Central Drugs Standard Control Organization

(Medical Devices Division)

Medical Devices

Frequently Asked Questions

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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.

Frequently Asked Questions on Medical Devices Rules, 2017

GENERAL

1. **Whether all Medical Devices are regulated under the Medical Devices Rules, 2017?**
   - **Yes, as per the notification S.O. 648 (E) dated 11.02.2020, all Medical Devices are regulated under the Medical Devices Rules, 2017.**

2. **Whether the mandatory registration number obtained for the new category of Medical devices consequent to G.S.R. 102(E) dated 11.02.2020 is still valid?**
   - **No. Consequent to the implementation on the notification G.S.R. 102 (E) dated 11.02.2020, all Medical devices are under the licensing regime (except for Class A (non-sterile and non-measuring) medical devices) and license is required for the import/manufacture of Medical devices in the country. The registration number obtained by the applicant shall not be considered as a regulatory approval for the manufacture/import of devices in the country.**

3. **Where can we get a copy of the Medical Devices Rules, 2017 (MDR-2017) and its amendments?**
   - **The copy of the Medical Devices Rules, 2017 and its amendments are available in the CDSCO Website (www.cdsco.gov.in).**

4. **Whether Medical devices intended by its manufacturer to be used specially for animals are also regulated under Medical Devices Rules, 2017?**
   - **Yes.**

5. **Who is the Central Licensing Authority for Medical Devices in India and its location?**

   - **The Drugs Controller General (India) is the Central Licensing Authority for Medical Devices in India.**
   - **Address:**

     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 are the activities regulated by the Central Licensing Authority (CLA) & State Licensing Authority (SLA) with respect to Medical Devices in India?**

   - **The responsibility of the CLA and SLA under the MDR-2017 are as under:**

Central Licensing Authority	State Licensing Authorities
Enforcement of rules in matters related to: • **Import of all Classes of Medical Devices.** • **Manufacture of Class C and Class D Medical Devices.** • **Clinical Investigation and approval of Medical Device that does not have predicate device.** • **Registration of Notified Bodies** • **Registration of Laboratories for carrying out test or evaluation.** • **Test licences for manufacture or import of all classes of Medical Devices.** • **Risk based classification of medical devices**	**Enforcement of rules in matters related to:** • **Manufacture for sale or distribution of Class A or Class B Medical Devices** • **Sale, stock, exhibit or offer for sale or distribution of Medical Devices of all classes.**

7. **Whether CDSCO provides any consultation system for Start-ups/ Innovators/ Importers/ Manufacturers?**
   - **Yes. The Public Relation Office (PRO) cell is established in CDSCO Head Quarter to address the issue of startups/ innovators/ importers/ manufacturers in the field of Medical devices pertaining to regulatory pathway.**
   - **Link: https://cdsco.gov.in/opencms/opencms/en/PRO/;**
   - **Email ID: startupinnov@cdsco.nic.in**

8. **What is the mode of submission of various applications in MDR-2017 to the Licensing Authority?**
   - **The applicant is required to submit their application through online mode for which specific provision for submission of application is available as under:**
     Website link: www.cdscomdonline.gov.in , www.nsws.gov.in

9. **What are the details of the Plant Master File (PMF) / Site Master File (SMF)?**
   - **The contents of PMF/SMF have been prescribed in Appendix - I of Fourth Schedule of MDR-2017.**

10. **Whether Essential principles for safety and performance of medical devices shall be applicable for all risk class of medical devices?**
    - **Yes**

11. **Can Third party / Authorized Consultant ask the status of the application to the Licensing Authority?**
    - **Only authorized person of the company can ask the status of their application.**

12. **What are the essential documents required for submission to the Licensing Authority under various application forms prescribed under Medical Devices Rules, 2017?**
    - **The essential documents shall be submitted as per the checklist available in the Medical Devices Online portal under Medical Devices Rules, 2017.**

13. **What is the Fee required to be submitted for various applications under Medical Devices Rules, 2017?**

- **The Fee required to be submitted for various applications is prescribed in the Second Schedule of Medical Devices Rules, 2017.**

14. **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?**

- **As per Medical Devices Rules, 2017, there is no provision/ clause for the refund of the fee paid by the applicant.**

15. **Whether a separate fee is required for multiple Brands of a device applied for grant of manufacturing or import licence?**

- **Yes, a separate fee is required to be submitted for each applied Brands of a device as per Second Schedule of MDR-2017.**

16. **Whether the manufacturer may send their devices to private testing laboratory for test or evaluation?**

