed from the date of issuance of the base license. The retention fee for both the base license and its endorsements must be paid within this five-year period, in accordance with MDR, 2017. The validity of such endorsements is inherently linked to the validity of the base license.

3. **Whether, In the event of a change in the location of a domestic manufacturing site in India, is a QMS re-inspection/audit mandatory under the MDR-2017?**

   Ans: Yes. In such cases, QMS re-inspection is required to obtain fresh manufacturing license.

4. **Whether, in case of a change in the constitution of the firm, is the licence holder require to create a new login credential on the CDSCO Medical Devices online portal in order to obtain a fresh licence?**

   Ans: It is advised that the firm may create a new login credential for obtaining the fresh licence, the existing credential must be deactivated. The licence holder should inform the IT Cell/Registration Desk to initiate the deactivation process for easy tracking of changes in the portal.

5. **Whether multiple Bharatkosh fee receipts submitted in an application, need to be linked with the application?**

Ans: Yes, each Bharatkosh fee receipt must be linked to the application so that the total fee amount paid can be verified and locked with the application on the portal.

6. How the Overseas documents should be notarized/apostilled for authentication?

Ans: A valid notarization should include the official notary seal along with the registration number issued in the respective country, the notary's signature and date, and a stamp indicating the relevant jurisdiction such as the state or district. If the document is an affidavit or undertaking, it should be executed on appropriate stamp paper, wherever required. The document needs to be notarized/apostilled at the country; the document is issued/originated. Additionally, each page of the document shall be duly authenticated to ensure completeness and validity.

7. Who will be considered as Subsequent Importer in the country and how to apply as a Subsequent Importer?

Ans: An authorised agent of the foreign manufacturer who intends to obtain the import license for import of already approved IVD medical device(s) which is already licensed to another agent/importer under MDR-2017 provided the legal and actual manufacturing site of the device is the same. The importer/applicant is required to submit an application under Subsequent Importer through the Medical Devices Online Portal.

8. How many products can be applied in a single application for Import/Manufacturing licence?

Ans: It is advised to apply not more than 15 products in single application; further additional products can be endorsed in order to expedite the early approval process and avoid delay.

9. Whether any alert system is available in the online portal for applicant to submit the query response?

Ans: With respect to the different application submitted to the IVD Division of CDSCO, an automated alert email would be sent to the applicant to submit the

response. The timeline for alert to different application type is mentioned below.

1st Reminder- Refer Table below

2nd Reminder- 30 days after 1st Reminder/ Communication

3rd Reminder- 30 days of 2nd Reminder/ Communication

4th Reminder- 30 days of 3rd Reminder/ Communication

Application Type	Days
Form MD-7	90
Form MD-8	90
Form MD-14	90
Form MD-24	90
Form MD-28	90
Form MD-39	45
FSC	30
Condition fulfilment	60
PAC	30

It is recommended to submit a response within the first reminder, however, in any circumstances, if the response is not submitted after the 4th reminder, the application will be considered as deemed withdrawn and will be disposed of without further notice. In such case, the applicant has to make fresh application under the provisions of the Medical Devices Rules, 2017.

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

Ans: 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 of the IVD manufacturing site 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	

11. What is the applicable fee for importing Class C/D product under already issued Import license for Class A and Class B IVD products?

Ans: For importing Class C/D IVD medical devices under endorsement if the firm already have import license 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 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 products)	$3000	$4500
3 products are applied under Class C	3 * $500 = $ 1500	

12. What is the provision of late fee in case of Import license retention application?

Ans: As per Rule 37 MDR 2017, the Central Licensing authority may permit to deposit the licence retention fee after due date but before expiry of 90 days with a late fee calculated at the rate of two percent per mensem.

13. What is the provision of late fee in case of Manufacturing license retention application?

Ans: As per Rule 29 MDR 2017, the Central Licensing authority may permit to deposit the licence retention fee after due date but before expiry of 180 days with a late fee calculated at the rate of two percent per mensem.

14. Whether a product intended for both the In-vivo/Ex-vivo and In-vitro diagnosis, would be considered as an In-vitro diagnostics device/product.

Ans: No. If a device is intended for multiparameter detection including In-vivo/Ex-vivo and In-vitro diagnosis, it would be considered as Medical Device and not as an In-vitro Diagnostics Device.

Example:

If the product includes parameters such as ECG, Blood Pressure monitoring, Pulse Oximetry (SpO_2), Temperature Monitoring, Respiration Rate (Medical Device parameters) along with an IVD testing module such as blood glucose monitoring, HbA1c, cholesterol testing, the device would be considered as medical device and not as an In-vitro diagnostics device.

15. **Whether NOC from Department of Animal Husbandry and Dairying (DAHD) is required to be obtained for new In-vitro diagnostic medical devices intended for Veterinary purpose prior to grant of license?**

Ans- The NOC of DAHD is required only for the Veterinary IVD Medical Devices which does not have a predicate device.

16. **Whether Clinical Performance Evaluation (CPE) is applicable (or not) for a new Veterinary IVD?**

Ans- The Clinical Performance Evaluation (CPE) is not applicable for a new Veterinary IVD.

17. **If the applicant intends to apply for a license for a product, how can the applicant determine the applicable risk class of the product when it is not listed in the IVD classification list published on the CDSCO website?**

Ans- The applicant seeking risk classification for the device which is not listed in the IVD published classification list, may submit application through CDSCO Online system for Medical Devices (http://cdscomdonline.gov.in) to obtain risk classification of In-vitro Diagnostics Device under Medical Device Rules, 2017.

18. **Whether Firm can apply application for Form MD-24 and Form MD-28 simultaneously?**

Ans- Yes, it can be applied simultaneously with prescribed fees as per MDR 2017.

19. **Whether the firm require to submit a fresh license application for change in Name of actual manufacturing site, without any change in the constitution of the firm?**

Ans: No. In such cases, the firm is required to obtain approval from the licensing authority through a Post Approval Change Application.

20. **What is the regulatory provision for any change in the accessories/components of an already approved In-vitro diagnostic medical device?**

Ans- In such cases, the applicant is required to submit an application for Post-Approval Change (PAC) under "Change in respect of accessories/components

of the device" category to the Licensing Authority through the Medical Devices Online Portal.

21. Since software requires periodic updates during its lifecycle, is the importer/manufacturer required to register each new version separately?

Ans- Yes. For any change or update in the version of already approved software, the Importer/Manufacturer is required to submit an application under Post-Approval Change (PAC) through the Medical Devices Online Portal.

22. How to apply for conditional fulfilment, if any specific condition is stated under Import/Manufacturing license?

Ans- The Importer/Manufacturer is required to submit an application under Conditional Fulfilment (CF) through the Medical Devices Online Portal (https://cdscomdonline.gov.in/) to obtain approval from CLA.

23. What is the process of obtaining Market Standing Certificate/ Non-Conviction Certificate for Class C & D IVD Medical Devices?

Ans- The applicant may submit an application through Medical devices online portal (https://cdscomdonline.gov.in/) to obtain system auto-generated Market Standing Certificate/ Non-Conviction Certificate.

24. Whether the firm can endorse the brand name/additional brand name for approved Class C & D IVD Medical Devices brand name?

Ans- Yes, the applicant may submit a separate application through Medical Devices Online Portal (https://cdscomdonline.gov.in/) to obtain approval from CLA.

Central Drugs Standard Control Organization

(Medical Devices and Diagnostic Division)

In-VitroDiagnostic(IVD) Medical Devices

Frequently Asked Questions

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Frequently Asked Questions on *In-Vitro* Diagnostic Medical Devices

GENERAL POLICY

1. Whether In-Vitro Diagnostic kits/reagents are regulated in India?

Ans: Yes, all In -Vitro Diagnostic kits/reagents are regulated in India under the provisions of the Medical Devices Rules, 2017.

2. Where can we get a copy of the Medical Devices Rules, 2017?

Ans: The copy of the Medical Devices Rules, 2017 is available in the CDSCO Website under the link:
http://www.cdsco.nic.in/writereaddata/Medical%20Device%20Rule%20gsr78E.pdf

3. Name and address of the Regulatory Authority that governs the regulations of Import of IVD kits/reagents in India?

Ans: The Drugs Controller General (India),
Central Drugs Standard Control Organization (CDSCO),
Directorate General of Health Services,
Ministry of Health and Family Welfare,
Government of India,

Address:
FDA Bhavan, ITO, Kotla Road,
New Delhi -110002
Phone: 91-11-23236965 / 23236975,
Fax: 91-11-23236973,
E-mail:- dci@nic.in.

4. What are the activities regulated by the CLA & SLA with respect to In Vitro diagnostic in India?

Ans.:

Central Licensing Authority	State Licensing Authorities
Enforcement of rules in matters related to: • Import of all Classes of IVDs. • Manufacture of Class C and Class D IVDs. • Clinical performance evaluation and approval of new in vitro diagnostic. • Registration of Notified Bodies • Registration of Laboratories for carrying out test or evaluation. • Test licences for manufacture or import of all classes of IVDs	Enforcement of rules in matters related to: • Manufacture for sale or distribution of Class A or Class BIVD • Sale, stock, exhibit or offer for sale or distribution of IVDs of all classes.

5. Which division of CDSCO (HQ) is responsible for review of IVD kits/reagents?

Ans: In-vitro Diagnostics Division, Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, FDA Bhavan, ITO, Kotla Road, New Delhi -110002.

6. What is an In-Vitro Diagnostic (IVD)?

Ans: IVDs are substances intended to be used outside human or animal bodies for the diagnosis of any disease or disorder in human beings or animals covered under sub-clause (i) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 and IVDs that are notified, from time to time, as a device under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940.

7. What is an in –Vivo Diagnostics?

Ans: When Diagnosis of disease and disorders are carried out in the body of living human or animal that is done in vivo as opposed to in a laboratory method that does not use the living organism as the host of the test. In vivo is the opposite of in vitro.
These materials are chemical, biological, or radioactive substances used in diagnosing or monitoring the state of human or veterinary health by identifying and measuring normal or abnormal constituents of body fluids or tissues.
For Example: Angio-urographic diagnostic agents, Barium diagnostic agents, Cold kits for labeling with technetium, Contrast media diagnostic products (e.g., iodine and barium)

8. Whether MDR 2017 is also applicable for in vivo diagnostic products?

Ans: Since in-Vivo Diagnostics are interventional and put into systemic circulation in living bodies, all principles and norms applicable for regulations of chemical, biological and radiological drugs shall also be applicable in such products.

9. How are IVDs classified in India under Medical Device Rules, 2017?

Ans: IVDs are classified under Chapter II, Rule 4, Sub-rule (2) of Medical Device Rules 2017 on the basis of parameters specified in Part II of the First Schedule, in the following classes, namely: —
(i) low risk - Class A;
(ii) low moderate risk- ClassB;
(iii) moderate high risk- ClassC;
(iv) high risk- ClassD.

10. Who will have the responsibility of doing Classification of IVD as per Class A/B/C/D?

Ans: Reference Rule 4 (3) This rule specifies that Central Licensing Authority shall classify the Medical Devices.

11. Whether on market approved products, in India have to be newly registered as per Medical Devices Rules, 2017, when the existing license gets expired?

Ans: Yes, IVD products which are currently registered in India have to be registered according to the provisions of Medical Devices Rules, 2017.

12. Are Analyzers, Instruments and Software used with IVDs covered in the scope of Medical Devices Rules, 2017?

Ans: Yes. Analyzers, Instruments and Software intended to be used for In-vitro Diagnosis are regulated in phase wise manner under the provisions of Medical Devices Rules, 2017. Classification of IVD Analyzers, Instruments and Software is published in CDSCO website.

Classification of IVDs	Voluntary registration	Mandatory registration	Licensing Regime
Class A & B	01/04/2020 to 30/09/2021 (18 months)	01/10/2021 to 30/09/2022 (12 months)	From 01/10/2022
Class C & D	01/04/2020 to 30/09/2021 (18 months)	01/10/2021 to 30/09/2023 (24 months)	From 01/10/2023

13. Which IVD kits/reagents fall under the category of Class A, Class B, Class C, Class D products?

Ans: Please refer to the classification list issued by CLA available at CDSCO website.

14. Whether the wholesale license issued under the Drugs and Cosmetics Rules, 1945 will be valid as per the Medical Devices Rules, 2017.

Ans: Yes.

15. Whether any product, intended for use in determining the presence of host cell protein contamination, in products manufactured by expression in the CHO cell line and other technology for Research and manufacturing use only and is not intended for diagnostic use in humans or animals, are being regulated under the provision ofMedical Devices Rules, 2017?

Ans: No.

16. **Whether any product used in determining the presence of histamine, substances, Microbial detection in food & food products, animal feeds, liquor (wine, beer), environmental samples like water, soil etc. and is not intended for In-vitro diagnostic use in humans or animals, are being regulated under the provision of Medical Devices Rules, 2017?**

Ans: No.

17. **Will products such as RUO – Research Use Only, Q.C material for accreditation, panel for Q.C testing & product used for food, water, sterility testing used by various industry for Q.C etc., and is not intended to be used in human or animals for diagnosisof any disease or disorder, be regulated under MDR, 2017?**

Ans: No

18. **Will products such as microbiological culture media, stains indicators and reagents used for food and water testing and is not intended to be used in human or animals for diagnosis of any disease or disorder be regulated under MDR, 2017?**

Ans: No

19. **Whether Specimens collection tubes (vacuum type or not) without needle used for the collection of Blood, Urine, Stool, Sputum, Semen, etc., for purpose of specimens collection are being regulated under the provision of Medical Devices Rules,2017?**

Ans: Yes. Specimen collection tubes are regulated under the definition of "specimen receptacle" as specified in Sub-clause (zs) of Rule 3 of MDR-2017 and are classified as Class A as per First Schedule, Part II (2(v)(3)) of MDR-2017.

