Central Drugs Standard Control Organization

(Medical Devices Division)

Medical Devices

Frequently Asked Questions (FAQ)

Doc No.:CDSCO/FAQ/MD/01/2024

Addendum No.: 02

Date: 09.07.2025

Notice:

The replies to the FAQs are aimed only for creating public awareness about 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 from time to time for all their professional needs.

Addendum to FAQ on Medical Devices Rules, 2017

1. **What are the requirements for re-import of medical device in the country?**
   - **The requirement for re-import of the medical device is prescribed in the Guidance document for functions and responsibilities of Zonal, Sub-zonal & Port offices of CDSCO, 2024.**
   - **The decision on the requirement for testing of such consignment at the lab before re-import into the country and its release may be taken by the Port office in consultation with concerned Zonal office of CDSCO/ State Drugs Control office, as appropriate.**

2. **What is the requirement for carrying out outsourced activity (e.g. Coating, Laser Engraving, batch testing, etc) by the manufacturer at an overseas site?**
   - **The manufacturer needs to obtain a No objection certificate (NOC) from the concerned Licensing Authority for carrying out such activity at the overseas premises, by submitting relevant documents viz. copy of manufacturing license, the name and quantity of the medical device to be sent for such activity, copy of the agreement with the overseas firm to carry out such activity, etc.**

3. **Whether change from Partnership firm to LLP firm, or vice versa, is also considered as change in constitution?**
   - **Yes. In such cases the applicant may obtain fresh license under the MDR-2017.**

4. **Whether change from firm to company, as defined in the MDR-2017, or vice versa, is also considered as change in constitution?**
   - **Yes. In such cases the applicant may obtain fresh license under the MDR-2017.**

5. **Whether approval is required from Licensing authority for endorsement/change of competent Technical staff for manufacturing or testing of medical devices under MDR-2017?**
   - **No. The manufacturer shall appoint the competent Technical staff for manufacturing or testing of medical devices as per Rule 22 of MDR-2017.**

6. **Whether the product manufactured in the premises located at Special Economic Zone (SEZ) can be diverted to Domestic Tariff Area (DTA) for sale?**

   - **For import of medical devices in India, an Import license is required to be obtained under Chapter V of Medical Devices Rules, 2017.**
   - **For the medical devices manufactured in the premises located at Special Economic Zone (SEZ) and which need to be diverted to Domestic Tariff Area (DTA) for sale, by the manufacturer, the following procedure should be followed for transfer of the medical device to DTA to ensure that the devices shall meet the quality, safety and performance requirement as per the Drug & Cosmetics Act, 1940 and rules made thereunder:**
     - **In case, the device manufactured in the SEZ, the manufacturer shall comply with the requirement specified under Chapter IV of MDR-2017 for obtaining manufacturing license.**
     - **If the critical component of the medical device which attract medical device definition under the Rule, is imported for manufacturing of Finished Device which is manufactured in SEZ to be diverted to DTA for sale and distribution, the applicant shall comply with the requirement specified under Chapter V of MDR-2017 for obtaining import license for such component.**
     - **Further, the applicant may also refer to the Circular issued by CDSCO vide IMP/141/024-eoffice dated 08.04.2025 in this regard.**

7. **For regulation of medical devices whether the provisions of Drug Rules, 1945 is applicable?**

   - **As per Rule 96 Overriding effect, the provisions of Medical Devices Rules, 2017 shall have effect, notwithstanding anything inconsistent therewith contained in the Drug Rules, 1945.**
   - **However, if any specific provisions under the Drug Rules, 1945 for which there is no provision under the MDR-2017, the same may be applicable for Medical devices also.**

8. **What is the provision for inclusion of additional brand name in the existing license?**

   - **The applicant shall apply separately as per exclusive provision viz. 'Brand approval' made under the Medical Devices Online portal.**

9. **Whether a single use medical device claimed by the manufacturer can be reused?**
   - **No, as such medical device is assessed by the manufacturer for its safety and performance for single use only.**