- **Yes, the manufacturers may send their devices for test or evaluation to the Medical Device Testing Laboratory (MDTL) registered with CDSCO under MDR-2017. A list of the registered MDTL is published on CDSCO website which is dynamic in nature.**

17. **What is the approval procedure for addition of medical devices as an additional product in the existing licence?**

- **An endorsement application along with requisite fees and requisite documents as per Fourth Schedule of MDR-2017 & checklist available in the Medical Devices Online portal.**

18. **What is a License granted for the purpose of Clinical Investigations or Test or Evaluation or Demonstration or Training under MDR-2017?**
    - **Under MDR-2017, the License for Manufacture is issued in Form MD-13 and License for Import is issued in Form MD-17 for the purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training.**

19. **Whether the License granted in Form MD-13/ Form MD-17 for the purpose of Clinical Investigations or Test or Evaluation or Demonstration or Training under MDR-2017 is issued in perpetuity?**
    - **No, the licence is issued with the validity of three years from the date of issue of the license under MDR-2017.**

20. **What is Central Medical Device Testing Laboratory (CMDTL)?**
    - **Central medical devices testing laboratory (CMDTL) means a medical devices testing laboratory established or designated by the Central Government under rule 19 of MDR-2017.**

21. **What is considered as "Change of constitution" of the company under the MDR-2017?**
    - **The Change of constitution is defined under Rule 3(j) of MDR-2017 as under:**
        - **a firm means change from proprietorship to partnership including Limited Liability Partnership or vice versa;**
        - **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;**

22. **In case of Change of constitution of the company whether fresh license is required?**
    - **Yes, the applicant 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.**

23. **Who are the competent body to audit the manufacturing facility of Class A & Class B medical devices in the country?**
    - **Only those Notified body who are registered with the CDSCO are eligible for audit the manufacturing facility of Class A & Class B medical devices in the country.**

24. **Where can we get a list of registered Notified bodies?**
    - **The list of Notified bodies registered with CDSCO is available on the CDSCO website. The list is dynamic in nature.**

25. **If a device is complying with ISO/IEC standards, would it still need to follow BIS standards?**
    - **If the BIS standard is available for the particular medical device, then in such cases, the fulfilment of BIS standard is mandatory. In case, there is no BIS standard available, then other international standards (ISO/IEC) would be applicable.**

26. **In case if there is no BIS/ISO/IEC standard for medical devices then which standard to be followed?**
    - **In such cases, the medical device shall conform to any other pharmacopoeial standards or validated manufacturers standard.**

27. **What is the timeline for carrying out the inspection for Class C & Class D medical devices for grant of manufacturing licence?**

- **For Class C and Class D medical device, the inspection will be carried out by the Medical Device Officers within a period of 60 days from the date of application, provided the data submitted by the applicant is found satisfactory.**

28. **Is it sufficient to provide a single IFU (Instructions for use) for Multi pack of a medical device used by Health Care Professionals?**

- **The medical device when offered for sale as single or multi pack, shall be accompanied by either its IFU (Instructions for use), prescribing information, relevant literature, etc.**

29. **Will e-IFU (electronic Instructions for use) be allowed under the MDR-2017?**

- **Yes.**

30. **Who is responsible for the submission of Post Marketing Surveillance (PMS) data?**

- **It is the responsibility of the licensed holder for the submission of Post Marketing Surveillance (PMS) data to the Licensing Authority.**

31. **What are the Labeling requirements for Medical Devices in India?**

- **Product labels shall comply with the Labelling requirements as prescribed in Chapter VI of Medical Devices Rules, 2017.**

32. **Can the date of manufacture/sterilization/expiry be mentioned as DD/MM/YY or MM/YY?**

- **The date of expiry shall be in terms of the month and the year.**

33. **What is the residual shelf life applicable for Medical Devices?**

- **The Residual shelf life for the medical devices is specified in Rule 47 of MDR-2017.**

34. **What are the documents to be provided to support the Claimed Shelf Life of a Medical Device?**

- **A real-time aging data shall be submitted to support the claimed shelf life. However, if real-time data is not available, accelerated stability data shall be submitted to support the claimed shelf life. Such a provisional claimed shelf life may be approved provided that the manufacturer immediately initiates real-time stability testing to validate the proposed shelf life and the real-time stability data shall be submitted after completion of the study by the manufacturer.**

35. **What are the documents to be provided to get approval for Shelf Life of a medical device beyond 5 years under MDR-2017?**

- **A real-time aging data of the medical device generated by the manufacturer along with the accelerated stability data and other relevant supporting data shall be submitted to support the claimed shelf life beyond 5 years.**