20. **Whether IVDs for HBsAg, HIV and HCV approved to manufacture or import by the CLA or SLA, as the case may be, permitted to use for both the purposes; for blood screening and diagnostic.**

Ans: Yes. In – Vitro Diagnostic devices for HBsAg, HIV and HCV manufactured / Imported under valid license issued by the CLA or SLA, may also be used in Blood Bank, as the criteria like Sensitivity (%) and Specificity (%) for evaluation of the HBsAg, HIV and HCV diagnostic kits for the Transfusion purpose (Blood Banks) and Diagnostic purpose aresame, Provided the manufacturer claims in the product labels or in the IFU that the product is intended both the purposes; for blood screening and diagnostic.

21. **Which IVD reagents/kits are prohibited in India?**

Ans: (1) Serodiagnostic test kits for diagnosis of tuberculosis are prohibited to Import, Manufacture, Sale, Distribution and Use in the country under Section 10A and Section 26A of the Drugs and Cosmetics Act, 1940 Gazette notification(s) GSR432(E) & GSR433(E) dated June 7, 2012.

(2) Antibody Detecting Rapid Diagnostic Tests for routine diagnosis of malaria are prohibited to Import, Manufacture, Sale, Distribution and Use in the country under Section 26A and Section 10A of the Drugs and Cosmetics Act, 1940, Gazette notification(s) GSR1352(E) dated March 23, 2018 and GSR1074(E) dated October 30, 2018 respectively.

22. What are considered to be the major changes in Post approval of IVD?

Ans: As per Sixth Schedule of Medical Devices Rules, 2017, following changes have been included in the list of major changes which needs prior approval from the competent authority.

(A) Changes in respect of following shall be considered as major change in,-

1. material of construction;
2. design which shall affect quality in respect of its specifications, indication for use; performance and stability of the medical device;
3. the intended use or indication for use ;
4. the method of sterilization;
5. the approved Shelf life;
6. the name or address of,-
   (i) the domestic manufacturer or its manufacturing site;
   (ii) overseas manufacturer or its manufacturing site (for import only);
   (iii) authorised agent (for import only);
7. label excluding change in font size, font type, color, label design;
8. manufacturing process, equipment or testing which shall affect quality of the device;
9. primary packaging material.

23. Whether manufacture/ import of Coated (Ab/Ag) Uncut sheet of a Rapid POCT based IVD, intended to be used for further manufacture of finished IVD kit is regulated under the provisions of Medical Devices Rules, 2017?

Ans: Yes.

24. What is the fee structure required for multiple Brand names of a product applied in the manufacturing/ import licence application?

Ans: For multiple brand names of a product, the firm needs to submit applicable product fee as per Second schedule for each of the Brand name.

25. Whether CDSCO provides any consultation system for Start-ups/ Importers/ Manufacturers?

Ans: Yes. The Public Relation Office (PRO) cell is established in CDSCO Head Quarter and at all zonal offices to address the issue of startups/ importers/ manufacturers in the field of In-vitro Diagnostic medical devices pertaining to regulatory pathway.
(Link: https://cdsco.gov.in/opencms/opencms/en/PRO/ ; Email ID: startupinnov@cdsco.nic.in)

26. How many products can be applied in a single application for Import/Manufacturing licence?

Ans: It is advised to apply not more than 30 products in single application; further additional products can be endorsed in order to expedite the early approval process and avoid delay.
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27. Whether five-year period for the payment of license retention fees of an endorsement iscalculated based on issue date of that particular endorsement or of base license?

Ans: The five year period for the payment of license retention fees of an endorsement issued on a particular base license is calculated based on the issue date of base license and not endorsement.

28. What is regulatory pathway for import/manufacture of new IVD?

Ans: (1) In case of new In-vitro Diagnostic Medical Device i.e. Device for which predicate device is not available in the country, firstly, applicant has to submit application in Form MD-12(domestic manufacture) / Form MD-16 (Import) to obtain Test license in Form MD-13 (domestic manufacture)/ Form MD-17 (Import)) in order to manufacture or import test batches for generation of in-house quality/ validation data or evaluation in external lab as the case may be.
(2) Thereafter, in order to generate data on clinical performance, applicant needs to submit application in Form MD-24 to obtain Permission to conduct clinical performance evaluation in Form MD-25 (for protocol approval in consultation with IVD experts committee). After getting permission in Form MD-25, applicant may initiate the study and study outcome and datagenerated will be submitted along with application in Form MD-28 for obtaining permission to Import or manufacturer New IVD in Form MD-29 (for clinical data approval in consultation with IVD experts committee). (3) Thereafter, applicant need to apply in Form MD-3/ Form MD-4 to obtain manufacturing license for Class A & B for sale or distributions in Form MD-5/ MD-6 approved by State Licensing Authority or needs to apply in Form MD-7/ Form MD-8 for Class C & D to obtain manufacturing license in Form MD-9/ Form MD-10 approved by Central Licensing Authority or needs to apply in Form MD-14 to obtain import license in Form MD-15 approved by the Central Licensing Authority (DCGI).

29. Whether any changes in approved Test licence applications under Form MD-13 and Form MD-17 can be done for IVD devices or not?

Ans: No, applicant has to apply in fresh with the proposed changes and applicant will get a new test licence.

30. Whether manufacturing/production capacity certificate is issued by CDSCO for IVD devices?

Ans: No, manufacturing/production capacity certificate is currently not specified under provision of Medical devices Rules, 2017.

31. Whether Point of care testing/near-patient testing In-Vitro Diagnostic Medical Devices fall under the category of Class C?

Ans: Yes, Point of care testing/near-patient testing In-Vitro Diagnostic Medical Devices fall under the category of Class.

32. Whether IVF is regulated in In-Vitro Diagnostic Category?

Ans: No, Kit intended for In-vitro fertilization (IVF) is regulated in Medical Device Category.

33.. Whether Instrument or Analyzer used for Research Use Only (RUO) not intended to be used for In-vitro Diagnosis Purpose of Specimen from human or animal to be regulated under MDR 2017?

Ans: No

ADMINISTRATIVE NORMS

34. Can Third party / Authorized Consultant ask the status of the application?

Ans: No, The Regular employee, authorized by the competent person of the applicant company may only ask the status of their application.

35. Who is authorized to make a Technical Presentation, on behalf of applicant, when asked by the CDSCO?

Ans: Only Subject Expert or Technical Person of the company who is equally competent to make technical presentation.

36. How should the documents be notarized?

Ans: The notary should ensure that documents are properly authenticated by either signing the total document set together in a set or each pages in case of a standalone certificate. (Declaration from notary).

37. Where can I submit my enquiries related to Import and Manufacture of IVDs?

Ans: All enquiries regarding the submission and approvals can be sent to the Drugs Controller General India (dci@nic.in) - CDSCO, FDA Bhawan, ITO, Kotla Road, New Delhi - 110002. Phone: 91-11-23236965 / 23236975. Fax: 91-11-23236973.

38. What is the method for getting refund of challan amount if any manufacturer/importer does not want to register the product or withdraw theirapplication?

Ans: As per Medical Devices Rules, 2017, there is no provision/ clause for the refund of paid application fee.

39. Will post-approval change notification approval require submission of fee?

Ans: No, except for change notification of address of the domestic manufacturer or its manufacturing site and address of overseas manufacturer or its manufacturing site (for import only)

40. Which will be the Medical Device Testing Laboratory (MDTL) for IVD Medical devices?

Ans: List of Medical Device Testing Laboratory (MDTL) is available and updated in CDSCO website.

41. What will be time-period for approval by CLA for implementation of a Major change?

Ans: 60 days. In case CLA do not indicate approval or rejection within sixty days, such change shall be deemed to have been approved by the licensee.

42. What will be time-period for approval by CLA for implementation of a Minor change?

Ans.: Implementation of minor change do not need prior approval provided licensee inform CLA within a period of thirty days after the change takes place or becomes effective.

43. What are the documents need to be furnished for Constitution details?

Ans: Applicant shall submit following documents for the Constitution details of the firm:
1. Certificate of Incorporation
2. Memorandum of Association (MOA)
3. Articles of Association (AOA)

44. Whether registration on online system for medical device for non-sterile and non-measuring (NSNM) class A Medical device is applicable for IVD or not?

Ans: No, the term non-sterile and non-measuring (NSNM) is globally applicable to medical devices, not applicable to IVD.
Classification of IVD published in CDSCO website vide F. No. IVD/Misc./196/2020 dated 25.10.2023 which is updated regularly.

IMPORT POLICY

45. What are the requirements for import of Class-A/B/C/D in Vitro Diagnostic Medical device in India?

Ans: For the import of Class A, B, C & D IVDs, applicant have to submit the documents as per Fourth Schedule Part I, Part II and Part III (Appendix I & III, only), along with fee as per second schedule. Guidance document on import of IVDs is available on CDSCO website

46. Who can apply for grant of licence to import IVD kits and reagents in to India?

Ans: An authorised agent holding licence to manufacture or wholesale licence under issued under MDR, 2017, may submit an application for grant of import licence for IVD to the Central Licensing Authority.

47. Whether multiple Indian agents are allowed to apply for import licence for same product having same manufacture?

Ans: Yes. All the applicants shall need to submit separate application under MDR, 2017.

48. Whether manufacturing site of IVD will be inspected before grant of Manufacturing License?

Ans: For Indigenous manufacturers of IVDs:

(i) For Class A IVDs, 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 IVDs; and

(ii) For Class B, Class C and Class D IVDs, before grant of the manufacturing licence the audit/inspection of the manufacturing site shall be carried out.

49. Whether overseas manufacturing site of IVD will be inspected before grant of import License?

Ans: No. However, if the Central Licensing Authority, believes, as it thinks fit, may carry out an inspection of the overseas manufacturing site before grant of import licence.

50. In case CLA changes the risk based Classification of any product, after approval under the Medical Device Rules 2017, then the license issued under new Rules will continue to be valid for what period? What will be the transition time period given to the industry to adjust according to the new classification?

Ans: In case CLA changes the classification of any IVD product (eg. from Class B to C), the earlier license shall continue to be valid till the final decision taken on the application by the CLA or SLA, as the case may be. Adequate transition time from the date of such notification will be given to industry to prepare documents according to the new classification.

51. In case of such a change in classification, whether applicant needs to do fresh application or only additional documents and fees will be required to be submitted?

Ans: Only additional documents along with the fees (only in case of change from A to C/D or B to C/D) shall be submitted by the applicant to the CLA or SLA, as the case may be.

52. Whether essential principles for safety and performance of IVDs shall be applicable for both importer and indigenous manufacturers?

Ans: Yes.

53. Since the nature of the class A product is intended to be used in conjunction with the IVD products (example: washing solutions, buffers etc) no separate EP checklist is generated during the design and development. Can a manufacturer's declaration suffice?

Ans: Only relevant provisions of the Essential Principles for Safety and Performance of IVDs shall need to be complied with the manufacturers, with the justification that why other provisions are not applicable.

54. What is the validity of Import License or licence to manufacture for IVD issued under MDR, 2017?

Ans: Import License or licence to manufacture for IVD issued under MDR, 2017 shall continue to be perpetually valid till suspension or cancellation, provided that the licencee shall pay a Licence Retention fee in every five years under the provisions of MDR, 2017.

55. How to register additional Class-A/B/C/D IVD Medical Device in the already approved/valid Import License (MD-15)?

Ans: Subsequent application for Licence (Endorsement to respective base licence number) for additional IVD medical device manufactured at the same manufacturing site and having same legal manufacturer shall be made by the same authorised agent accompanied with only additional product license fee as specified in the Second Schedule and respective documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.

56. How much fees required to be paid along with the application for grant of import licence for IVDs.

Ans: For each distinct Class-A, Class B, Class C and Class D IVDs:

Category	Product Fees (USD)	manufacturing site (USD)
Class-A	10	1000
Class-B	10	1000
Class-C	500	3000
Class-D	500	3000

57. How much fees required to be paid along with the application for grant of licence to manufacture of IVDs.

Ans: For each distinct Class-A, Class B, Class C and Class D IVDs:

Category	Product Fees (INR)	manufacturing site (INR)
Class-A	500	5000

Class-B	500	5000
Class-C	1000	50000
Class-D	1000	50000

58. How to endorse/add additional IVD kits in the approved/valid Import License of the same manufacturing site?

Ans: The applicant shall endorse/add additional product under a valid import license in MD-15, provided the legal and actual manufacturer are same, by submitting the additionalproduct Registration fee (as per second schedule) and documents mentioned in Fourth schedule (Part I, Part II and Part III (Appendix I & Appendix III, only)) of medical deviceRules 2017.

59. Whether IVD kits/reagents, having valid Import License, can be imported from any notified ports of India?

Ans: Yes

60. Whether authorised agent holding valid Import licence is required to stock for any state in the India?

Ans: No. Single license may be issued, in respect of the import of more than one IVD Medical device or a group/class of IVD medical device manufactured by the same legal and actual manufacturer to the Importer through which importer can import the products through any notified port under Medical Device Rules, 2017.

61. Is it mandatory for IVD medical devices to be imported into India initially only at the warehouse address that is listed on the medical device import licence?

Ans: No, IVD Medical Devices, having valid Import Licence, can be imported from any notified ports of India and stored and distributed from any registered warehouse. It is not mandatory to initially stock in the warehouse address that is listed in the import license.

62. Whether IVD medical device imported under valid import license can stock in any other wholesale license premises other than stated in the ImportLicense?

Ans: Yes

63. What are all the In-Vitro Diagnostic Kits / Reagents need NOC from the otherdepartments for import?

Ans:

a. NOC from department of Animal Husbandry, Dairying and Fisheries (DADF), Government of India, KrishiBhavan, New Delhi in respect of products intended for veterinary purpose
b. NOC from Bhabha Atomic Research Centre (BARC), Mumbai, In case Radio Immuno Assay IVD Kits.
c. NOC from Department of the Pre-Natal Diagnostic Techniques (PNDT), Ministry of Health and Family Welfare, Government of India in case of IVD having the potential of sex selection/ determination.

