Central Drugs Standard Control Organization

(Medical Devices Division)

Medical Devices

Frequently Asked Questions (FAQ)

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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 risk classification criteria for medical devices intended to be used on animals?**
   - **Risk parameters for classification devices used in animal are the same as per prescribed under First schedule of MDR-2017 and same risk class as mentioned in the risk classification notice is applicable.**

2. **In case if a Medical Device intended for animal use, is not regulated in the country of origin, not approved by any other stringent regulatory authority and facility not audited for Quality Management System (QMS) as per ISO 13485; what are the documents to be submitted with the import application?**
   - **In such case, the applicant can submit the any other relevant certificates issued by the competent authority, confirming the Quality Management System in the manufacturer premises.**

3. **Whether the Power of Attorney (PoA) signed by the manufacturer and undertaking signed by the authorised agent and thereafter apostille or authenticate together either in country of origin or in India; need to be a single binded/punched document?**
   - **Yes.**

4. **In case of change in Actual manufacturing site name, without change in constitution, whether fresh license is required?**
   - **No, in such case, the firm need to obtain approval from the licensing authority through Post Approval Change.**

5. **For an authorised agent having multiple retail or wholesale license under Drug Rules, 1945 or registration certificate (From MD-42) under MDR-2017, whether address of all such premises licensed/registered for sell or stock for sale or distribute need to be mentioned as authorised agent address in the import license obtained under MDR 2017?**
   - **No.**

6. **Who will be considered as Subsequent importer for import of medical device in the country?**
   - **An authorised agent of the foreign manufacturer who intend to obtain the import license for import of 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.**

7. **Whether the AERB type approval or compliance certificate, is a mandatory requirement prior to obtain license for import or manufacture of ionization radiation medical devices for marketing in the country?**
   - **No. However the applicant shall submit AERB approvals to the licensing authority, prior to use of such device on Indian population.**

8. **Whether an import license is required to be obtained for importing raw materials/components to be used for further manufacturing of finished Single-Use medical devices under a valid manufacturing license issued under the provisions of D&C Act and Rules made thereunder?**
   - **No. However, such raw materials/components need to qualify applicable standards and Quality Management System.**

9. **Whether an import license is required to be obtained for importing components/parts to be used for further manufacturing/assembling of finished Medical Equipment/instrument under a valid manufacturing license issued under the provisions of D&C Act and Rules made thereunder?**
   - **As per the existing practice, in case if such component or part which is to be imported is critical in nature which attracts the definition of medical device and affects the performance or safety characteristics or the intended purpose of the medical device, then import license is required.**

10. **Whether import license required to be obtained for importing unfinished medical devices in bulk for carrying out further manufacturing activity viz. sterilization, labelling and packaging to make finished Medical device under a valid manufacturing license issued under the provisions of D&C Act and Rules made thereunder?**
    - **Yes.**

11. **Whether an Investigational medical device can be imported by any hospital for treatment of patient?**
    - **Only a Government hospital or a statutory medical institution allowed to import small quantity of investigational medical device which is approved in the country of origin, for treatment of a patient suffering from a life threatening disease or disease causing serious permanent disability or disease requiring therapy for unmet medical need. Application in Form MD-18 need to be submitted through Online System for Medical Devices. www.cdscomdonline.gov.in/NewMedDev/ViewDevicePersonal**

12. **Whether the hospital can also import medical devices other than investigational medical devices in Form MD-21 for treatment of patient?**
    - **No.**

13. **Whether the products (eg: clinical mannequin etc) intended to be used for the purpose of education (not for planning or practicing clinical procedures with actual patient data) only by healthcare professionals, academician etc. comes under the purview of MDR-2017?**
    - **No.**

14. **Whether Radiopharmaceutical products are covered under the MDR-2017?**
    - **No. For import/manufacture of radiopharmaceutical products, the applicant may obtain license under Drug Rules,1945 of Drug & Cosmetics Act, 1940.**

15. **In case of only "change in constitution" of the firm, does the manufacturing premises require QMS re-inspection/audit?**
    - **Not required, however the authority may verify if there is any change in the QMS requirement.**

16. **In case of only "Change in constitution" of the Medical Devices Testing Laboratory registered with Central Licensing Authority, does the laboratory need to be re-inspected as per MDR-2017 requirement?**
    - **Not required, however the authority may verify if there is any change in the laboratory QMS requirement.**

17. **In case of change in location of a manufacturing site in India, whether QMS re-inspection/audit is mandatory under MDR-2017?**
    - **Yes.**

18. **Whether products such as laminar flow safety cabinet, industrial sterilizer, microscope, protective coveralls etc. which is intended for non-medical purposes in production unit or testing or R&D of various sectors/industry like food technology, pharmaceutical or biotechnology or chemical or electronic, etc. comes under the purview of MDR-2017?**
    - **No.**