36. **Whether Shelf life is applicable for Medical Equipments/Instruments/Apparatus?**

- **In case of Medical Equipments/Instruments/Apparatus, the date of expiry may not be necessary, however, the applicant may mention use life of such device in the Technical dossier.**

37. **In case the real-time stability study data is not available for the devices at the time of submission of application, whether accelerated stability data can be considered?**

- **The accelerated stability study data can be considered provided the applicant submits the on-going real-time stability study data initiated at the time of accelerated stability study and the detailed real time stability study data shall be submitted after completion of the study to the Licensing authority.**

38. **Whether any change in labeling need to be notified to Licensing Authority?**

- **Yes. The changes in respect of label excluding change in font size, font type, color, label design shall be considered as major change as per Sixth Schedule of MDR-2017.**

39. **Whether GMP compliance and GMP certification is applicable to medical devices as per Medical Devices Rules, 2017?**

- **Under the Medical Devices Rules, 2017, the applicant needs to comply with the requirements of the Quality Management System (QMS) in respect of the manufacturing of Medical devices.**

40. **Whether WHO GMP certificate is issued for medical devices?**

- **No. The WHO GMP certificate is generally issued for drug formulations based on the WHO guidelines. However, for any certificate required for export purpose, the Licensing authority may consider for issuance of necessary certificate for this purpose under MDR-2017.**

41. **Who will issue the certificates like Non-Conviction Certificate, Free Sale Certificate, Market Standing certificate etc. which are required on request of procurement / tendering agencies or for export purpose?**

- **The Licensing Authority who has issued license may issue such certificates.**

42. **What is the validity of Market Standing Certificate issued by the Licensing Authority?**

- **The Market Standing Certificate issued by the Licensing Authority is valid for a period of one year from the date of issuance of the certificate.**

43. **What is the validity of Free Sale Certificate issued by the Licensing Authority?**

- **Free Sale Certificate issued by the Licensing Authority is valid upto the validity of the manufacturing licence.**

44. Is there any provision for issue of GLP certificate in MDR-2017 for testing laboratory?

- **There is no provision in MDR-2017 for issuance of GLP certificate. However, the testing lab shall conform to the requirements of Laboratory Quality Management System (LQMS).**

45. What is the regulatory expectation to ensure quality of components (raw materials which are to be used for further manufacturing of finished medical devices) under the valid licence for manufacturing?

- **As regard to ensuring the quality of components/ raw materials to be used for further manufacturing of finished medical devices, it is required that manufacturer of these components need to qualify product standards and Quality Management System.**

46. What is the Environmental requirements for manufacturing of medical devices?

- **The Environmental requirements for certain category of medical devices are prescribed in Annexure A of the Fifth Schedule of MDR-2017. For other medical devices which are not specified in the Annexure A, the manufacturer shall adhere the applicable standards/norms for such manufacturing activities.**

47. Whether single Test licence can have multiple testing site?

- **Yes. If the applicant intends to send the medical device to different testing centers, they may submit single test license application by mentioning each testing site along with the quantity to be tested at each site.**

48. What is distinct medical device and Medical Device Grouping?

- **For this purpose, the Grouping Guidelines for Medical Devices Applications is published by the Ministry of Health & Family Welfare, Government of India which is available in CDSCO website.**

49. **If an Investigational medical device is approved by the Central Licensing Authority for export purpose only, whether such devices can be considered as a predicate device?**

- **No.**

50. **What information is required to be submitted for the substantial equivalence with respect to the predicate device?**

- **The applicant shall submit a comparative statement/document between applied product and predicate device in respect to the name and address of the manufacturer, intended use, risk class, Material of construction, applicable standards, design characteristics, energy used or delivered, manufacturing and testing process, biocompatibility, performance, safety, effectiveness other characteristics etc (as applicable) as per Rule 51 of MDR-2017.**

51. **Whether the massagers intended for soothing or wellness purpose are regulated under Medical Devices Rules, 2017?**

- **If the massager is intended for soothing or general wellness purpose and not for any therapeutic purpose, then it does not come under the regulation. However, if it is intended for the purpose like therapeutic, alleviation of disease or disorder, etc. are regulated under the provisions of Medical Devices Rules, 2017.**

52. **What is the mode of submission of application for Free Sale Certificate/ Market Standing Certificate/ Non-Conviction Certificate etc. to the Licensing Authority?**

- **The applicant may submit all such applications through Online mode in Medical Devices online portal (www.cdscomdonline.gov.in) to concerned Licensing Authority.**