64. Whether the applicant has to mention intended use of the proposed product in the product list or Form No. MD-14 during the submission of the applications?

Ans: Yes; applicant has to mention the specific intended use of the proposed product in the product list matching with the Intended Use/Purpose/ claim statement in product insert / brochure/Instructions for use,

65. What is a Central Medical Device Testing Laboratory?

Ans: Central medical devices testing laboratory means a medical devices laboratory established or designated by the Central Government under rule 19 and shall be deemed to be a Central Drug Laboratory established for the purpose of section 6 of the Act.

66. How many batches have to be evaluated for the submission of Performance evaluation reports for grant of import license for Class B, class- C & class- D IVDs?

Ans: The applicant shall submit performance evaluation reports (PER) for three independent batches of IVDs, manufactured by using three different lots of key raw materials (e.g. Antigen, antibody).

67. When Central Medical Device Testing Labs or Laboratories registered with CLA for carrying out evaluation are unable to conduct the Performance Evaluation, whether PE can be conducted at any other Government Laboratory / hospital of national repute or NABL accredited Labs?

Ans: Yes, provided the reports generated by such Government Laboratory / hospital of national repute or NABL accredited Labs shall meet the specification criteria as per the Guidance Document issued by the CLA. The applicant may refer to the Guidance document on Performance Evaluation of In-vitro Diagnostic Medical Devices published in CDSCO website.

68. Whether approval / Marketing authorization, issued by the competent Authorities in EU, U.K., Australia, Canada, Japan and USA, will be considered for exemption of Clinical Performance Evaluation (CPE) of New IVDs (Class B, Class C & Class D) in India.

Ans: No. Clinical Performance Evaluation has to be conducted in India for approval of new IVDs, irrespective of it's regulatory status in these countries.

69. Will clinical performance evaluation be required for grant of permission to manufacture or import any new IVD of Class A?

Ans: No. Clinical performance evaluation (CPE) may not be necessary, except in cases, where the CLA, considers it necessary depending on the nature of the IVD.

70. What is the criteria for evaluation of Rapid ELISA & CLIA-based (HIV, HBsAg, HCV) Diagnostic kit adopted by NIB, Noida. Whether the same criteria will also be applicable for other medical device testing labs.

Ans:

Analyte	ELISA / CLIA/ ELFA/ ECLIA/ CMIA/MEIA etc.		Rapid Kit	
	Sensitivity	Specificity	Sensitivity	Specificity
Anti-HIV	100%	≥ 98%	100%	≥ 98%
HBsAg	100%	≥ 98%	100%	≥ 98%
HCV	100%	≥ 98%	≥ 99%	≥ 98%

All medical device testing labs shall follow the above specified criteria for Rapid, ELISA & CLIA based HIV, HBsAg & HCV diagnostic kits.

71. What is the sample size required to conduct performance evaluation of IVDs of Class B, Class C & Class D in the designated medical device testing labs?

Ans: The sample size shall be statistically significant as per the protocol designed and approved by respective MDTL.

72. What are the Minimum criteria for evaluation of IVD Kits/reagents intended for Malaria, TB, Dengue, Chikunguniya, Typhoid, Syphilis and Cancer and other Class B & C IVD kits?

Ans: IVDs shall comply with the minimum performance criteria (Clinical sensitivity, specificity, repeatability, reproducibility, accuracy, Linearity, Variance etc.) as claimed in the IFU/COA/Product insert issued by the manufacturer.

73. What is the structure, content and format for Performance Evaluation Reports?

Ans: Typically a Performance Evaluation Report should mention following details:
Product name, lot / Batch number, Date of Manufacture, date of Expiry, manufacturer's name, importer name, number of samples tested, testing principle (ELISA/Rapid/NAAT etc.,)
, information about reference used, Testing procedure, Specificity, Sensitivity, Positive predictive value, Negative predictive value, Report number, Date of analysis, designation & Signature of analyst and authorized signatory of the laboratory etc.
Performance indicators for example Sensitivity, Specificity, PPN and NPN, Repeatability, Reproducibility and Accuracy criteria should be accepted as applicable for any specific IVD product with rational.

74. What is the Test license?

Ans: The Test License(s) in Form MD-13/ Form MD-17 are for manufacture or import small quantities of IVDs, for the purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training.

75. What are essential documents required for import of IVDs for Test or evaluation, Demonstration or training inMD-17?

Ans: Please download and refer to the document checklist for Import test licence applicationin Form MD-16. Under link:
https://cdscomdonline.gov.in/NewMedDev/viewChecklistReport

76. How much fees for the "Test License" to import for IVD kits/reagents in India?

Ans:

Classification	Fee (USD)
Class-A, class B, Class C & Class D	**100**

77. What is the validity period of "Test License" for IVD kits/reagents in India?

Ans: Test licence shall, unless cancelled earlier, be in force for a period of three years from the date of its issue (refer Rule 41(5) of Medical Device Rules, 2017).

78. Could it be possible to mention multiple sites in a "single" test license application for the purpose of Clinical Investigation, Testing, Evaluation, demonstration and training?

Ans: Yes.

79. What is a New IVD?

Ans: New IVD means any medical device as referred to in sub-clause (A) of clause (zb) used for invitro diagnosis that has not been approved for manufacture for sale or for import by the Central Licensing Authority and is being tested to establish its performance for relevant analyte or other parameter related thereto including details of technology and procedure required;

80. What is a predicate device?

Ans: 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;

81. Whether the products which are already approved to import or manufacture for sale in India shall be considered as a predicate device when the application for the same products is made under the Medical Device rules2017?

Ans: Yes.

82. Whether both legal (If any) and actual manufactures name and address should be stated in the Free Sale Certificate issued by the National Regulatory agency for the purpose of Import of IVDs in India?

Ans: Yes.

83. Any changes in name and/or address of Indian agent/ Importer or change in constitution after issue of import licence are required to be communicated to the Licensing Authority?

Ans: Yes, Indian authorized agent shall inform such change to CLA in writing within a period of forty five days in the event of any change in the constitution of the overseas manufacturer or authorized agent.

84. Any changes in name and/or address of legal and/or actual manufacturer after issue of Import License are required to be communicated to the Licensing Authority?

Ans: Yes, licensee or, authorized agent in India need to take prior approval from licensing authority in case of change in name and/or address of legal and/or actual manufacturer.

85. Whether fees required for change in address of authorized agent, without change in constitution as Post Approval Change under MDR-2017?

Ans: No. (Reference letter vide F.No. 29/Misc/03/2020-DC(124) dated 31.08.2020).

86. Whether acquisition/merger of one company by another company is considered as change in constitution of the company?

Ans: Change of constitution is defined as:

(i) a firm means change from proprietorship to partnership including Limited Liability Partnership or vice versa;

(ii) (ii)a company means-

(A) its conversion from a private to a public company, or from a public to a private company; or

(B) any change in the ownership of shares of more than fifty per cent. of the voting capital in the body corporate or in case of a body corporate not having a share capital, any change in its membership; and where the managing agent, being a body corporate is a subsidiary of another body corporate, includes a change in the constitution of that other body corporate within the meaning of this clause;

87. What are the changes that require an applicant to make a fresh import license application?

Ans: Fresh import license application shall be made only in case of change of constitution.

88. Is it correct that a major change can be implemented after 60 days in case CDSCO does not respond to the change notification?

Ans: Yes.

89. Whether the Importer who is having valid import license but there is some change in the name of importer or address of Importer, still can he import till another license is granted?

Ans: No.

90. What is the procedure for expanding/ modifying the currently registered indications?

Ans: Expanding or modifying the indications/ intended use are considered as a major change under Sixth schedule of Medical Devices Rules, 2017. This shall require prior approval before the implementation.

91. Whether any major change which is notified to the Regulatory Authority but response from CLA is awaited can be imported in India?

Ans: No. In case response/approval is not received within 60 days from the notification submission, the products undergone a major change shall be allowed for import.

92. What is the time line to notify CLA for a major post approval changes mentioned in sixth schedule?

Ans: All major changes specified in the Sixth schedule of Medical Devices Rules, 2017, shall need prior approval from CLA to carry out or, implement the change.

93. What the post approval changes are as specified in the sixth schedule that require prior approval from CLA or SLA?

Ans: For major changes, prior approval is required from CLA or SLA, as the case may be, before implementation and for minor changes the licencee shall notify the CLA or SLA, as the case may be. Further, the application for Post Approval changes (minor or major change) shall be submitted through an identified online portal of the Ministry of Health and Family Welfare.

94. In case the registered manufacturing site (Actual Manufacturer) remain unchanged (Plant master file to be precise), but Legal manufacturer entity changes to a different entity, whether same Plant Master Files shall be acceptable when submitted towards fresh registration?

Ans: Yes; provided the Plant Master File is updated with consequential changes.

95. Whether authorised agent can submit single application for grant of import licence for same product manufactured at more than one manufacturing sites?

Ans: Yes, provided that the applicant shall submit separate fee for each of the sites. Any subsequent application by the same authorised agent, after the grant of import licence, for endorsement of additional product or additional manufacturing site may also be made under the provisions of MDR, 2017.

96. What are the Labeling requirements for IVD in India?

Ans: Product labels shall comply with the requirements of the Chapter VI of Medical Device Rules, 2017.

97. At the time of submitting applications for Import of IVDs, are original labels as per Rule 44 to be submitted to the CLA?

Ans: Specimen Original Labels should be submitted as per Chapter-VI of MDR-2017

98. Can the importers of IVDs stickered for India-specific requirements on labels after/post landing in India at customs warehouse/FTWZ or place approved by the Licensing Authority?

Ans: Yes, provided that the India-specific requirements are specified in the Chapter VI of MRD, 2017.

99. Whether shelf life of the IVDs can be stated on the label instead of date of manufacture?

Ans: No. Both shelf life or expiry date and date of manufacture shall require on the labels.

100. Whether Certificate of Exportability (which reflects that the proposed products maynot be freely sold in the country of origin but can be exported), is acceptable as Free Sale Certificate?

Ans: No.

101. Whether Free Sale Certificate issued for IVDs manufactured and authorized for sale in countries other than Australia, Canada, Japan, European Union Countries, United Kingdom or the United States of America is acceptable? If not, what are the additional requirements for the same?

Ans: No. Where a Class C and Class D IVD intend to be imported from countries other than Australia, Canada, Japan, European Union Countries, United Kingdom or the United States of America, the import licence may be granted after its safety and effectiveness has been established through clinical performance evaluation in India. And where a Class A and Class B IVD intend to be imported from countries other than Australia, Canada, Japan, European Union Countries, United Kingdom or the United States of America, the import licence may be granted after its safety and performance has been established through published safety and performance data or through clinical investigation in the country of origin and a free sale certificate from the country of origin is furnished.

102. Can an importer import a IVDs having residual shelf life less than 60 % for non-Commercial or testing purpose?

Ans: Yes, notification # IMPORT/Misc / 2015-DC Dt 1/12/2015 will still be valid for the import of IVDs for testing purpose under a test license under Medical Devices Rules, 2017. However, the same shall also be applicable for the products imported under a test license forthe purpose of demonstration or training.

103. If yes, for the above question, whether the same will be communicated by CLA to all the port offices and Medical Device Testing labs?

Ans: Yes, CLA shall inform to all port offices and medical device testing labs on permission of import of IVD products using test license, having residual shelf life less than 40%, 50%, 60%, as compared to total shelf life of the product, with reference to Rule 44 of medical device rules 2017.

104. When applying for import license application in MD-14, if three batches are not available with the manufacturer for performance evaluation, whether the applicant can submit the import license application?

Ans: Yes; Import License in Form 14 application can be submitted with one lot report, along-with undertaking of availability of remaining two lots. Import license in Form MD-15 shall be issued by CLA with the condition on submission of performance evaluation reports for remaining 2 lots prior to the sale of the product in Indian market.

105. Whether trader can import bulk products for sale to manufacture?

Ans: Yes, with the undertaking that they will sell bulk product only to the manufacturer for further processing.

106. Whether Equivalence to predicate device will be mentioned 'Yes' in case of new IVD in legal form (MD-14)?

Ans: No, in case of new In-vitro Diagnostic Medical Device i.e. similar product not approved by CDSCO, Equivalence to predicate device needs to mention as 'No'.

107. Whether NTRP Challan could be considered as valid fee receipt?

Ans: No, transaction receipt generated by bharat kosh shall be considered as valid fee receipt.

108. What is regulatory pathway for Import of IVD for sale and distribution in India for which similar device is available in India?

Ans: (1) In case of In-vitro Diagnostic Medical Device for which predicate device is already available in the country, applicant need to submit application in Form MD-16 to obtain Test license in Form MD-17 in order to import test batches for generation of in-house quality/validation data or evaluation in external lab as the case may be. (2) Thereafter, applicant needs to apply in Form MD-14 to obtain import license in Form MD-15 approved by the Central Licensing Authority (DCGI).

109. Whether for each and every consignment, Manufacturer should obtain Neutral Code Certificate for export?

Ans: Neutral code is license specific, for export purpose only with respect to the licensed manufacturing site.

110. When applying for retention of import license, in case of change in Power of attorney, is it required to submit fresh power of attorney?

Ans: Yes, a copy of fresh 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 apostille along with under taking from the authorized agent as specified in PartI of Forth Schedule of MDR,2017 may be submitted.

111. Whether Certificate of Marketability/FSC issued for other than India is acceptable for submitting application for MD-15 Import licence?

Ans: No, it should mention issued for India.

MANUFACTURING POLICY

112. Which authority, an Indian Manufacturing company should approach for Licence to manufacture IVDs.

Ans.: For Class A & Class B IVDs, the manufacturing company shall approach the State Licensing Authority under whose Jurisdiction, the manufacturing premises is located. Whereas, for Class C & Class D IVDs, the manufacturing company shall approach the Central Licensing Authority (i.e. respective CDSCO Zonal/Sub-Zonal office) under whose Jurisdiction, the manufacturing premises is located. All license application shall be made through an identified online portal of the Ministry of Health and Family Welfare.