10. **Can multiple models comprising of different intended use, material of construction, design characteristics, etc may be considered under a same medical device grouping category?**
    - **No, products/models having different intended use, material of construction, design characteristics, etc which are beyond the permissible limits cannot be applied under a single medical device category. The manufacturer has to apply separately for the same.**

11. **Whether the stickering activity is allowed to the importer at the licensed/registered warehouse?**
    - **Yes, in case of import, the license holder may carry out the stickering of India specific information as provided in Rule 44(n) of MDR-2017 on label of medical device.**

12. **Is it mandatory to perform a design qualification test for every batch released for a particular medical device having same material composition, manufacturing process, etc.**
    - **It is not mandatory to perform a full Design Qualification test for every batch, provided, the material of composition of the device and its manufacturing process remain same and the validation of the manufacturing process (such as Process Validation and periodic requalification) is carried out to ensure the product's safety and effectiveness.**
    - **However, if there are significant changes to the design, material composition, or manufacturing process, a requalification or additional testing might be required.**

13. Whether the Standard prescribed under Rule 7 of MDR-2017 is mandatory for medical devices manufactured exclusively for export purpose?

- **The manufacturer of the medical device in India shall obtain manufacturing license under the provisions of Chapter IV of MDR-2017 to manufacture medical devices that meets the standards as prescribed under said rules.**
- **Further, in case of export, the manufacturer may follow the applicable standard as per the requirement of the importing country.**

14. What information needs to be mentioned in the specimen/draft label in case of the import of a medical device for marketing in the country?

- **The specimen label of the imported device shall conform to the requirement as prescribed under Rule 44 of MDR-2017. The label should also provide the specific space for stickering of India specific label in case if it is to be stickered in India.**

15. What information needs to be mentioned in the specimen/draft label in case of the manufacturing of a medical device for marketing in the country ?

- **The specimen label of the device to be manufactured shall conform to the requirement as prescribed under Rule 44 of MDR-2017.**

16. In case of multiple Bharatkosh fee receipts submitted in an application, do all Bharatkosh fee receipts need to be linked with the application?

- **Yes. Each Bharatkosh fee receipts needs to be linked with the application if there are multiple challans so that total fee details shall be freezed with the application on the portal.**

17. What are the requirements of the checklist for obtaining various types of approvals under MDR-2017?

- **The checklist of the various types of application forms for obtaining approvals is available on the website of CDSCO (https://cdsco.gov.in/) / MD online portal (https://cdscomdonline.gov.in/) /NSWS (https://www.nsws.gov.in/).**

18. How to fill in the application form (legal form) while submitting applications for obtaining approval under MDR-2017?

- **For submitting specific information in the application form (legal form) a requisite tooltip has been provided at the applicant end on the portal so that the applicant may be aware on specific information to be filled in the legal form.**

19. Whether Free Sale Certificate from any of the following countries viz. USA, UK, EU, Canada, Japan or Australia is required for obtaining Import license for Class A & Class B ?

- **Yes. However, incase if it is not approved by any of the said authority the applicant may submit published safety and performance data or clinical investigation report generated in the country of origin and a free sale certificate from the country of origin or any other country where the device is being marketed.**

20. Whether Free Sale Certificate from any of the following countries viz. USA, UK, EU, Canada, Japan or Australia is required for obtaining Import license for Class C & Class D ?

- **Yes. However, incase if it is not approved by any of the said authority the applicant may submit clinical investigation report generated in India and a free sale certificate from the country of origin or any other country where the device is being marketed.**

21. Is there any requirement for obtaining test license for testing of a custom-made medical device?

- **No**

22. Whether the devices intended for human beings for its intended purpose, can also be used for veterinary purposes?

- **No. The device intended for veterinary use shall be licensed under the MDR-2017 by the Licensing Authority separately for veterinary purpose.**

23. What is the residual shelf life required for a medical device for its import into the country for marketing?

- **The residual shelf-life of a medical device is prescribed under Rule 47 of Medical Devices Rules, 2017 as under:**