53. **What is the payment mode for submission of application for the grant of manufacturing license for Class A (other than Class A (Non-sterile and Non-measuring) devices)) and Class B medical devices ?**
    - **The fee as specified in Second Schedule of MDR-2017 is payable to the State Licensing Authority, through a challan or by electronic mode as may be specified by the State Government concerned.**

54. **Whether any exemption on the labeling requirement for Software as a Medical Device (SaMD)/ Standalone software?**
    - **No.**

55. **What is the validity of Import License, Manufacturing License or Registration certificate issued under MDR-2017?**
    - **Import License, Manufacturing License or Registration certificate issued under MDR-2017 shall continue to be perpetually valid till suspension or cancellation, provided that the licencee/registration holder shall pay a Licence/ Registration retention fee in every five years under the provisions of MDR- 2017.**

56. **What is the validity of an Endorsement license?**
    - **The endorsement license issued by the Licensing Authority is valid till the date of validity of its base license.**

57. **Whether all disinfectants are regulated under Medical Devices Rules, 2017?**
    - **Only those disinfectants which are intended for the disinfection of Medical devices are regulated under the Medical Devices Rules, 2017.**

58. **Whether license is required for medical devices that are meant for Research use purposes or quality control testing under Medical Devices Rules, 2017?**
    - **The devices which attracts the definition as per S.O. 648(E) dated 11.02.2020 are regulated under the Medical Devices Rules, 2017 and a license is required under the said rule.**

59. Do we need to get test license for prototype medical devices, that are manufactured /Imported for the purpose of techno-commercial feasibility testing, verification & validation testing?

- **In such cases, the applicant may obtain Test licence in Form MD-13 for manufacturing of test batches or obtain Test licence in Form MD-17 for the import of small quantity of devices under the provisions of Medical Devices Rules, 2017.**

60. What is an 'Accessory' to a Medical Device?

- **An 'Accessory' means a device which attracts the definition of device as per S.O. 648 (E) dated 11.02.2020.**
- **Such accessory shall be intended specifically by its manufacturer to be used together (in combination) with a particular medical device (parent) to enable or assist that medical device (parent) to be used in accordance with its intended use.**

61. What is meant by a component of a Medical device?

- **Component means any raw material, substance, piece, part, software, firmware, labeling, or assembly which is intended to be included as part of the finished, packaged, and labeled device.**

62. What is meant by 'Spare part' of a Medical Device?

- **Spare parts refer to component or part of a medical device, specifically intended to replace an identical or similar integral part or component of a medical device that is defective or worn in order to maintain or restore the function of the medical device without changing its performance or safety characteristics or its intended use and which does not adversely affect the safety and performance of the device.**
- **If such component or part of a medical device, changes the performance or safety characteristics or the intended purpose of the medical device, then it shall be considered to be a medical device and shall meet the requirements laid down the Medical Devices Rules, 2017.**

63. **What are the documents required to be submitted for obtaining license for 'Accessory' to a Medical Device which is to be marketed individually?**
    - **At the time of submission of application, the applicant may follow the Medical Devices Grouping Guideline for requisite fee and submit requisite documents of the main device(s).**

64. **Which accessories or components needs to be listed under the application for manufacturing/import license?**
    - **Accessories or components which are clearly defined in the Device master file as a part of the main device(s) and also in its Instruction for use, are only to be listed under the application for manufacturing/import license.**

65. **Is there any exemptions for requirement of provisions for Medical devices under MDR-2017?**
    - **The Eighth Schedule prescribes the exemptions for certain provisions for Medical devices under MDR-2017.**
    - **The Central Government may, by notification, from time to time, amend or modify the entries in the Eighth Schedule.**

66. **What are the conditions of the License/ permission issued by the Licensing Authority?**
    - **The conditions of the License/ permission issued by the Licensing Authority is mentioned in the respective rules under MDR-2017 and also mentioned in the covering letter issued along with the License/ permission.**

67. **Does Standalone Software require registration/ license?**
    - **Yes. Standalone software which attracts the definition of device as per S.O. 648 (E) dated 11.02.2020 are regulated under the Medical Devices Rules, 2017.**

68. **Whether the software meant for monitoring of fitness, or wellbeing or wellness purpose are regulated?**
    - **Software which attracts the definition of device as per S.O. 648 (E) dated 11.02.2020 are regulated under the Medical Devices Rules, 2017.**

CLASS A (NON-STERILE AND NON-MEASURING) MEDICAL DEVICES

69. Whether Class A (non-sterile and non-measuring) medical devices require license to import or manufacturing under Medical Devices Rules, 2017 for marketing in the country?