113. Whether any inspection shall be conducted by the regulatory body before grant of licence for IVD manufacturing?

Ans.:

For Class A IVDs:

(i) 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; and

(ii) 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 andtwenty days from the date on which the licence was granted by the State Licencing Authority.

For Class B IVDs:

(i) the audit of the manufacturing site shall be carried out within ninety days from the date of application by the registered Notified Body in the manner specified in the Third Schedule and furnish its report to State Licensing Authority.

For Class C & Class D IVDs:

(i) the Central Licensing Authority shall cause an inspection of the manufacturing site carried out under rule 23 by a team of Medical Device Officers accompanied by such experts, as may be considered necessary.

114. During the validity period of a manufacturing Licence, how many Inspections shall be warranted?

Ans: One Inspection shall be warranted with a gap of one year.

115. Whether PER needs to be conducted on the test batches of IVD before introduction in the market? if so how many batch samples to be forwarded and where?

Ans: Yes. Firm shall obtain Test Licence in Form-MD-13 to develop three or more trial batches of the IVD product. The prescribed number of sample from three consecutivebatches of such IVD products should be forwarded to testing laboratory specified in the Test licence.

116. Does the New Rule MDR-2017 mandate the manufacturer to maintain Quality Manual and Plant Master File (PMF)?

Ans. Yes, as per the Schedule-V ref. Clause 4.2.2 these two are mandated.

117.Where in MDR-2017 the details of PMF are available?

Ans. The contents of Plant Master File have been detailed in appendix - I of Fourth schedule.

118. Is there any requirement to maintain IVD master file?

Ans. For each type of IVD there is a requirement to maintain a —IVD Master File. The Contents of IVD Master File have been detailed in appendix - II of Fourth schedule.

119. What is manufacturing under Loan Licence?

Ans. Loan licence means 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 other licencee for manufacturing the same medical device as manufactured by the licencee at that site. Reference Rule-3(Z).

120. What is regulatory pathway to manufacture of IVD for sale and distribution in India for which similar device is available in India?

Ans: (1) In case of In-vitro Diagnostic Medical Device for which predicate device is already available in the country, applicant need to submit application in Form MD-12 to obtain Test license in Form MD-13 in order to manufacture test batches for generation of in-house quality/ validation data or evaluation in external lab as the case may be. (whenever applicable) (2) Thereafter, applicant needs to apply in Form MD-3/ FormMD-4 to obtain manufacturing license for Class A & B for sale or distributions in Form MD-5/ FormMD-6 approved by State Licensing Authority or needs to apply in Form MD-7/ Form MD-8 for Class C & D to obtain manufacturing license in Form MD-9/ Form MD-10 approved by Central Licensing Authority

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Note: Any suggestions with respect to this document may be communicated to this office through e-mail at ivd-division@cdsco.nic.in

Central Drugs Standard Control Organisation

(Medical Devices and Diagnostic Division)

In-Vitro Diagnostic (IVD) Medical Devices

Frequently Asked Questions

Doc No.: CDSCO/IVD/FAQ/03/2022

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

DIRECTORATE GENERAL OF HEALTH SERVICES

MINISTRY OF HEALTH & FAMILY WELFARE

GOVERNMENT OF INDIA

Notice:

The replies to the FAQs are aimed only for creating public awareness about In-Vitro Diagnostic Medical Devices Regulation by CDSCO and are not meant to be used for legal or professional purposes. The readers are advised to refer to the statutory provisions of Drugs and Cosmetics Act & Rules and respective Guidelines / Clarifications issued by CDSCO time to time for all their professional needs.

Frequently Asked Questions on *In-Vitro* Diagnostic Medical Devices

GENERAL POLICY

1. Whether In-Vitro Diagnostic kits/reagents are regulated in India?

Ans: Yes, all In -Vitro Diagnostic kits/reagents are regulated in India under the provisions of the Medical Devices Rules, 2017.

2. Where can we get a copy of the Medical Devices Rules, 2017?

Ans: The copy of the Medical Devices Rules, 2017 is available in the CDSCO Website under the link:
http://www.cdsco.nic.in/writereaddata/Medical%20Device%20Rule%20gsr78E.pdf

3. Name and address of the Regulatory Authority that governs the regulations of Import of IVD kits/reagents in India?

Ans: The Drugs Controller General (India),
Central Drugs Standard Control Organization (CDSCO),
Directorate General of Health Services,
Ministry of Health and Family Welfare,
Government of India,

Address:
FDA Bhavan, ITO, Kotla Road,
New Delhi -110002
Phone: 91-11-23236965 / 23236975,
Fax: 91-11-23236973,
E-mail:- dci@nic.in.

4. What are the activities regulated by the CLA & SLA with respect to In Vitro diagnostic in India?

Ans.:

Central Licensing Authority	State Licensing Authorities
Enforcement of rules in matters related to: • Import of all Classes of IVDs. • Manufacture of Class C and Class D IVDs. • Clinical performance evaluation and approval of new in vitro diagnostic. • Registration of Notified Bodies • Registration of Laboratories for carrying out test or evaluation. • Test licences for manufacture or import of all classes of IVDs	Enforcement of rules in matters related to: • Manufacture for sale or distribution of Class A or Class B IVD • Sale, stock, exhibit or offer for sale or distribution of IVDs of all classes.

5. Which division of CDSCO is responsible for review of IVD kits/ reagents ?

Ans: Medical Devices & Diagnostics Division, Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, FDA Bhavan, ITO, Kotla Road, New Delhi -110002.

6. What is an In-Vitro Diagnostic (IVD)?

Ans: IVDs are substances intended to be used outside human or animal bodies for the diagnosis of any disease or disorder in human beings or animals covered under sub-clause (i) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 and IVDs that are notified, from time to time, as a device under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940.

7. What is an In –Vivo Diagnostics?

Ans: When Diagnosis of disease and disorders are carried out in the body of living human or animal that is done in vivo as opposed to in a laboratory method that does not use the living organism as the host of the test. In vivo is the opposite of in vitro.
These materials are chemical, biological, or radioactive substances used in diagnosing or monitoring the state of human or veterinary health by identifying and measuring normal or abnormal constituents of body fluids or tissues.
For Example : Angio-urographic diagnostic agents, Barium diagnostic agents, Cold kits for labeling with technetium, Contrast media diagnostic products (e.g., iodine and barium)

8. Whether MDR 2017 is also applicable for in vivo diagnostic products?

Ans: Since in-Vivo Diagnostics are interventional and put into systemic circulation in living bodies, all principles and norms applicable for regulations of chemical, biological and radiological drugs shall also be applicable in such products.

9. How are IVDs classified in India under Medical Device Rules, 2017?

Ans: IVDs are classified under Chapter II, Rule 4, Sub-rule (2) of Medical Device Rules 2017 on the basis of parameters specified in Part II of the First Schedule, in the following classes, namely:—
(i) low risk - Class A;
(ii) low moderate risk- Class B;
(iii) moderate high risk- Class C;
(iv) high risk- Class D.

10. Who will have the responsibility of doing Classification of IVD as per Class A/B/C/D ?

Ans: Reference Rule 4 (3) This rule specifies that Central Licensing Authority shall classify the Medical Devices.

11. Whether on market approved products, in India have to be newly registered as per Medical Devices Rules, 2017, when the existing license gets expired?

Ans: Yes, IVD products which are currently registered in India have to be registered according to the provisions of Medical Devices Rules, 2017.

12. Are Analyzers, Instruments and Software used with IVDs covered in the scope of Medical Devices Rules, 2017?

Ans: Yes. Analyzers, Instruments and Software intended to be used for In-vitro Diagnosis are regulated in phase wise manner under the provisions of Medical Devices Rules, 2017. Classification of IVD Analyzers, Instruments and Software is published in CDSCO website.

Classification of IVDs	Voluntary registration	Mandatory registration	Licensing Regime
Class A & B	01/04/2020 to 30/09/2021 (18 months)	01/10/2021 to 30/09/2022 (12 months)	From 01/10/2022
Class C & D	01/04/2020 to 30/09/2021 (18 months)	01/10/2021 to 30/09/2023 (24 months)	From 01/10/2023

13. Which IVD kits/reagents fall under the category of Class A, Class B, Class C, Class D products?

Ans: Please refer to the classification list issued by CLA available at CDSCO website.

14. Whether the wholesale license issued under the Drugs and Cosmetics Rules, 1945 will be valid as per the Medical Devices Rules, 2017.

Ans: Yes.

15. Whether any product, intended for use in determining the presence of host cell protein contamination, in products manufactured by expression in the CHO cell line and other technology for Research and manufacturing use only and is not intended for diagnostic use in humans or animals, are being regulated under the provision of Medical Devices Rules, 2017?

Ans: No.

16. **Whether any product used in determining the presence of histamine, substances , Microbial detection in food & food products, animal feeds, liquor (wine, beer), environmental samples like water, soil etc. and is not intended for In-vitro diagnostic use in humans or animals, are being regulated under the provision of Medical Devices Rules, 2017?**

Ans: No.

17. **Will products such as RUO – Research Use Only, Q.C material for accreditation, panel for Q.C testing & product used for food, water, sterility testing used by various industry for Q.C etc., and is not intended to be used in human or animals for diagnosis of any disease or disorder, be regulated under MDR, 2017 ?**

Ans: No

18. **Will products such as microbiological culture media, stains indicators and reagents used for food and water testing and is not intended to be used in human or animals for diagnosis of any disease or disorder be regulated under MDR, 2017 ?**

Ans: No

19. **Whether Specimens collection tubes (vacuum type or not) without needle used for the collection of Blood, Urine, Stool, Sputum, Semen, etc., for purpose of specimens collection are being regulated under the provision of Medical Devices Rules, 2017?**

Ans: Yes. Specimen collection tubes are regulated under the definition of "specimen receptacle" as specified in Sub-clause (zs) of Rule 3 of MDR-2017 and are classified as Class A as per First Schedule, Part II (2(v)(3)) of MDR-2017.

20. **Whether IVDs for HBsAg, HIV and HCV approved to manufacture or import by the CLA or SLA, as the case may be, permitted to use for both the purposes; for blood screening and diagnostic.**

Ans: Yes. In – Vitro Diagnostic devices for HBsAg, HIV and HCV manufactured / Imported under valid license issued by the CLA or SLA, may also be used in Blood Bank, as the criteria like Sensitivity (%) and Specificity (%) for evaluation of the HBsAg, HIV and HCV diagnostic kits for the Transfusion purpose (Blood Banks) and Diagnostic purpose are same, Provided the manufacturer claims in the product labels or in the IFU that the product is intended both the purposes; for blood screening and diagnostic.

21. **Which IVD reagents/kits are prohibited in India?**

Ans: (1) Serodiagnostic test kits for diagnosis of tuberculosis are prohibited to Import, Manufacture, Sale, Distribution and Use in the country under Section 10A and Section 26A of the Drugs and Cosmetics Act, 1940 Gazette notification(s) GSR432(E) & GSR433(E) dated June 7, 2012.

(2) Antibody Detecting Rapid Diagnostic Tests for routine diagnosis of malaria are prohibited to Import, Manufacture, Sale, Distribution and Use in the country under Section 26A and Section 10A of the Drugs and Cosmetics Act, 1940, Gazette notification(s) GSR1352(E) dated March 23, 2018 and GSR1074(E) dated October 30, 2018 respectively.

22. What are considered to be the major changes in Post approval of IVD?

Ans: As per Sixth Schedule of Medical Devices Rules, 2017, following changes have been included in the list of major changes which needs prior approval from the competent authority.

(A) Changes in respect of following shall be considered as major change in,-

1. material of construction;
2. design which shall affect quality in respect of its specifications, indication for use; performance and stability of the medical device;
3. the intended use or indication for use ;
4. the method of sterilization;
5. the approved Shelf life;
6. the name or address of,-
   (i) the domestic manufacturer or its manufacturing site;
   (ii) overseas manufacturer or its manufacturing site (for import only);
   (iii) authorised agent (for import only);
7. label excluding change in font size, font type, color, label design;
8. manufacturing process, equipment or testing which shall affect quality of the device;
9. primary packaging material.

23. Whether manufacture/ import of Coated (Ab/Ag) Uncut sheet of a Rapid POCT based IVD, intended to be used for further manufacture of finished IVD kit is regulated under the provisions of Medical Devices Rules, 2017?

Ans: Yes.

24. What is the fee structure required for multiple Brand names of a product applied in the manufacturing/ import licence application?

Ans: For multiple brand names of a product, the firm needs to submit applicable product fee as per Second schedule for each of the Brand name.

25. Whether CDSCO provides any consultation system for Start-ups/ Importers/ Manufacturers?

Ans: Yes. The Public Relation Office (PRO) cell is established in CDSCO Head Quarter and at all zonal offices to address the issue of startups/ importers/ manufacturers in the field of In-vitro Diagnostic medical devices pertaining to regulatory pathway.
(Link : https://cdsco.gov.in/opencms/opencms/en/PRO/ ; Email ID: startupinnov@cdsco.nic.in)

ADMINISTRATIVE NORMS

26. Can Third party / Authorized Consultant ask the status of the application?

Ans: No, The Regular employee, authorized by the competent person of the applicant company may only ask the status of their application.

27. Who is authorized to make a Technical Presentation, on behalf of applicant, when asked by the CDSCO?

Ans: Only Subject Expert or Technical Person of the company who is equally competent to make technical presentation.

28. How should the documents be notarized?

Ans: The notary should ensure that documents are properly authenticated by either signing the total document set together in a set or each pages in case of a standalone certificate. (Declaration from notary).

29. Where can I submit my enquiries related to Import and Manufacture of IVDs?

Ans: All enquiries regarding the submission and approvals can be sent to the Drugs Controller General India (dci@nic.in) - CDSCO, FDA Bhawan, ITO, Kotla Road, New Delhi - 110002. Phone: 91-11-23236965 / 23236975. Fax: 91-11-23236973.

