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. **Whether the manufacturer or importer need to conduct the Biocompatibility test on the all applied products?**
   - **The biocompatibility is required for the devices which comes in direct or indirect contact of human body. The manufacturer shall generate the Biocompatibility data on the applied device as per applicable standard. These tests need to be conducted by the manufacturer as a part of the Material validation initially and shall revalidate if there are any changes to the manufacturer of the material or change in the process or supplier. The Biocompatibility testing of medical devices need to be viewed rationally and shall be tested as per IS/ISO 10993 series of standards.**
   - **However, if the manufacturer is already carried out the Biocompatibility test on the particular category of the devices and subsequently applied for approval of the similar devices which is being manufactured by using the same manufacturing process, same supplier / vendor of raw materials of the particular devices, in such cases the manufacturer may submit the initial biocompatibility data generated on the particular category of the devices along with the justification & biological risk assessment reports of the applied devices for consideration.**
   - **Further, if the material is used for a product with different invasiveness, the additional tests which need to be conducted as per the requirements listed in IS/ISO10993-part 1 standard need to be conducted and validated.**
   - **However, the manufacturer shall perform a fore cause testing based on adverse event reported to the them or based on trending result of the complaints received by them.**

2. **Whether the manufacturer can release the sterile medical device to the market based on parametric release?**
   - **As per Clause 7.5.2.2 of Fifth Schedule of Medical Devices Rules, 2017 which prescribes the requirements of Quality Management System for manufacture, storage, installation and distribution of Medical Devices, the manufacturer shall establish documented procedures for the**

validation of the sterilization process. The sterilization process shall be validated prior to initial use. As per Rule 7 of the Medical Devices Rules, 2017, the manufacturers need to comply with the Bureau of Indian Standards (BIS) and in the absence of BIS standards shall comply with ISO / IEC/ Pharmacopoeial standards. If no standards are available, then validated manufacturers standard shall be used.

- **The BIS has standards for various sterilization validation process viz Ethylene Oxide (IS/ISO 11135), Gamma (IS/ISO 11137-1) and Steam sterilization (IS 17812 (Part 1)/ ISO 17665)**
- **All these standards as a part of routine control and release of sterilized material, allow parametric release. The requirements of the parametric release for each method of sterilization is mentioned in the said standard under routine control and release.**
- **If the manufacturer has validated the sterilization process as per the respective BIS/ISO standards and has plans/records for routine revalidation of sterilization process, then the manufacturer may release the sterilized medical device based on the criteria mentioned in the routine process control requirements of the respective sterilization standards.**

3. **Whether for a Medical device which is supplied in non-sterile state, the expiry/shelf life is mandatory on its label?**

   - **For the Medical Device which is supplied in non-sterile state, the date of expiry/shelf life on the label of such device may not be necessary.**

4. **Whether the validation and QC data of medical device generated by the manufacturer for the medical device which is marketed in the country prior to implementation of the mandatory licensing regime under MDR, 2017 can be considered for grant of manufacturing license in the country?**

   - **Yes, if the data found satisfactory by the Licensing Authority and for such cases test license in Form MD -13 is not mandatory.**

5. **In case of Change of constitution of the company/firm holding the manufacturing license under the MDR-2017, whether fresh license is required?**

   - **Yes. The licensee shall inform to the Licensing Authority about such change within 45 days and submit an application under MDR-2017 within a period of 180 days from the date of such change in constitution.**
   - **In such cases, the existing licence shall be deemed to be valid till such time, a fresh licence is issued or application is rejected by the Licensing Authority.**

6. **In case of Change of constitution of the company/firm holding the import license under the MDR-2017, whether fresh license is required?**
   - **Yes. The licensee shall inform the Central Licensing Authority in writing within a period of 30 days in the event of any change in the constitution of the overseas manufacturer or the authorized agent and submit an application under MDR-2017 within a period of 180 days from the date of such change in constitution.**
   - **In such cases, the existing licence shall be deemed to be valid till such time, the fresh licence is issued or application is rejected by the Central Licensing Authority.**

7. In case of Change of constitution of the company/firm holding the registration certificate under the MDR-2017, whether fresh registration is required?

- **Yes. The registration holder shall inform to the Central Licensing Authority in writing in the event of any change in its constitution and where such change in the constitution takes place, the current registration shall be deemed to be valid for a maximum period of 90 days from the date on which the change took place unless, in the meantime, a fresh approval has been taken from the Central Licensing Authority with the changed constitution.**

8. Whether the applicant can submit a single application for multiple actual manufacturing site for obtaining import license?

- **No. A separate application along with requisite fees and documents need to be submitted.**

9. In case of change in the location of manufacturing site of the manufacturer whether a fresh license is required?

- **Yes. The manufacturer shall obtain fresh manufacturing license under MDR-2017.**

10. What is a 'non-sterile medical device' ?

- **A medical device that is intended by the manufacturer to be supplied in a non-sterile state.**

11. What are the packaging and labelling requirements for a 'non-sterile medical device' if it is intended to be sterilized before use?

- **If such device is intended to be sterilized before it is used, then the device must be packed in a way that:**
  - **(a) The label of such device must clearly indicate that the device is in a 'non-sterile' state.**
  - **(b) ensures that the risk of microbial contamination is minimized.**
  - **(c) is suitable, having regard to the method of sterilization that the**

manufacturer indicates is to be used for the device.

(d) the finished product package shall include Instructions for use which clearly mentions the method of sterilization to be used for the device prior to its end-use/use on the patients.

12. What is a 'sterile medical device' ?

- A medical device that is intended by its manufacturer to be supplied in a sterile state.
- The label of such device must clearly indicate that the device is in a 'sterile' state along with method of sterilization.
- Such device must be designed, produced and sterilized using an appropriate validated method and packed in a way that ensures that the device is sterile when it is supplied, and will remain sterile, until the protective packaging is opened or damaged.

13. Whether wholesale licence in Form 20B/21B under Drug Rules, 1945 or Registration certificate in Form MD-42 under Medical Devices Rules,2017 is mandatory for Class A (non-sterile and non-measuring) medical devices?

- No. Class A (non-sterile and non-measuring) medical devices are exempted from the requirements of Chapter XI (Sale of Medical Devices).

14. What is the regulatory pathway to be followed for obtaining manufacturing/ import license for medical device under MDR-2017?

- The information on the Regulatory pathway to be followed for the Medical Device from its development to commercialization under Medical Devices Rules, 2017 is available in CDSCO website.
  (https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/medical-device/RegulatoryMDR-2017.pdf)

15. Whether the manufacturer of medical device require to obtain ISO 13485:2016 certificate for obtaining manufacturing license under MDR-2017?

- No

16. In case of Import of medical devices, whether Brand name of a medical device owned by an Indian authorized agent can be mentioned on the application for import in Form MD-14?

- **Brand names (which is /registered under the Trade Marks Act, 1999) for a medical device in Form MD-14 need to be present in the Free Sale Certificate (FSC) issued to the legal manufacturer for indicating it is freely sold in the countries viz. Australia, Canada, Japan, European Union Countries, United Kingdom or the United States of America. In case if the Brand name is not mentioned in the FSC, then the Brand name should be mentioned as 'Not Applicable' in the Form MD-14.**

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