# 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:<br>• Import of all Classes of IVDs.<br>• Manufacture of Class C and Class D IVDs.<br>• Clinical performance evaluation and approval of new in vitro diagnostic.<br>• Registration of Notified Bodies<br>• Registration of Laboratories for carrying out test or evaluation.<br>• Test licences for manufacture or import of all classes of IVDs | Enforcement of rules in matters related to:<br>• Manufacture for sale or distribution of Class A or Class B IVD<br>• 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**