30. What is the method for getting refund of challan amount if any manufacturer/importer does not want to register the product or withdraw their application?

Ans: As per Medical Devices Rules, 2017, there is no provision/ clause for the refund of paid application fee.

31. Will post-approval change notification approval require submission of fee?

Ans: No

32. Which will be the Medical Device Testing Laboratory (MDTL) for IVD Medical devices?

Ans: List of Medical Device Testing Laboratory (MDTL) is available and updated in CDSCO website.

33. What will be time-period for approval by CLA for implementation of a Major change?

Ans: 60 days. In case CLA do not indicate approval or rejection within sixty days, such change shall be deemed to have been approved by the licensee.

34. What will be time-period for approval by CLA for implementation of a Minor change?

Ans.: Implementation of minor change do not need prior approval provided licensee inform CLA within a period of thirty days after the change takes place or becomes effective.

IMPORT POLICY

35. What are the requirements for import of Class-A/B/C/D In Vitro Diagnostic Medical device in India?

Ans: For the import of Class A, B, C & D IVDs, applicant have to submit the documents as per Fourth schedule Part I, Part II and Part III (Appendix I & III, only), along with fee as per second schedule. Guidance document on import of IVDs is available on CDSCO website

36. Who can apply for grant of licence to import IVD kits and reagents in to India?

Ans: An authorised agent holding licence to manufacture or wholesale licence under issued under MDR, 2017, may submit an application for grant of import licence for IVD to the Central Licensing Authority.

37. Whether multiple Indian agents are allowed to apply for import licence for same product having same manufacture?

Ans: Yes. All the applicants shall need to submit separate application under MDR, 2017.

38. Whether manufacturing site of IVD will be inspected before grant of Manufacturing License.

Ans: For Indigenous manufacturers of IVDs:

(i) For Class A IVDs, 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 IVDs; and

(ii) For Class B, Class C and Class D IVDs, before grant of the manufacturing licence the audit/inspection of the manufacturing site shall be carried out.

39. Whether overseas manufacturing site of IVD will be inspected before grant of import License.

Ans: No. However, if the Central Licensing Authority, believes, as it think fit, may carry out an inspection of the overseas manufacturing site before grant of import licence.

40. In case CLA changes the risk based Classification of any product, after approval under the Medical Device Rules 2017, then the license issued under new Rules will continue to be valid for what period? What will be the transition time period given to the industry to adjust according to the new classification?

Ans: In case CLA changes the classification of any IVD product (eg. from Class B to C), the earlier license shall continue to be valid till the final decision taken on the application by the CLA or SLA, as the case may be. Adequate transition time from the date of such notification will be given to industry to prepare documents according to the new classification.

41. In case of such a change in classification, whether applicant needs to do fresh application or only additional documents and fees will be required to be submitted?

Ans: Only additional documents along with the fees (only in case of change from A to C/D or B to C/D) shall be submitted by the applicant to the CLA or SLA, as the case may be.

42. Whether essential principles for safety and performance of IVDs shall be applicable for both importer and indigenous manufacturers?

Ans: Yes.

43. Since the nature of the class A products is intended to be used in conjunction with the IVD products (example: washing solutions, buffers etc) no separate EP checklist is generated during the design and development. Can a manufacturer's declaration suffice?

Ans: Only relevant provisions of the Essential Principles for Safety and Performance of IVDs shall need to be complied with the manufacturers, with the justification that why other provisions are not applicable.

44. What is the validity of Import License or licence to manufacture for IVD issued under MDR, 2017?

Ans: Import License or licence to manufacture for IVD issued under MDR, 2017 shall continue to be perpetually valid till suspension or cancellation, provided that the licencee shall pay a Licence Retention fee in every five years under the provisions of MDR, 2017.

45. How to register additional Class-A/B/C/D IVD Medical Device in the already approved/valid Import License (MD-15)?

Ans: Subsequent application for Licence (Endorsement to respective base licence number) for additional IVD medical device manufactured at the same manufacturing site and having same legal manufacturer shall be made by the same authorised agent accompanied with only additional product license fee as specified in the Second Schedule and respective documents as specified in the Fourth Schedule of Medical Devices Rules, 2017.

46. How much fees required to be paid along with the application for grant of import licence for IVDs.

Ans: For each distinct Class-A, Class B, Class C ad Class D IVDs:

Category	Product Fees (USD)	manufacturing site (USD)
Class-A	10	1000
Class-B	10	1000
Class-C	500	3000
Class-D	500	3000

47. How much fees required to be paid along with the application for grant of licence to manufacture of IVDs.

Ans: For each distinct Class-A, Class B, Class C ad Class D IVDs:

Category	Product Fees (INR)	manufacturing site (INR)
Class-A	500	5000

Class-B	500	5000
Class-C	1000	50000
Class-D	1000	50000

48. How to endorse/add additional IVD kits in the approved/valid Import License of the same manufacturing site?

Ans: The applicant shall endorse/add additional product under a valid import license in MD-15, provided the legal and actual manufacturer are same, by submitting the additional product Registration fee (as per second schedule) and documents mentioned in Fourth schedule (Part I, Part II and Part III (Appendix I & Appendix III, only)) of medical device Rules 2017.

49. Whether IVD kits/reagents, having valid Import License, can be imported from any notified ports of India?

Ans: Yes

50. Whether authorised agent holding valid Import licence is required to stock for any state in the India?

Ans: No. Single license may be issued, in respect of the import of more than one IVD Medical device or a group/class of IVD medical device manufactured by the same legal and actual manufacturer to the Importer through which importer can import the products through any notified port under Medical Device Rules, 2017.

51. Is it mandatory for IVD medical devices to be imported into India initially only at the warehouse address that is listed on the medical device import licence?

Ans: No, IVD Medical Devices, having valid Import Licence, can be imported from any notified ports of India and stored and distributed from any registered warehouse. It is not mandatory to initially stock in the warehouse address that is listed in the import license.

52. Whether IVD medical device imported under valid import license can stock in any other wholesale license premises other than stated in the Import License?

Ans: Yes

53. What are all the In-Vitro diagnostic Kits / Reagents need NOC from the other departments for import?

Ans:

a. NOC from department of Animal Husbandry, Dairying and Fisheries (DADF), Government of India, Krishi Bhavan, New Delhi in respect of products intended for veterinary purpose
b. NOC from DG, ICMR, New Delhi OR NABL Accredited Lab or Govt recognized Agency.
c. NOC from Bhabha Atomic Research Centre (BARC), Mumbai, In case Radio Immuno Assay IVD Kits.
d. NOC from Department of The Pre-Natal Diagnostic Techniques (PNDT) , Ministry of Health and Family Welfare, Government of India.

54. Whether the applicant has to mention intended use of the proposed product in the product list or Form No. MD-14 during the submission of the applications?

Ans: Yes; applicant has to mention the specific intended use of the proposed product in the product list matching with the Intended Use/Purpose/ claim statement in product insert / brochure/Instructions for use,

55. What is a Central Medical Device Testing Laboratory?

Ans: Central medical devices testing laboratory means a medical devices laboratory established or designated by the Central Government under rule 19 and shall be deemed to be a Central Drug Laboratory established for the purpose of section 6 of the Act.

56. How many batches have to be evaluated for the submission of Performance evaluation reports for grant of import license for Class B, class- C & class- D IVDs ?

Ans: The applicant shall submit performance evaluation reports (PER) for three independent batches of IVDs , manufactured by using three different lots of key raw materials (e.g. Antigen, antibody) .

57. When Central Medical Device Testing Labs or Laboratories registered with CLA for carrying out evaluation are unable to conduct the Performance Evaluation, whether PE can be conducted at any other Government Laboratory / hospital of national repute or NABL accredited Labs?

Ans: Yes, provided the reports generated by such Government Laboratory / hospital of national repute or NABL accredited Labs shall meet the specification criteria as per the Guidance Document issued by the CLA. The applicant may refer to the Guidance document on Performance Evaluation of In-vitro Diagnostic Medical Devices published in CDSCO website.

58. Whether approval / Marketing authorization, issued by the competent Authorities in EU, U.K., Australia, Canada, Japan and USA, will be considered for exemption of Clinical Performance Evaluation (CPE) of New IVDs (Class B, Class C & Class D) in India.

Ans: No. Clinical Performance Evaluation has to be conducted in India for approval of new IVDs, irrespective of it's regulatory status in these countries.

59. Will clinical performance evaluation be required for grant of permission to manufacture or import any new IVD of Class A ?

Ans: No. Clinical performance evaluation (CPE) may not be necessary, except in cases, where the CLA, considers it necessary depending on the nature of the IVD.

60. What is the criteria for evaluation of Rapid ELISA & CLIA-based (HIV, HBsAg, HCV) Diagnostic kit adopted by NIB, Noida. Whether the same criteria will also be applicable for other medical device testing labs.

Ans:

Analyte	ELISA / CLIA/ ELFA/ ECLIA/ CMIA/MEIA etc.		Rapid Kit	
	Sensitivity	Specificity	Sensitivity	Specificity
Anti-HIV	100%	≥ 98%	100%	≥ 98%
HBsAg	100%	≥ 98%	100%	≥ 98%
HCV	100%	≥ 98%	≥ 99%	≥ 98%

All medical device testing labs shall follow the above specified criteria for Rapid, ELISA & CLIA based HIV, HBsAg & HCV diagnostic kits.

61. What is the sample size required to conduct performance evaluation of IVDs of Class B, Class C & Class D in the designated medical device testing labs ?

Ans: The sample size shall be statistically significant as per the protocol designed and approved by respective MDTL.

62. What are the Minimum criteria for evaluation of IVD Kits/reagents intended for Malaria, TB, Dengue, Chikunguniya, Typhoid, Syphilis and Cancer and other Class B & C IVD kits?

Ans: IVDs shall comply with the minimum performance criteria (Clinical sensitivity, specificity, repeatability, reproducibility, accuracy, Linearity, Variance etc.) as claimed in the IFU/COA/Product insert issued by the manufacturer.

63. What is the structure, content and format for Performance Evaluation Reports?

Ans:
Typically a Performance Evaluation Report should mention following details:
Product name, lot / Batch number, Date of Manufacture, date of Expiry, manufacturer's name, importer name, number of samples tested, testing principle (ELISA/Rapid/NAAT etc.,) , information about reference used, Testing procedure, Specificity, Sensitivity, Positive predictive value, Negative predictive value, Report number, Date of analysis, designation & Signature of analyst and authorized signatory of the laboratory etc.
Performance indicators for example Sensitivity, Specificity, PPN and NPN, Repeatability, Reproducibility and Accuracy criteria should be accepted as applicable for any specific IVD product with rational.

64. What is the Test license?

Ans: The Test License(s) in Form MD-13/ Form MD-17 are for manufacture or import small quantities of IVDs, for the purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training.

65. What are essential documents required for import of IVDs for Test or evaluation, Demonstration or training in MD-17?

Ans: Please down load and refer to the document checklist for Import test licence application in Form MD-16. Under link:
https://cdscomdonline.gov.in/NewMedDev/viewChecklistReport

66. How much fees for the "Test License" to import for IVD kits/reagents in India?

Ans:

Classification	Fee (USD)
Class-A, class B, Class C & Class D	**100**

67. What is the validity period of "Test License" for IVD kits/reagents in India?

Ans: Test licence shall, unless cancelled earlier, be in force for a period of three years from the date of its issue (refer Rule 41(5) of Medical Device Rules, 2017).

68. Could it be possible to mention multiple sites in a "single" test license application for the purpose of Clinical Investigation, Testing, Evaluation, demonstration and training?

Ans: Yes.

69. What is a New IVD?

Ans: New IVD means any medical device as referred to in sub-clause (A) of clause (zb) used for in vitro diagnosis that has not been approved for manufacture for sale or for import by the Central Licensing Authority and is being tested to establish its performance for relevant analyte or other parameter related thereto including details of technology and procedure required;

70. What is a predicate device?

Ans: predicate deviceǁ 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;

71. Whether the products which are already approved to import or manufacture for sale in India shall be considered as a predicate device when the application for the same products is made under the Medical Device rules 2017?

Ans: Yes.

72. Whether both legal (If any) and actual manufactures name and address should be stated in the Free Sale Certificate issued by the National Regulatory agency for the purpose of Import of IVDs in India?

Ans: Yes.

73. Any changes in name and/or address of Indian agent/ Importer or change in constitution after issue of import licence are required to be communicated to the Licensing Authority?

Ans: Yes, Indian authorized agent shall inform such change to CLA in writing within a period of forty five days in the event of any change in the constitution of the overseas manufacturer or authorized agent.

74. Any changes in name and/or address of legal and/or actual manufacturer after issue of Import License are required to be communicated to the Licensing Authority?

Ans: Yes, licensee or, authorized agent in India need to take prior approval from licensing authority in case of change in name and/or address of legal and/or actual manufacturer.

75. Whether fees required for change in address of authorized agent, without change in constitution as Post Approval Change under MDR-2017 ?

Ans: No. (Reference letter vide F.No. 29/Misc/03/2020-DC(124) dated 31.08.2020).

76. Whether acquisition/merger of one company by another company is considered as change in constitution of the company?

Ans: Change of constitution is defined as:

(i) a firm means change from proprietorship to partnership including Limited Liability Partnership or vice versa;

(ii) (ii)a company means-

(A) its conversion from a private to a public company, or from a public to a private company; or

(B) any change in the ownership of shares of more than fifty per cent. of the voting capital in the body corporate or in case of a body corporate not having a share capital, any change in its membership; and where the managing agent, being a body corporate is a subsidiary of another body corporate, includes a change in the constitution of that other body corporate within the meaning of this clause;

77. What are the changes that require an applicant to make a fresh import license application?

Ans: Fresh import license application shall be made only in case of change of constitution.

78. Is it correct that a major change can be implemented after 60 days in case CDSCO does not respond to the change notification?

Ans: Yes.

79. Whether the Importer who is having valid import license but there is some change in the name of importer or address of Importer, still can he import till another license is granted?