- **No. Class A (non-sterile and non-measuring) medical devices are exempted from the requirements of Chapter VI, V, VII, VIII and XI of Medical Devices Rules, 2017.**
- **However, the applicant has to do mandatory registration through Medical Devices Online portal and comply with the labeling requirements prescribed in Chapter VI of MDR-2017 & applicable standards.**

70. Whether any Registration certificate is issued by the licensing authority to the applicant after registration of Class A (non-sterile and non-measuring) medical devices ?

- **A system generated registration number for a Class A (non-sterile and non-measuring) medical device is obtained after furnishing of the requisite information on the Medical Devices online portal.**

71. Whether any fees is required for the obtaining registration number for Class A (non-sterile and non-measuring) medical device?

- **No**

72. How to identify medical device having a measuring function?

- **Any medical device which is intended by the manufacturer to measure quantitatively a physiological or anatomical parameter or measure a quantity or a quantifiable characteristic of energy or of substances (including medicinal products) delivered to or removed from the human body and the result of the measurement is displayed in legal units or other acceptable units of measurement, by the device is considered as a measurable medical device.**

73. Who will issue the Free Sale Certificate/ Non Conviction Certificate/ Market Standing Certificate in respect of Class A (non-sterile and non-measuring) medical device?

- **As the control of Class A medical devices is under the State Licensing Authority, therefore the applicant may approach to the concerned State Licensing Authority for obtaining such certificates.**

CLASSIFICATION OF MEDICAL DEVICES

74. What are the criteria for classification of Medical Devices under Medical Devices Rules, 2017?

- **The parameters for risk based classification for Medical devices are prescribed in Part I of the First Schedule of MDR-2017, as under :—**
  a. **low risk - Class A;**
  b. **low moderate risk- Class B;**
  c. **moderate high risk- Class C;**
  d. **high risk- Class D**

75. What is the process for risk classification of medical devices prior to submission of application to the licensing authority?

- **As per Rule 3 of MDR-2017, the Central Licensing Authority classifies medical devices based on their intended use and other parameters specified in the First Schedule of Medical Devices Rules, 2017.**
- **Risk-based classification list of medical devices are published on the website of the Central Drugs Standard Control Organization (CDSCO). The Central Licensing Authority may, from time to time, make additions or deletions in such list of medical devices or modify the class of any medical device.**
- **CDSCO has already displayed the list of medical devices with risk-classification, which is dynamic in nature.**

76. Which Medical Device fall under the category of Class A, Class B, Class C or Class D?

- **Please refer to the Risk-based classification list issued by Central Licensing Authority available in CDSCO website.**

77. Will a list of products classified into Class A, B, C and D be released by CDSCO or the manufacturer has to classify their devices as per risk factors?

- **Only the Central Licensing Authority under MDR, 2017 is the competent authority to classify the medical devices as per the risk-based parameters specified in the First Schedule of MDR-2017.**

78. In case, if the classification of medical device is not included in risk classification published by Central Licensing Authority, then which class will be followed for such medical device?

- **The applicant may submit separate request to Central Licensing Authority along with the product technical documents (label and IFU), regulatory status of the product / similar product in the other countries to classify the devices and same will be conveyed to the applicant and the existing risk-classification list will be updated accordingly.**

79. Will the risk-based classification be harmonized with the already existing and established global classification systems?

- **Yes.**

MANUFACTURING OF MEDICAL DEVICES

80. Who is the authority for issuance of manufacturing license for medical devices in the country?

- **The applicant may submit the application to the Licensing authority as under:**
  - **For Class A & Class B Medical Devices - approach the State Licensing Authority under whose jurisdiction, the manufacturing premises is located.**
  - **For Class C & Class D Medical Devices - Central Licensing Authority.**

81. Whether manufacturing site of Medical Device will be inspected before grant of Manufacturing License?

- **For Indigenous manufacturers of Medical Devices:**

  (i) For Class A (other than Class A (non-sterile and non-measuring) Medical device) medical device, no audit of the manufacturing site shall be necessary prior to grant of licence or loan licence to manufacture for sale or for distribution; and

  (ii) For Class B, Class C and Class D medical devices, before grant of the manufacturing licence the audit/inspection of the manufacturing site shall be carried out.