19. **What is the regulatory pathway to be followed for obtaining license for marketing an Investigational medical device (i.e. Device for which predicate device is not available in the country)?**
    - **In such cases the applicant may follow the pathways as under:**
      The applicant may initially obtain Test license in Form MD-13/MD-17 (for purpose of testing or clinical investigation, as the case may be) to manufacture/import test batches for generation of validation data, etc. Thereafter, apply in Form MD-26 along with the requisite fees and documents including clinical evidence data generated on the device to obtain Form MD-27 prior to apply for license to manufacture or import in relevant forms from the concerned licensing authority. In case no clinical data or inadequate

data on safety and performance is generated on the device, the applicant may conduct the study after obtaining permission in Form MD-23 and submit the same for consideration of their application for marketing in the country.

20. What are the extent and conditions of exemption for Custom-made medical devices?

- **Mass produced devices, which only need adaption to meet the specific requirement of a medical practitioner or any other professional user, shall not be considered as Custom-made device.**

  All provisions of Chapter IV and Chapter V of MDR-2017 are exempted, subject to the condition that the device is being specifically made in accordance with a duly qualified medical practitioner's written prescription under his responsibility, in accordance with specific design, characteristics and the same is intended for the sole use of a particular patient and the label contains the words 'Custom made device'. Only change in dimension of devices cannot be considered under custom medical devices.

21. Whether medical devices with different dimensions only are considered as Custom-made device as prescribed by the registered medical practitioner's?

- **No.**

22. Whether clinical investigation permission in Form MD-23 is required for Class A (non-sterile and non-measuring) medical device?

- **No.**

23. How to obtain permission to import small quantity of medical devices for personal use by the patient?

- **The patient or his nominee, may apply in Form MD-20 along with documents and medical prescriptions to the Central licensing authority, through Online System for Medical Devices for obtaining the permission in Form MD-21.**
  www.cdscomdonline.gov.in/NewMedDev/ViewDevicePersonal

24. Whether the import or manufacturing license holder need to submit endorsement application to add model name or model number of an approved device?

- **In cases where the model name or number added is in consonance risk class, intended use and technical characteristics as mentioned in the current device master file, the applicant need to submit Post approval change application for its addition.**

25. What procedure need to follow for approval, if the medical device is licensed as a 'System' as per grouping guideline and license holder intended to include additional model of the said system?

- **In such cases, the applicant may obtain post approval changes in respect of grouping from 'System' to 'Family' and addition of model name/number**

26. How to delete or modify an existing model name or model number of device from the license?

- **The applicant needs to submit an application under Post approval changes for change in model name or model number of the licensed device.**

27. **What is the procedure to be followed by license holder to inform licensing authority on any change or anticipated change in approved medical device or manufacturing site?**
    - **Any changes on the device or site licensed by the licensing authority require submission of post approval change application to concerned licensing authority under the respective category through Online systems for medical devices.**

28. **Whether applicant need to submit fee for change in address of authorized agent without change in constitution as post approval changes under MDR 2017?**
    - **No. The applicant may refer CDSCO notice vide F.No. 29/Misc/03/2020-DC(124) dated 31.08.2020.**

29. **What is the procedure to change registered office address/correspondence address of a licensee in Online System for Medical Devices?**
    - **Applicant may write to IT cell of CDSCO-HQ through CRU (cru.division@cdsco.nic.in) for making changes in registered office address/correspondence address in Online System for Medical Devices.**

30. **Incase of change in constitution of the firm , whether the license holder need to create separate login credential in CDSCO Medical devices online portal to obtain the fresh license?**
    - **Not mandatory, in such cases the license holder may submit a separate request to IT cell, CDSCO for necessary changes in the existing login credential along with relevant documents and updated credentials may be used for submitting fresh application. However, if they wish to create a separate credential for obtaining the fresh license, the existing credentials may be considered deactivated and the same need to be informed to IT cell-registration desk for necessary action to deactivate the credential.**

31. **Whether registered Class A (non-sterile and non-measuring) medical device under MDR-2017, can be imported from any Ports of India?**

- **No. The devices can only be imported through the port notified under the Drug Rules, 1945 from time to time.**

32. **Can the State/UT Licensing Authority who initially referred the application to Notified body for QMS audit and want to transfer the application to other Notified body due to certain reasons?**

- **Yes. The State/UT Licensing Authority can transfer the application file to another Notified body through their concerned Nodal officer to another Notified body for the conduct of QMS audit.**

33. **What is the mode of communication between the State/UT Licensing Authority and the Notified body in the Online System for Medical Devices with respect to QMS audit?**

- **The communication between State/UT Licensing Authority and the Notified body can be made through e-vartalap (communication box) as provided in Online System for Medical Devices.**

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