Total shelf life claim of the medical device as per its manufacturer	Residual shelf life of the medical device on the date of import
(a) Less than ninety days	Not Less than 40%
(b) Between ninety days to one year	Not Less than 50%
(c) more than one year	Not Less than 60%

24. What is a custom-made medical device?

- **As per the definition prescribed under Rule 3(r) of MDR-2017, "custom made medical device" means a medical device made specifically in accordance with a written prescription of a registered medical practitioner, specialised in the relevant area, under his responsibility for the sole use of a particular patient, but does not include a mass production of such device.**

25. Whether license is required under MDR-2017 for manufacture/import of Custom-made medical Devices for marketing in the country?

- **The custom-made medical device is exempted for the provisions of Chapter IV and Chapter V of MDR-2017. However, the facility of such devices shall conform to the requirement of the Quality management system and the labelling provisions under the said rule.**

26. Whether Custom-made medical device manufactured/imported in bulk also exempted from the provisions of Chapter IV and Chapter V of MDR-2017?

- **No. Mass produced devices, which only need adoption to meet the specific requirement of a medical practitioner or any other professional user, shall not be considered as custom made device and license is required for such devices for marketing in the country.**

27. Whether the veterinary medical devices can be approved if it is not approved by National regulatory authority of countries viz. USA, UK, EU, Canada, Japan or Australia?

- **Incase if the veterinary medical device is not approved by above authorities, the applicant may submit approval obtained from other competent authority from the said countries for its marketing.**

28. Whether NOC from Department of Animal Husbandry and Dairying (DAHD) is required to be obtained for all medical devices intended for veterinary purpose prior to grant of license?

- **The NOC of DAHD is required only for the veterinary medical devices which does not have predicate device.**

29. What are the documents required to be submitted for obtaining NOC from Central Licensing Authority for import of small quantity of medical devices for donation to a charitable hospital for treatment of patients free of cost by that hospital?

- **The applicant may submit following documents for obtaining NOC from Central Licensing Authority:**
  - **A copy of registration document of Charitable hospital/trust**
  - **Bill of Entry or Bill of Landing/ Commercial Invoice**
  - **Undertaking from charitable hospital stating that the devices will be donated free of cost to the patients.**
  - **Undertaking stating that the Charitable hospital will take the responsibility of any safety issues related to the device to be used on the patient.**

30. What is the requirement for becoming an Indian-authorized agent for the import of medical devices in the country?

- **The Indian-authorized agent shall possess a valid wholesale license obtained in Form 20B and Form 21B under the Drug Rules, 1945 or a Registration Certificate obtained in Form MD-42 under the Medical Devices Rules, 2017 or manufacturing license obtained under Medical Devices Rules, 2017.**

31. Whether the requirement of Quality Management system is applicable in case of Class A (non-sterile and non-measuring) medical devices?

- **For manufacturing of such medical devices, the manufacturing facility shall conform to the requirements of Quality Management system for medical devices.**

32. Whether all gloves are covered under the Medical Devices Rules, 2017?

- **No. Only the Surgical Gloves, Medical Examination gloves and other gloves which are intended for medical purposes, are regulated under the Medical Devices Rules 2017.**

33. Whether import license is required under the Medical Devices Rules, 2017 for import of small quantity of medical devices for donation to a charitable hospital for treatment of patients free of cost by that hospital?

- **No.**
- **In such case, the provisions of Chapter V of MDR-2017 are exempted, the applicant shall obtain No Objection Certificate for such purpose from the Central Licensing Authority.**

34. What is the regulatory requirements for outsourcing sterilization activity of medical devices by the manufacturer under MDR-2017?

- **Please refer to CDSCO Letter no. MED/48/2025-eoffice dated 24.06.2025 published in CDSCO website.**

35. Whether the components/accessories of the Medical device require license under MDR-2017?

- **The 'Component' or 'Accessory' of a parent medical device which attracts the definition of 'medical device' as per S.O. 648 (E) dated 11.02.2020 and which is packed or labelled for the commercial distribution, require license under MDR-2017.**

36. Whether change in the method of sterilization of medical device (eg. from Gamma to ETO sterilization, etc) is considered as a separate device ?