82. What is Loan Licence?

- **Loan licence means a licence issued by the State Licensing Authority or the Central Licensing Authority, for manufacturing a medical device by, as the case may be, to a person who intends to utilize the manufacturing site of other licencee for manufacturing the same medical device as manufactured by the licencee at that site.**

83. Will the manufacturer have an option to choose Notified body?

- **No. The Notified body which is registered with the CDSCO for the purpose will be assigned by the concerned State Licensing Authority after review of the online applications.**

84. If Notified body is not having competency to evaluate specific class(es) of devices, what would be the process?

- **In such cases, the notified body shall inform the scope of their audit to the concerned State Licensing Authority inorder to designate the alternate Notified body for the QMS verification.**

85. **In case of submission of application of grant of manufacturing license, whether it is mandatory to submit an undertaking by the manufacturer that their manufacturing facility complies with the provisions of the Fifth schedule of MDR-2017?**

- **Yes, the manufacturer shall submit an undertaking signed stating that their manufacturing site is in compliance with the provisions of the Fifth Schedule of MDR-2017.**

86. **Who approves the Neutral code/ Special code number for export purpose?**

- **The Central Licensing Authority approves the Neutral code/ Special code number for export purpose in respect of all the classes of medical devices.**

87. **If a manufacturer intends to manufacture medical device only for "Export purpose", whether they need to specify the same in the application form?**

- **Yes, the applicant shall mention the term "For Export only" under the Generic name of the medical device in the application form.**

IMPORT OF MEDICAL DEVICES

88. **Whether a license is required for import of Medical device for marketing in India?**

- **Yes, for the import of Medical Devices, the applicant has to obtain import license under MDR-2017 from the Central Licensing Authority. However, for Class A (non-sterile and non-measuring) medical devices, the importer has to fulfil the registration requirements to obtain the registration number.**

89. **What is the procedure to obtain Import license?**

- **The importer shall submit an application in Form MD-14 along with the relevant documents as prescribed in the Fourth schedule (Part I, Part II and Part III (Appendix I & II only)) and requisite fee as per Second schedule of Medical Devices Rules, 2017.**

90. Who can Import a Medical device in the country?

- **Any firm or organization who is holding valid license to manufacture the devices or holding wholesale licence or holding a registration certificate in Form MD-42 for sale or distribution under Medical Devices Rules, 2017.**

91. Who is an "Authorized agent" for import of medical devices in the country?

- **An "Authorized agent" means a person including any firm or organisation who has been appointed by an overseas manufacturer through a power of attorney to undertake import of medical device in India.**

92. What are the changes that require an applicant to obtain a fresh import license?

- **Fresh import license application shall be made (1) in case of change in the constitution of a licensee and (2) in case of the change in the location of the overseas manufacturer or its manufacturing site.**

93. What if the classification of a product being imported is different in IMDRF (GHTF) countries from the classification in India?

- **In such cases, the higher risk class of Medical device may be considered by the Licensing Authority for approval of the devices in the country.**

94. Could there be multiple authorized Indian agent for import of the same product(s) for marketing in the country (i.e. same legal & actual manufacturer)?

- **Yes.**

95. In case of multiple importers for same product, do all the documents related to site and product need to be submitted?

- **The subsequent applicant (new agent) has to submit the documents viz. Form MD-14, Power of Attorney, Free sale certificate, requisite fees, wholesale license/ Form MD-42/ manufacturing license, Label, IFU and copy of import licence issued to earlier authorized agent along with the undertaking from the manufacturer stating that there is no change in the Device master file, Plant master file, under MDR-2017.**

96. **Would there be a provision to list multiple sites for a specific product on an existing license?**

- **If the legal manufacturer, having multiple manufacturing sites for manufacturing of a specific product, that may be endorsed in the existing Import license provided a requisite documents and fee are submitted.**

97. **What is the timeline for grant of Import license in Form MD-15?**

- **As per Medical Devices Rules, 2017, the timeline for grant of Import license is nine months, provided the documents are found satisfactory.**

98. **Whether it is mandatory that the overseas manufacturing site of Medical device will be inspected before grant of import License?**

- **The Central Licensing Authority may carry out an inspection of the overseas manufacturing site before or after grant of the import licence as and when it is required.**

99. **Can Importer affix the India specific details as a sticker on retail pack in India or would the manufacturer be required to do so prior to shipping to India?**

- **Importer can provide the India specific label, by way of stickering, when such details are not already printed on the label of the importer devices, which may include import licence number, name and address of the importer, address of the actual manufacturing premises, etc.**

100. **What fee would be applicable for the manufacturing site, if the importers wish to register devices belonging to multiple risk classes?**

- **As per the second schedule the applicant needs to submit the applicable fee based on the risk class of the devices.**

101. **Is the Quality Management System as prescribed in Fifth Schedule of MDR-2017 applicable for importers?**

- **The importers need to submit Quality certificate conforming to the Quality Management System as per Fourth Schedule of MDR-2017.**

102. What shall be the content of a Power of Attorney that needs to be submitted in the application for grant of Import license?