Ans: No.

80. What is the procedure for expanding/ modifying the currently registered indications?

Ans: Expanding or modifying the indications/ intended use are considered as a major change under Sixth schedule of Medical Devices Rules, 2017. This shall require prior approval before the implementation.

81. Whether any major change which is notified to the Regulatory Authority but response from CLA is awaited can be imported in India?

Ans: No. In case response/approval is not received within 60 days from the notification submission, the products undergone a major change shall be allowed for import.

82. What is the time line to notify CLA for a major post approval changes mentioned in sixth schedule?

Ans: All major changes specified in the Sixth schedule of Medical Devices Rules, 2017, shall need prior approval from CLA to carry out or, implement the change.

83. What are the post approval changes as specified in the sixth schedule that require prior approval from CLA or SLA?

Ans: For major changes, prior approval is required from CLA or SLA, as the case may be, before implementation and for minor changes the licencee shall notify the CLA or SLA, as the case may be. Further, the application for Post Approval changes (minor or major change) shall be submitted through an identified online portal of the Ministry of Health and Family Welfare.

84. In case the registered manufacturing site (Actual Manufacturer) remain unchanged (Plant master file to be precise), but Legal manufacturer entity changes to a different entity, whether same Plant Master Files shall be acceptable when submitted towards fresh registration?

Ans: Yes; provided the Plant Master File is updated with consequential changes.

85. Whether authorised agent can submit single application for grant of import licence for same product manufactured at more than one manufacturing sites?

Ans: Yes, provided that the applicant shall submit separate fee for each of the sites. Any subsequent application by the same authorised agent, after the grant of import licence, for endorsement of additional product or additional manufacturing site may also be made under the provisions of MDR, 2017.

86. What are the Labeling requirements for IVD in India?

Ans: Product labels shall comply with the requirements of the Chapter VI of Medical Device Rules, 2017.

87. At the time of submitting applications for Import of IVDs, are original labels as per Rule 44 to be submitted to the CLA?

Ans: Specimen Original Labels should be submitted as per Chapter-VI of MDR-2017

88. Can the importers of IVDs stickered for India-specific requirements on labels after/post landing in India at customs warehouse/FTWZ or place approved by the Licensing Authority?

Ans: Yes, provided that the India-specific requirements are specified in the Chapter VI of MRD, 2017.

89. Whether shelf life of the IVDs can be stated on the label instead of date of manufacture?

Ans: No. Both shelf life or expiry date and date of manufacture shall require on the labels.

90. Whether Certificate of Exportability (which reflects that the proposed products may not be freely sold in the country of origin but can be exported), is acceptable as Free Sale Certificate?

Ans: No.

91. Will Free Sale Certificate be acceptable for IVDs manufactured and authorized for sale in countries other than Australia, Canada, Japan, European Union, or the United States of America? If no, what are the additional requirements for the same?

Ans: No. Where a Class C and Class D IVD intend to be imported from countries other than Australia, Canada, Japan, European Union, or the United States of America, the import licence may be granted after its safety and effectiveness has been established through clinical performance evaluation in India. And where a Class A and Class B IVD intend to be imported from countries other than Australia, Canada, Japan, European Union, or the United States of America, the import licence may be granted after its safety and performance has been established through published safety and performance data or through clinical investigation in the country of origin and a free sale certificate from the country of origin is furnished.

92. Can an importer import a IVDs having residual shelf life less than 60 % for non-Commercial or testing purpose?

Ans: Yes, notification # IMPORT/Misc / 2015-DC Dt 1/12/2015 will still be valid for the import of IVDs for testing purpose under a test license under Medical Devices Rules, 2017. However, the same shall also be applicable for the products imported under a test license for the purpose of demonstration or training.

93. If yes, for the above question, whether the same will be communicated by CLA to all the port offices and Medical Device Testing labs?

Ans: Yes, CLA shall inform to all port offices and medical device testing labs on permission of import of IVD products using test license, having residual shelf life less than 40%, 50%, 60%, as compared to total shelf life of the product, with reference to Rule 44 of medical device rules 2017.

94. When applying for import license application in MD-14, if three batches are not available with the manufacturer for performance evaluation, whether the applicant can submit the import license application?

Ans: Yes; Import License in Form 14 application can be submitted with one lot report, along-with undertaking of availability of remaining two lots. Import license in Form MD-15 shall be issued by CLA with the condition on submission of performance evaluation reports for remaining 2 lots prior to the sale of the product in Indian market.

95. Whether trader can import bulk products for sale to manufacture.

Ans: Yes, with the undertaking that they will sell bulk product only to the manufacturer for further processing.

MANUFACTURING POLICY

96. Which authority, an Indian Manufacturing company should approach for Licence to manufacture IVDs.

Ans : For Class A & Class B IVDs, the manufacturing company shall approach the State Licensing Authority under whose Jurisdiction, the manufacturing premises is located. Whereas, for Class C & Class D IVDs, the manufacturing company shall approach the Central Licensing Authority (i.e. respective CDSCO Zonal/Sub-Zonal office) under whose Jurisdiction, the manufacturing premises is located. All license application shall be made through an identified online portal of the Ministry of Health and Family Welfare.

97. Whether any inspection shall be conducted by the regulatory body before grant of licence for IVD manufacturing?

Ans. :

For Class A IVDs:

(i) 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; and

(ii) 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 Licencing Authority.

For Class B IVDs:

(i) the audit of the manufacturing site shall be carried out within ninety days from the date of application by the registered Notified Body in the manner specified in the Third Schedule and furnish its report to State Licensing Authority.

For Class C & Class D IVDs:

(i) the Central Licensing Authority shall cause an inspection of the manufacturing site carried out under rule 23 by a team of Medical Device Officers accompanied by such experts, as may be considered necessary.

98. During the validity period of a manufacturing Licence, how many Inspection shall be warranted?

Ans : One Inspection shall be warranted with a gap of one year.

99. Whether PER needs to be conducted on the test batches of IVD before introduction in the market? if so How many batch samples to be forwarded and where?

Ans: Yes. Firm shall obtain Test Licence in Form-MD-13 to develop three or more trial batches of the IVD product. The prescribed number of sample from three consecutive batches of such IVD products should be forwarded to testing laboratory specified in the Test licence.

100. Does the New Rule MDR-2017 mandate the manufacturer to maintain Quality Manual and Plant Master File (PMF) ?

Ans. Yes, as per the Schedule-V ref. Clause 4.2.2 these two are mandated.

101. Where in MDR-2017 the details of PMF are available?

Ans. The contents of Plant Master File have been detailed in appendix - I of Fourth schedule.

102. Is there any requirement to maintain IVD master file?

Ans. For each type of IVD there is a requirement to maintain a —IVD Master File. The Contents of IVD Master File have been detailed in appendix - II of Fourth schedule.

103. What is manufacturing under Loan Licence?

Ans. Loan licence means 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 other licencee for manufacturing the same medical device as manufactured by the licencee at that site. Reference Rule-3(Z).

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Note: Any suggestions with respect to this document may be communicated to this office through e-mail at ivd-division@cdsco.nic.in

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

Central Drugs Standard Control Organisation

(Medical Devices and Diagnostic Division)

In - Vitro Diagnostic (IVD) Devices

Frequently Asked Questions

Doc No.: CDSCO/IVD/FAQ/02/17

Date :

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

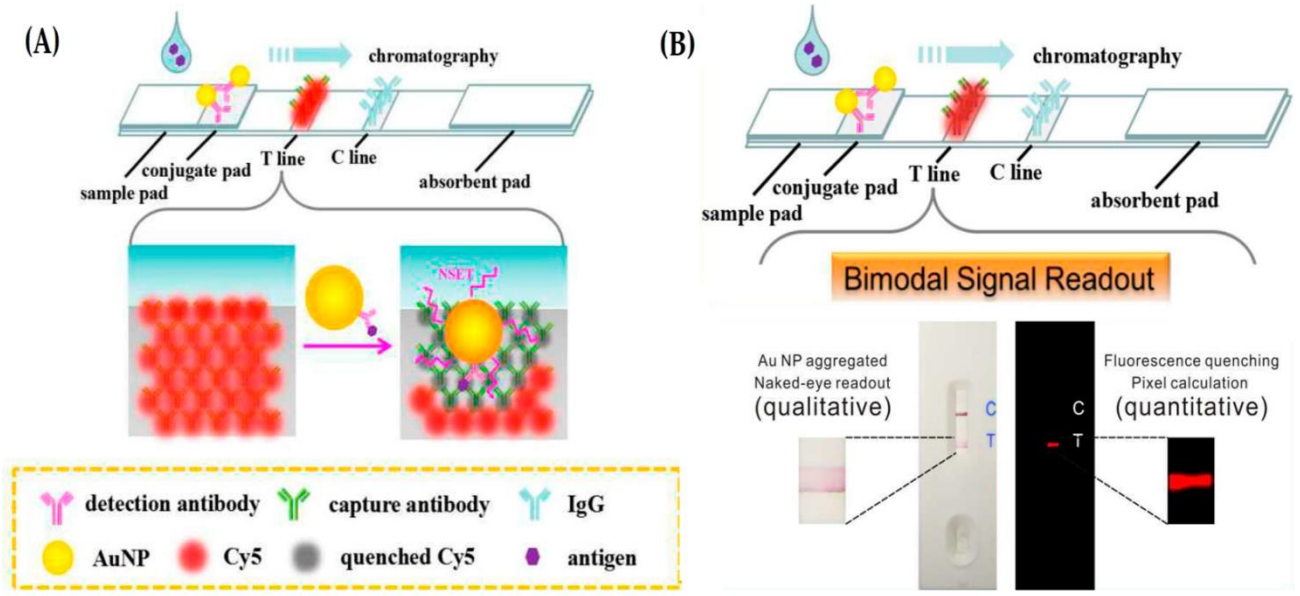
DIRECTORATE GENERAL OF HEALTH SERVICES

MINISTRY OF HEALTH & FAMILY WELFARE

GOVT. OF INDIA

Notice:

The replies to the FAQs are aimed only for creating public awareness about In-Vitro DiagnosticDevices Regulation by CDSCO and are not meant to be used for legal or professional purposes. The readers are advised to refer to the statutory provisions of Drugs and Cosmetics Act & Rules and respective Guidelines / Clarifications issued by CDSCO time to time for all their professional needs.



Frequently Asked Questions on In-Vitro Diagnostic Devices

GENERAL POLICY

1. **Whether In-Vitro Diagnostic kits/reagents are regulated in India?**

   Ans: Yes, all In -Vitro Diagnostic kits/reagents are regulated in India under the provisions of the Medical Device Rules, 2017.

2. **Where can we get a copy of the Medical Device Rules, 2017?**

   Ans: The copy of the Medical Device Rules 2017 is available in the CDSCO Website under the link: http://www.cdsco.nic.in/writereaddata/Medical%20Device%20Rule%20gsr78E.pdf

3. **Name and address of the Regulatory Authority that governs the regulations of Import of IVD kits/reagents in India?**

   Ans: The Drugs Controller General (India), Central Drugs Standard Control Organization (CDSCO), *Directorate General of Health Services ,* Ministry of Health and Family Welfare, Government of India , FDA Bhavan, ITO, Kotla Road, New Delhi -110002 Phone: 91-11-23236965 / 23236975, Fax: 91-11-23236973, E-mail:- dci@nic.in.

4. What are the activities regulated by the CLA & SLA with respect to In Vitro diagnostic in India?

Ans.:

Central Licensing Authority	State Licensing Authorities
Enforcement of rules in matters related to: • import of all Classes of IVDs. • Manufacture of Class C and Class D IVDs. • clinical performance evaluation and approval of new in vitro diagnostic. • Registration of Notified Bodies • Registration of Laboratories for carrying out test or evaluation. Test licences for manufacture or import of all classes of IVDs	Enforcement of rules in matters related to: • manufacture for sale or distribution of Class A or Class B IVD • Sale, stock, exhibit or offer for sale or distribution of IVDs of all classes.

5. Which division of CDSCO is responsible for review of IVD kits/reagents ?

Ans: Medical Devices & Diagnostics Division, Central Drugs Standard Control Organization (CDSCO), *Directorate General of Health Services,* Ministry of Health and Family Welfare, Government of India FDA Bhavan, ITO, Kotla Road, New Delhi -110002.

6. What is an In-Vitro Diagnostic (IVD)?

Ans: IVDs are substances intended to be used outside human or animal bodies for the diagnosis of any disease or disorder in human beings or animals covered under sub-clause (i) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 and IVDs that are notified, from time to time, as a device under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940.

7. What is an In –Vivo Diagnostics?

When Diagnosis of disease and disorders are carried out in the body of living human or animal that is done in vivo as opposed to in a laboratory method that does not use the living organism as the host of the test. In vivo is the opposite of in vitro.

These materials are chemical, biological, or radioactive substances used in diagnosing or monitoring the state of human or veterinary health by identifying and measuring normal or abnormal constituents of body fluids or tissues.

For Example : Angio-urographic diagnostic agents, Barium diagnostic agents, Cold kits for labeling with technetium, Contrast media diagnostic products (e.g., iodine and barium)

8. Whether MDR 2017 is also applicable for in vivo diagnostic products?

Ans:

Since in-Vivo Diagnostics are interventional and put into systemic circulation in living bodies, all principles and norms applicable for regulations of chemical, biological and radiological drugs shall also be applicable in such products.

9. How are IVDs classified in India under Medical Device Rules, 2017?

Ans: IVDs are classified under Chapter II, Rule 4, Sub-rule (2) of Medical Device Rules 2017 on the basis of parameters specified in Part II of the First Schedule, in the following classes, namely:—
(i) low risk - Class A;
(ii) low moderate risk- Class B;
(iii) moderate high risk- Class C;
(iv) high risk- Class D.

10. Who will have the responsibility of doing Classification of IVD as per Class A/B/C/D ?

Ans. Reference Rule 4 (3) This rule specifies that Central Licensing Authority shall classify the Medical Devices.

