

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 (SpO₂), 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/manufacture 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.