- **An applicant shall submit Power of Attorney along with the undertaking from authorized agent as specified in the Part I of Fourth Schedule of MDR-2017, duly authenticated in India either by a Magistrate of First Class or by Indian Embassy in the country of origin or by an equivalent authority through apostille, for the grant of Import license.**

103. In which form permission to import small quantities of medical devices for personal use can be obtained?

- **An applicant may apply in Form MD-20 with all requisite documents and permission can be issued by CLA in Form MD-21.**

104. Will change in authorized agent require Fresh Import License?

- **Yes. Change in Indian agent will require Fresh Import License.**

105. Are there any requirements for exporting medical devices already imported into the country under Import license in Form MD-15?

- **If the facility is located in the Special Economic Zone (SEZ) and the firm is export oriented unit, they may export the devices after obtaining necessary permission from the competent authority.**

106. Whether Medical Device, having valid Import License, 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.**

107. Is it mandatory for the importers to stock the imported medical devices only at the warehouse address that is mentioned on the import licence?

- **No, the importer can import the Medical Devices from any notified ports of India and stock for sale and distribution from any their registered warehouse in the country.**

108. 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 of the exporting country for the purpose of Import of medical devices in India?

- **Yes.**

109. 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?

- **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.**

110. Whether fees required for change in address of authorized agent, without change in constitution as Post Approval Change under MDR-2017 ?

- **Please refer to the public notice issued vide F. no. 29/Misc/03/2020-DC (124) dated 31.08.2020 issued in this regard.**

111. 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?

- **No.**

INVESTIGATIONAL MEDICAL DEVICES

112. What is an Investigational medical device?

- **Investigation medical device is a medical device:**
  - **i. which does not have its predicate device; or**
  - **ii. which is licensed and claims for new intended use or new population or new material or major design change, and is being assessed for safety or performance or effectiveness in a clinical investigation.**

113. Can a person or sponsor conduct clinical investigation in respect of Investigational medical device in human participants without obtaining any prior permission from the Central Licensing Authority?

- **No, the person or sponsor shall obtain prior permission from the Central Licensing Authority in Form MD-23 for conduct any clinical investigation in respect of Investigational medical device.**

114. What shall be the content of a Clinical Investigation Plan?

- **The applicant shall submit a Clinical Investigation Plan as prescribed in Table 5 of Seventh Schedule of MDR-2017.**

115. What shall be the content of a Clinical Investigation Report?

- **The applicant shall submit a Clinical Investigation Report as prescribed in Table 10 of Seventh Schedule of MDR-2017.**

116. In case of an Investigational medical device, does subsequent applicant need to obtain Investigational medical device approval?

- **Once an Investigational medical device is approved by the Central Licensing Authority and the product is already marketed in the country, then same can be considered as a predicate device & subsequent applicant may obtain license after complying with the requirements of MDR-2017.**

117. To import a medical device which does not have a predicate device, would the clinical investigation be waived off ?

- **No. However, if such medical device is approved by the regulatory authorities of either the UK or USA or Australia or Canada or Japan and the said device has been marketed for at least two years in that country and if the Central Licensing Authority is satisfied with the data of safety, performance and pharmacovigilance of the device, in such cases the requirement of the Clinical Investigation may be waived off which is decided on case to case basis in consultation with the Subject Expert Committee.**

118. Which Form is required to obtain the Permission for Import or manufacture of Investigational medical device?

- **The applicant shall submit an application in Form MD-26 to obtain the permission in Form MD-27 under MDR-2017.**

119. What documents are required for obtaining permission in Form MD-27 for Medical devices which does not have predicate device?

- **The applicant is required to submit documents as per Part IV of Fourth Schedule of Medical Devices Rules, 2017.**

120. In which Form the License to Import Investigational medical devices by a Government hospital or statutory medical institution for the treatment of patients can be obtained?

- **An application may be submitted in Form MD-18 with all requisite documents and fee as specified in Second Schedule for grant of Import license in Form MD-19 from Central Licensing Authority.**

121. Whether permission in Form MD-23 is required for conduct of academic Clinical study on licensed medical device?

- **No. However, the Ethics Committee approval needs to be obtained before initiation of the study and the data generated during the study shall not be used to furnish to the Central Licensing Authority to manufacture or to import for marketing any investigational medical device in the country.**

122. Whether permission in Form MD-23 is required for conduct of academic Clinical study on Investigational medical device?

- **Yes.**

123. Whether a Permission in Form MD-23 is required for conduct Clinical Investigation on the Medical devices having predicate device?