11. Whether on market approved products, in India have to be newly registered as per Medical Device Rules 2017, when the existing license gets expired?

Ans: Yes, IVD products which are currently registered in India have to be registered according to the provisions of Medical Device Rules 2017.

12. Are instruments, equipment and software used with IVDs covered in the scope of medical device rules 2017?

Ans: No. Instruments, equipment and software used with IVDs are not be covered in Medical Device Rules 2017.

13. Which IVD kits/reagents fall under the category of Class A, Class B, Class C, Class D products?

Ans: Please refer to the classification list issued by CLA available at CDSCO website

14. Whether the wholesale license issued under the Drugs and Cosmetics Rules, 1945 will be valid as per the Medical Device Rules 2017.

Ans: Yes.

15. Whether any product, intended for use in determining the presence of host cell protein contamination, in products manufactured by expression in the CHO cell line and other technology for Research and manufacturing use only and is not intended for diagnostic use in humans or animals, are being regulated under the provision of Medical Device Rules 2017?

Ans: No.

16. Whether any product used in determining the presence of histamine, substances , Microbial detection in food & food products, animal feeds, liquor (wine, beer), environmental samples like water & Soil etc. and is not intended for diagnostic use in humans or animals, are being regulated under the provision of Medical Device Rules 2017?

Ans: No.

17. Will products such as RUO – Research Use Only, Q.C material for accreditation, panel for Q.C testing & product used for food, water, sterility testing used by various industry for Q.C etc., and is not intended to be used in human or animals for diagnosis of any disease or disorder, be regulated under MDR, 2017 ?

Ans: No;

18. Will products such as microbiological culture media, stains indicators and reagents used for food and water testing and is not intended to be used in human or animals for diagnosis of any disease or disorder be regulated under MDR, 2017 ?

Ans: No;

19. Whether Empty Specimens collection tubes without needle used for the collection of Blood, Urine, Stool, Sputum, Semen, etc., for purpose of specimens collection are being regulated under the provision of IVD MD Medical device Rules, 2017?

Ans: No

20. Whether IVDs for HBsAg, HIV and HCV approved to manufacture or import by the CLA or SLA, as the case may be, permitted to use for both the purposes; for blood screening and diagnostic.

Ans: Yes. In – Vitro Diagnostic devices for HBsAg, HIV and HCV manufactured / Imported under valid license issued by the CLA or SLA, may also be used in Blood Bank, as the criteria like Sensitivity (%) and Specificity (%) for evaluation of the HBsAg, HIV and HCV diagnostic kits for the Transfusion purpose (Blood Banks) and Diagnostic purpose are same, Provided the manufacturer claims in the product labels or in the IFU that the product is intended both the purposes; for blood screening and diagnostic.

21. Whether all Serodiagnostic test kits are prohibited?

Ans: No**;** only "Serodiagnostic test kits for diagnosis of tuberculosis" are prohibited to Import, Manufacture, Sale, Distribution and Use in the country under Section 10A and Section 26A of the IVD MDs and Cosmetics Act, 1940 Gazette notification(s) GSR432(E) & GSR433(E) dated June 7, 2012.

22. What are considered to be the major changes in Post approval of IVD?

Ans. Reference Sixth Schedule: Changes in labels, manufacturing process, equipment or testing and primary packaging material have been included in the list of major changes which needs prior approval from the competent authority

ADMINISTRATIVE NORMS

23. Can Third party / Authorized Consultant ask the status of the application?

Ans: No, The Regular employee, authorized by the competent person of the applicant company may only ask the status of their application.

24. Who is authorized to make a Technical Presentation, on behalf of applicant, when asked by the CDSCO?

Ans: Only Subject Expert or Technical Person of the company who is equally competent to make technical presentation.

25. How should the documents be notarized?

Ans: The notary should ensure that documents are properly authenticated by either signing the total document set together in a set or each pages in case of a standalone certificate. (Declaration from notary).

26. What is the time limit for submission of Query Response?

Ans: As per CDSCO notice dated 13th July 2016, an application can be disposed off on the basis of merit unless extension is sought within 45 days of raising the query. In case query response couldn't be submitted by the applicant due to some reasonable issue, the applicant shall ask for the extension within 45 days of receiving query.

27. Where can I submit my enquiries related to Import and Manufacture of IVDs?

Ans. All enquiries regarding the submission and approvals can be sent to the Drugs Controller General India (dci@nb.nic.in) - CDSCO, FDA Bhawan, ITO, Kotla Road, New Delhi - 110002. Phone: 91-11-23236965 / 23236975. Fax: 91-11-23236973.

28. What is the method for getting refund of challan amount if any manufacturer does not want to register the product or withdraw their application?

Ans: Need industry inputs for drafting this answer

29. Will post-approval change notification approval require submission of fee?

Ans: No

30. Which will be the Medical Device Testing Laboratory for IVD Medical devices?

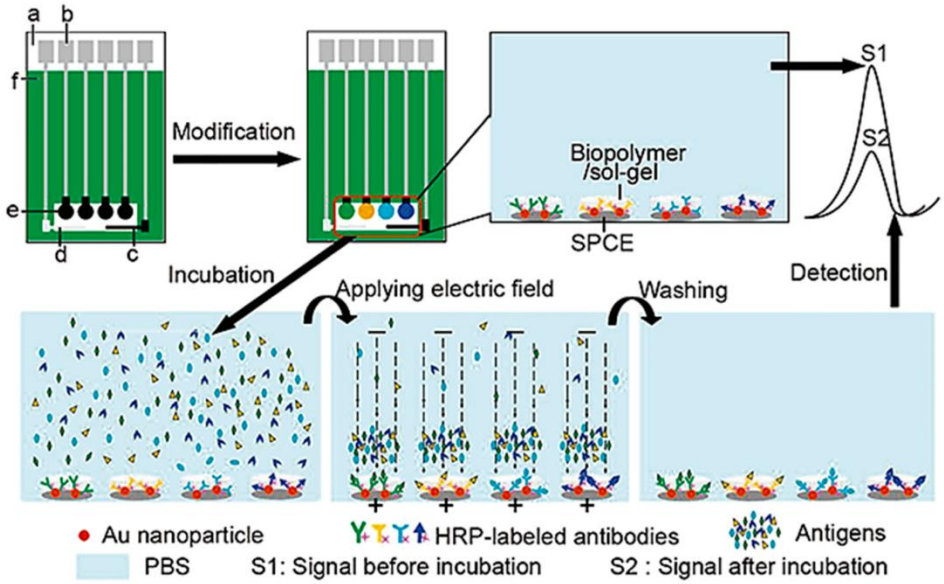
Ans: National Institute of Biologicals, Sec-62 Institutional Area, Noida-201 309 or as notified from time to time.

31. What will be time-period for approval by CLA for implementation of a Major change?

Ans.: 60 days. In case CLA do not indicate approval or rejection within sixty days, such change shall be deemed to have been approved by the licensee.

32. What will be time-period for approval by CLA for implementation of a Minor change?

Ans.: Implementation of minor change do not need prior approval provided licensee inform CLA within a period of thirty days after the change takes place or becomes effective.



IMPORT POLICY

33. What are the requirements for import of Class-A/B/C/D In Vitro Diagnostic Medical device in India?

Ans: For the import of Class A, B, C & D IVDs, applicant have to submit the documents as per Fourth schedule Part I, Part II and Part III (Appendix I & III, only), along with fee as per second schedule. Guidance document on import of IVDs is available on CDSCO website

34. Who can apply for grant of licence to import IVD kits and reagents in to India?

Ans: An authorised agent holding licence to manufacture or wholesale licence under issued under MDR, 2017, may submit an application for grant of import licence for IVD to the Central Licensing Authority.

35. Whether multiple Indian agents are allowed to apply for import licence for same product having same manufacture?

Ans: Yes. All the applicants shall need to submit separate application under MDR, 2017.

36. Whether manufacturing site of IVD will be inspected before grant of Manufacturing License.

Ans: For Indigenous manufacturers of IVDs:

(i) For Class A IVDs, 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 IVDs; and

(ii) For Class B, Class C and Class D IVDs, before grant of the manufacturing licence the audit/inspection of the manufacturing site shall be carried out

37. Whether overseas manufacturing site of IVD will be inspected before grant of import License.

Ans: No. However, if the Central Licensing Authority, believes, as it think fit, may carry out an inspection of the overseas manufacturing site before grant of import licence.

38. In case CLA changes the risk based Classification of any product, after approval under the medical device rules 2017, then the license issued under new Rules will continue to be valid for what period? What will be the transition time period given to the industry to adjust according to the new classification?

Ans: In case CLA changes the classification of any IVD product (eg. from Class B to C), the earlier license shall continue to be valid till the final decision taken on the application by the CLA or SLA, as the case may be. Adequate transition time from the date of such notification will be given to industry to prepare documents according to the new classification

39. In case of such a change in classification, whether applicant needs to do fresh application or only additional documents and fees will be required to be submitted?

Ans: Only additional documents along with the fees (only in case of change from A to C/D or B to C/D) shall be submitted by the applicant to the CLA or SLA, as the case may be.

40. Whether essential principles for safety and performance of IVDs shall be applicable for both importer and indigenous manufacturers?

Yes.

41. Since the nature of the class A products is intended to be used in conjunction with the IVD products (example: washing solutions, buffers etc) no separate EP checklist is generated during the design and development. Can a manufacturer's declaration suffice?

Ans: Only relevant provisions of the essential principles for safety and performance of IVDs shall need to be complied with the manufacturers, with the justification that why other provisions are not applicable.

42. What is the validity of Import License or licence to manufacture for IVD issued under MDR, 2017?

Ans: Import License or licence to manufacture for IVD issued under MDR, 2017 shall continue to be perpetually valid till suspension or cancellation, provided that the licencee shall pay a Licence Retention fee in every five years under the provisions of MDR, 2017.

43. How to register additional Class-A/B/C/D IVD Medical Device in the already approved/valid Import License (MD-15)?

Ans: Licence for additional medical device manufactured at the same manufacturing site and having same legal manufacturer shall be made by the same authorised agent accompanied with only additional product Registration fee as specified in the Second Schedule and respective documents as specified in the Fourth Schedule. (See Rule-36 sub-rule 4)

44. How much fees required to be paid along with the application for grant of import licence for IVDs.

Ans: For each distinct Class-A, Class B, Class C ad Class D IVDs:

Category	Product Fees (USD)	manufacturing site (USD)
Class-A	10	1000
Class-B	10	1000
Class-C	500	3000
Class-D	500	3000

45. How much fees required to be paid along with the application for grant of licence to manufacture of IVDs.

Ans: For each distinct Class-A, Class B, Class C ad Class D IVDs:

Category	Product Fees (INR)	manufacturing site (INR)
Class-A	500	5000

Class-B	500	5000
Class-C	1000	50000
Class-D	1000	50000

46. How to endorse/Add additional IVD kits in the approved/valid Import License of the same manufacturing site?

Ans: The applicant shall endorse/add additional product under a valid import license in MD-15, provided the legal and actual manufacturer are same, by submitting the additional product Registration fee (as per second schedule) and documents mentioned in Fourth schedule (Part I, Part II and Part III (Appendix I & Appendix III, only)) of medical device Rules 2017.

47. Whether IVD kits/reagents, having valid Import License, can be imported from any notified ports of India?

Ans: Yes

48. Whether authorised agent holding valid Import licence is required to stock for any state in the India?

Ans: No. Single license may be issued, in respect of the import of more than one IVD Medical device or a group/class of IVD medical device manufactured by the same legal and actual manufacturer to the Importer through which importer can import the products through any notified port under **Medical Device Rules, 2017.**

49. Is it mandatory for IVD medical devices to be imported into India initially only at the warehouse address that is listed on the medical device import licence?

Ans- No, IVD Medical Devices, having valid Import Licence, can be imported from any notified ports of India and stored and distributed from any registered warehouse. It is not mandatory to initially stock in the warehouse address that is listed in the import license.

50. Whether IVD medical device imported under valid import license can stock in any other wholesale license premises other than stated in the Import License?

Ans: Yes

51. What are all the In-Vitro diagnostic Kits / Reagents need NOC from the other departments for import?

Ans:

a. NOC from department of Animal Husbandry, Dairying and Fisheries (DADF), Government of India, KrishiBhavan, New Delhi in respect of products intended for veterinary purpose
b. NOC from DG, ICMR, New Delhi OR NABL Accredited Lab or govt recognized Agency.
c. NOC from Bhabha Atomic Research Centre (BARC), Mumbai, In case Radio Immuno Assay IVD Kits

52. Whether the applicant has to mention intended use of the proposed product in the product list or Form No. MD-14 during the submission of the applications?

Ans: Yes; applicant has to mention the specific intended use of the proposed product in the product list matching with the Intended Use/Purpose/ claim statement in product insert / brochure/Instructions for use,

53. What is a Central Medical Device Testing Laboratory?

Ans: “Central medical devices testing laboratory” means a medical devices laboratory established or designated by the Central Government under rule 19 and shall be deemed to be a Central Drug Laboratory established for the purpose of section 6 of the Act.

54. How many batches have to be evaluated for the submission of Performance evaluation reports for grant of import license for Class B, class- C & class- D IVDs ?

Ans: The applicant shall submit performance evaluation reports (PER) for three independent batches of IVDs , manufactured by using three different lots of key raw materials (e.g. Antigen, antibody) .

55. When Central Medical Device Testing Labs or Laboratories registered with CLA for carrying out evaluation are unable to conduct the Performance Evaluation, whether PE can be conducted at any other Government Laboratory / hospital of national repute or NABL accredited Labs?

Ans: Yes, provided the reports generated by such Government Laboratory / hospital of national repute or NABL accredited Labs shall meet the specification criteria as per the Guidance Document issued by the CLA.

56. Whether approval / Marketing authorization, issued by the competent Authorities in EU, U.K., Australia, Canada, Japan and USA, will be considered for exemption of Clinical Performance Evaluation (CPE) of New IVDs (Class B, Class C & Class D) in India.