- **Yes. In such cases the applicant need to obtain an endorsement to their license obtained under the MDR-2017.**

37. Whether the intended use of a medical device as mentioned in the CDSCO classification list is to be adhered by the applicant while submitting application for obtaining manufacturing/import license for marketing in the country?

- **No, the intended use of the medical device in the application for manufacturing/import may not be exactly the same as that of the intended use of the device mentioned in the CDSCO classification list. Further the essence of the intended use of the particular device should not deviate from that mentioned in the CDSCO classification list. Otherwise, the risk class of the device may change based on the intended use.**

38. Whether the medical devices manufactured or imported under the Test license in Form MD-13 or Form MD-17 can be used for commercialization in the country?

- **No. The medical devices manufactured or imported under Test license shall shall be used exclusively for purposes of clinical investigations/ test/ evaluation/ demonstration/ training and it shall not be commercialized. The unused quantity may be either exported (incase of import) or destroyed under the intimation to the Central Licensing Authority. Commercialization of devices manufactured/imported under Test license may attract penalty as per the Drugs & Cosmetics Act, 1940.**

39. Whether the risk-class of a medical device, as mentioned in the test license (MD-13/MD-17), can be considered for market authorization of the medical device in the country?

- **No, the risk-class mentioned in the Test license is the proposed risk classification of the applied medical device as applied by the applicant at the stage of development of the product.**
- **The applicant(s) may ensure whether the medical device, for which application is to be submitted for obtaining market authorization, is enlisted in the risk classification lists published by the CLA. In case if the said medical device is not enlisted in the published risk classification lists, they shall seek clarification from the CLA regarding its risk classification**

40. What is the process for obtaining Neural code for medical device under Medical Devices Rules, 2017?

- **The manufacturer who obtained license for medical device for marketing in the country may obtain system auto-generated Neutral code by applying through the Medical devices online portal (https://cdscomdonline.gov.in/) from the Central Licensing Authority.**

41. What is the process of obtaining Market Standing Certificate/ Non-Conviction Certificate for Class C & D medical devices?

- **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.**

42. What are the requirements for registering a testing laboratory under the Medical Devices Rules, 2017 for testing of medical devices on behalf of the manufacturer?

- **The Chapter X of the Medical Devices Rules, 2017 prescribes the procedure for obtaining registration certificate for such Medical Device Testing laboratory. Further the testing facility shall be NABL accredited and conform to the Laboratory Quality Management System as per ISO/IEC 17025.**

43. What is the mode of payment of fees for obtaining license under MDR-2017?

- **The applicant shall pay the fees to concerned Licensing Authority through a challan or by electronic mode as specified under MDR-2017. Further it is advisable that the applicant may upload the receipt of the payment as received after making the payment through challan.**

44. Whether all Beauty care equipments for human use are regulated under Medical Devices Rules, 2017?

- **No, provided, the Beauty care equipment is not intended for any therapeutic purpose, etc or modification of anatomy/physiology of the human body.**

45. Whether Batch release certificate/ Certificate of Analysis of consecutive three batches is required for Software as a Medical Device (SaMD) and Medical equipments?

- **For such devices the applicant may submit final software release certificate/factory release certificate indicating the product meets the applicable specifications, wherever required, along with proper justification with respect to the requirement.**

46. Whether a fresh application for obtaining Registration certificate for Notified body responsible for audit of class A & B devices can be obtained through MD online portal?

- **No. The applicant shall submit an application in Form MD-1 through NSWS only (https://www.nsws.gov.in/).**

47. What is the procedure for waiver of the additional condition mentioned in the permission/license granted for Class C & D medical devices under MDR-2017?

- **The applicant may submit an application through the provision made in the MD online portal.**

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