Ans: No. Clinical Performance Evaluation has to be conducted in India for approval of new IVDs, irrespective of it’s regulatory status in these countries.

57. Will clinical performance evaluation be required for grant of permission to manufacture or import any new IVD of Class A ?

Ans: No. Clinical performance evaluation (CPE) may not be necessary, except in cases, where the CLA, considers it necessary depending on the nature of the IVD.

58. What is the criteria for evaluation of Rapid ELISA & CLIA-based (HIV, HBsAg, HCV) Diagnostic kit adopted by NIB, Noida. Whether the same criteria will also be applicable for other medical device testing labs.

Ans:

Analyte	ELISA / CLIA/ ELFA/ ECLIA/ CMIA/MEIA etc.		Rapid Kit	
	Sensitivity	Specificity	Sensitivity	Specificity
Anti-HIV	100%	≥ 98%	100%	≥ 98%
HBsAg	100%	≥ 98%	100%	≥ 98%
HCV	100%	≥ 98%	≥ 99%	≥ 98%

All medical device testing labs shall follow the above specified criteria for Rapid, ELISA & CLIA based HIV, HBsAg & HCV diagnostic kits.

59. What is the sample size required to conduct performance evaluation of IVDs of Class B, Class C & Class D in the designated medical device testing labs ?

Ans: The sample size shall be statistically significant as per the protocol designed and approved by respective MDTL.

60. What are the Minimum criteria for evaluation of IVD Kits/reagents intended for Malaria, TB, Dengue, Chikunguniya, Typhoid, Syphilis and Cancer and other Class B & C IVD kits?

Ans: The IVDs shall comply with the minimum performance criteria (Clinical sensitivity, specificity, repeatability, reproducibility, accuracy, Linearity, Variance etc.) as claimed in the IFU/COA/Product insert issued by the manufacturer.

61. What is the structure, content and format for Performance Evaluation Reports?

Ans:
Typically a Performance Evaluation Report should mention following details:
Product name, lot / Batch number, Date of Manufacture, date of Expiry, manufacturer's name, importer name, number of samples tested, testing principle (ELISA/Rapid/NAAT etc.,) , information about reference used, Testing procedure, Specificity, Sensitivity, Positive predictive value, Negative predictive value, Report number, Date of analysis, designation & Signature of analyst and authorized signatory of the laboratory etc.
Performance indicators for example Sensitivity, Specificity, PPN and NPN, Repeatability, Reproducibility and Accuracy criteria should be accepted as applicable for any specific IVD product with rational.

62. What is the Test license?
Ans: The Test License(s) are for manufacture or import small quantities of IVDs, for the purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training.

63. What are essential documents required for import of IVDs for Test or evaluation, Demonstration or training in MD-17?

Ans: Please refer to the "Guidance document for Grant of Test License available on the CDSCO website. Under Link: _____

64. How much fees for the "Test License" to import for IVD kits/reagents in India?
Ans:

Classification	Fee (USD)
Class-A, class B, Class C & Class D	**100**

65. What is the validity period of "Test License" for IVD kits/reagents in India?
Ans: Test licence shall, unless cancelled earlier, be in force for a period of three years from the date of its issue (refer Rule 41(5) of Medical Device Rules, 2017).

66. Could it be possible to mention multiple sites in a "single" test license application for the purpose of Clinical Investigation, Testing, Evaluation, demonstration and training?

Ans: Yes,

67. What is a 'New IVD?

Ans: "New IVD" means any medical device as referred to in sub-clause (A) of clause (zb) used for in vitro diagnosis that has not been approved for manufacture for sale or for import by the Central Licensing Authority and is being tested to establish its performance for relevant analyte or other parameter related thereto including details of technology and procedure required;

68. What is a predicate device?

Ans: “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;

69. Whether the products which are already approved to import or manufacture for sale in India shall be considered as a predicate device when the application for the same products is made under the Medical Device rules 2017?

Ans: Yes.

70. Whether both legal (If any) and actual manufactures name and address should be stated in the Free Sale Certificate issued by the National Regulatory agency for the purpose of Import of IVDs in India?

Ans: Yes.

71. Any changes in name and/or address of Indian agent/ Importer or change in constitution after issue of import licence are required to be communicated to the Licensing Authority?

Ans: Yes, Indian authorized agent shall inform such change to CLA in writing within a period of forty five days in the event of any change in the constitution of the overseas manufacturer or authorized agent.

72. Any changes in name and/or address of legal and/or actual manufacturer after issue of Import License are required to be communicated to the Licensing Authority?

Ans: Yes, licensee or, authorized agent in India need to take prior approval from licensing authority in case of change in name and/or address of legal and/or actual manufacturer

73. Whether acquisition/merger of one company by another company is considered as change in constitution of the company?

Ans: Change of constitution is defined as:

(i) a firm means change from proprietorship to partnership including Limited Liability Partnership or vice versa;

(ii) (ii)a company means-

(A) its conversion from a private to a public company, or from a public to a private company; or

(B) any change in the ownership of shares of more than fifty per cent. of the voting capital in the body corporate or in case of a body corporate not having a share capital, any change in its membership; and where the managing agent, being a body corporate is a subsidiary of another body corporate, includes a change in the constitution of that other body corporate within the meaning of this clause;

74. What are the changes that require an applicant to make a fresh import license application?

Ans: Fresh import license application shall be made only in case of change of constitution.

75. Is it correct that a major change can be implemented after 60 days in case CDSCO does not respond to the change notification?

Ans: Yes.

76. Whether the Importer who is having valid import license but there is some change in the name of importer or address of Importer still can he imports till another license is granted.

Ans: No.

77. What is the procedure for expanding/ modifying the currently registered indications?

Ans: Expanding or modifying the indications/ intended use are considered as a major change under sixth schedule of Medical Device Rules 2017. This shall require prior approval before the implementation.

78. Whether any major change which is notified to the Regulatory Authority but response from CLA is awaited can be imported in India?

Ans: No. In case response/approval is not received within 60 days from the notification submission, the products undergone a major change shall be allowed for import.

79. What is the time line to notify CLA for a major post approval changes mentioned in sixth schedule?

Ans: All major changes specified in the sixth schedule of Medical device rules 2017, shall need prior approval from CLA to carry out or, implement the change.

80. What are the post approval changes that require as specified in the sixth schedule require prior approval from CLA or SLA?

Ans: For major changes, prior approval is required from CLA or SLA, as the case may be, before implementation and for minor changes the licencee shall notify the CLA or SLA, as the case may be.

81. In case the registered manufacturing site (Actual Manufacturer) remain unchanged (Plant master file to be precise), but Legal manufacturer entity changes to a different entity, whether same Plant Master Files shall be acceptable when submitted towards fresh registration?

Ans: Yes; provided the Plant Master File is updated with consequential changes.

82. Whether authorised agent can submit single application for grant of import licence for same product manufactured at more than one manufacturing sites.

Ans: Yes, provided that the applicant shall submit separate fee for each of the sites. Any subsequent application by the same authorised agent, after the grant of import licence, for endorsement of additional product or additional manufacturing site may also be made under the provisions of MDR, 2017.

83. What are the Labeling requirements for IVD in India?

Ans: Product labels shall comply with the requirements of the Chapter VI of Medical Device Rules, 2017.

84. At the time of submitting applications for Import of IVDs, are original labels as per Rule 44 **to be submitted to the CLA?**

Ans: Specimen Original Labels should be submitted as per Chapter-VI of MDR-2017

85. Can the importers of IVDs stickered for India-specific requirements on labels after/post landing in India at customs warehouse/FTWZ or place approved by the Licensing Authority?

Ans: Yes, provided that the India-specific requirements are spicified in the Chapter VI of MRD, 2017

86. Whether shelf life of the IVDs can be stated on the label instead of date of manufacture?

Ans: No. Both shelf life or expiry date and date of manufacture shall require on the labels.

87. Whether Certificate of Exportability (which reflects that the proposed products may not be freely sold in the country of origin but can be exported), is acceptable as Free Sale Certificate?

Ans: No.

88. Will Free Sale Certificate be acceptable for IVDs manufactured and authorized for sale in countries other than Australia, Canada, Japan, European Union, or the United States of America? If no, what are the additional requirements for the same?

Ans: No. Where a Class C and Class D IVD intend to be imported from countries other than Australia, Canada, Japan, European Union, or the United States of America, the import licence may be granted after its safety and effectiveness has been established through clinical performance evaluation in India. And where a Class A and Class B IVD intend to be imported from countries other than Australia, Canada, Japan, European Union, or the United States of America, the import licence may be granted after its safety and performance has been established through published safety and performance data or through clinical investigation in the country of origin and a free sale certificate from the country of origin is furnished.

89. Can an importer import a IVDs having residual shelf life less than 60 % for non-Commercial or testing purpose?

Ans: Yes, notification # IMPORT/Misc / 2015-DC Dt 1/12/2015 will still be valid for the import of IVDs for testing purpose under a test license under Medical Device Rules 2017. However, the same shall also be applicable for the products imported under a test license for the purpose of demonstration or training.

90. If yes, for the above question, whether the same will be communicated by CLA to all the port offices and Medical Device Testing labs?

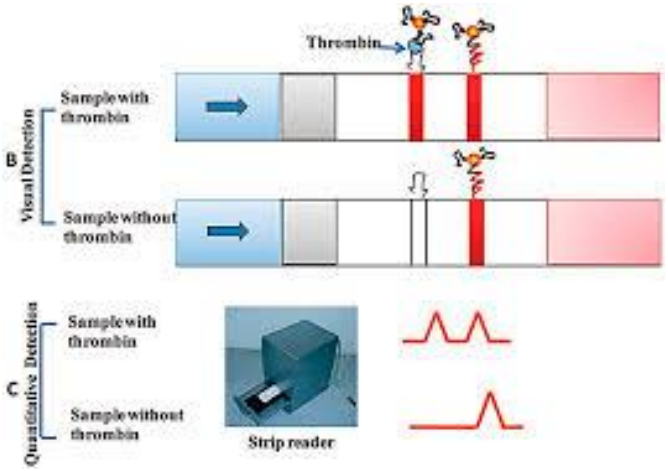
Ans: Yes, CLA shall inform to all port offices and medical device testing labs on permission of import of IVD products using test license, having residual shelf life less than 40%, 50%, 60%, as compared to total shelf life of the product, with reference to Rule 44 of medical device rules 2017.

91. When applying for import license application in MD-14, if three batches are not available with the manufacturer for performance evaluation, whether the applicant can submit the import license application?

Ans: Yes; Import License in Form 14 application can be submitted with one lot report, along-with undertaking of availability of remaining two lots. Import license in Form MD-15 shall be issued by CLA with the condition on submission of performance evaluation reports for remaining 2 lots prior to the sale of the product in Indian market.

92. Whether trader can import bulk products for sale to manufacture.

Ans: Yes, with the undertaking that they will sell bulk product only to the manufacturer for further processing.



MANUFACTURING POLICY

93. Whether NOC from the office of DCGI is required for the approval of manufacturing license from the state licensing authority for the Notified diagnostic kits / reagents and new diagnostic kits / reagents (First in India)?

Ans: Yes, this office is presently issuing NOC for manufacturing of Notified diagnostics kits and New diagnostic kits / reagents (First in India) on the basis of examination of the following documents:- · Detailed manufacturing process.
· Developmental studies.
· Stability data
· Testing protocols for raw materials and finished products
· In- house specification
· Labeling Details
· Evaluation Reports.
· Experts opinion(First in India) etc.

94. Which authority, an Indian Manufacturing company should approach for Licence to manufacture IVDs.

Ans : The manufacturing company shall submit their application to the State Drugs Control authority under whose Jurisdiction, the manufacturing Premises is located. The firm shall submit all relevant technical and administrative documents to the SLA requesting for Licence to manufacture IVDs.

95. Whether any inspection shall be conducted by the regulatory body before grant of licence for IVD manufacturing?

Ans. The State Drugs Control authority shall constitute a joint Inspection team comprising of DIs from his jurisdiction and Dis deputed by CDSCO and notify the manufacturer about the mutually convenient date for inspection. In critical cases, the said joint inspection team should also co-opt one expert of the related Diagnostic field.

96. During the validity period of a manufacturing Licence, how much Inspection shall be warranted?

Ans : One Inspection shall be warranted with a gap of one Year.

97. Does any Start-up entrepreneur need Licence to develop trail IVD products for Lab scale testing only?

Ans: Start up entrepreneur can work to develop IVD products after obtaining NOC from CDSCO (HQ) and Intimating the same to the Concerned State Drugs Controller with a n undertaking that the products developed shall not be diverted by any means to the commercial market / path labs.

98. Whether PER needs to be conducted on the test batches of IVD before introduction in the market? if so How many batch samples to be forwarded and where?

Ans. Yes. The applicant firm shall obtain Licence in Form-29 to develop three or more trial batches of the IVD product. The prescribed number of sample from three consecutive batches of such IVD products should be forwarded to NIB (NOIDA) or other notified Laboratory. The PER should be submitted to both CDSCO and the concerned State Drugs Control Authority.

99. Does the New Rule MDR-2017 mandate the manufacturer to maintain Quality Manual and Plant Master File (PMF) ?

Ans. Yes, as per the Schedule-V ref. Clause 4.2.2 these two are mandated.

100. Where in MDR-2017 the details of PMF are available?

Ans. The contents of Plant Master File have been detailed in appendix - I of Fourth schedule

101. Is there any requirement to maintain IVD master file?

Ans. for each type of IVD there is a requirement to maintain a “IVD Master File”. The Contents of IVD Master File have been detailed in appendix - II of Fourth schedule

102. What is manufacturing under Loan Licence?

Ans. “loan licence” means 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 other licencee for manufacturing the same medical device as manufactured by the licencee at that site. Reference Rule-3(Z).

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Note: Any suggestions with respect to this document may be communicated to this office through e-mail at ddcimd-cdsco@nic.in