- **No, the permission for Clinical Investigation study in Form MD-23 is required for medical devices which falls under the definition of Investigational medical device.**

124. Whether permission fee is required for any institute, organisation, hospital run or funded by the Central Government or the State Government, as the case may be, for conduct of clinical investigation?

- **No.**

125. Whether Clinical Investigation can be initiated after a period of one year from the date of grant of permission in Form MD-23?

- **If the study is not initiated by the sponsor within a period of one year from the date of grant of permission, they need to take prior permission in Form MD-23 from the Central Licensing Authority.**

126. What is the frequency for submission of Periodic Safety Update Report (PSUR) to the Central Licensing Authority?

- **The permission holder in Form MD-27 shall submit the Periodic Safety Update Report to the Central Licensing Authority from the date of launch of device in the market and such report shall be submitted every six months for first two years followed by submission of the said report annually for the two more successive years.**

127. Whether the Pilot Clinical Investigation is mandatory for Investigational medical device developed in India?

- **Yes, the Pilot Clinical Investigation data generated may be required to be submitted to the Central Licensing Authority and will be useful for designing of Pivotal study.**

128. Will clinical investigation be required for any Class A Investigational medical device?

- **The Clinical investigation for Class A Investigational medical device may not be required, however, where depending on the nature of the medical device, the Central Licensing Authority, may considers such requirement.**

129. Whether the fee for the grant of permission to import or manufacture a medical device which does not have its predicate device is for distinct product?

- **Yes.**

POST APPROVAL CHANGES

130. What are considered to be the major changes and minor changes in Post approval change application for Medical devices?

- **Certain Major changes and Minor changes are prescribed in the Sixth Schedule of Medical Devices Rules, 2017.**

131. Will post-approval change notification approval require submission of fee?

- **For major changes there may be requirement of fees as per Second Schedule of MDR-2017 however for minor changes no fee is required.**

132. What is the provision for change of Model Number or Accessories in already approved medical device?

- **In such case, the applicant may submit an application under Post approval changes to the Licensing Authority.**

133. Is any documentation required including approval certificate from Country of Origin or any other IMDRF countries to include additional Accessory/component under Post approval category?

- **The applicant may submit the documents as per the checklist for Post approval changes provided in the CDSCO Medical Devices online portal.**

134. If there is any change in the location of the manufacturing site approved under the license, then what would be the procedure?

- **In such cases, the applicant has to inform to the Licensing Authority through Post approval changes (notification), thereafter, necessary approval is required to be obtained from the Licensing Authority as per the requirement.**

135. As software will require updates at certain time over its lifetime, does the importer/manufacturer need to register different versions individually?

- **For any change in the version of the approved software the importer/manufacturer shall submit an application through Post Approval Change in Medical Devices Online portal.**

136. What will be time-period for approval by CLA for implementation of a Major change?

- **In case of manufacturing the timeline is 45 days and for import it is 60 days.**

137. What will be time-period for approval by CLA for implementation of a Minor change?

- **Implementation of minor change do not need prior approval provided licensee inform CLA within a period of 30 days after the change takes place or becomes effective.**

RETENTION OF LICENSE/REGISTRATION CERTIFICATE

138. When the applicant is required to submit retention of their endorsement licence?

- **Once the application for the retention of the base license is submitted by the applicant, they may submit retention application to Licensing Authority for retention of their endorsement license issued under the base license**

139. What is the proof of issuance of retention of license in CDSCO Medical Devices online portal?

- **An acknowledgment email is received from the official email ID of the Licensing Authority. The validity of this retention will be effective from the date of expiry of the original manufacturing/import license.**

140. What is the mode for inclusion of medical device(s) that were deleted/removed by the applicant at the time of submission of their retention application and obtained the retention acknowledgment email copy?

- **In such cases, the applicant may submit subsequent endorsement application to the Licensing authority.**

141. Whether the application for the retention is submitted by the applicant in due timeline, however the application is still under process and the applicant did not receive the acknowledgment of their retention application, then can they continue to market their product in the country?

- **Yes. If the applicant has submitted their Retention application along with the requisite fee, then their license is deemed to be valid and they can market their product in the country.**

142. What are the documents required for the submission of Retention application to the Licensing Authority?

- **The applicant may submit their retention application to the concerned Licensing Authority along with the requisite fee and the documents as per the checklist for retention available on the Medical devices online portal.**

SALE OF MEDICAL DEVICES

143. Whether the wholesale license issued under the Drugs and Cosmetics Rules, 1945 will be applicable for stock and distribution of medical devices under Medical Devices Rules, 2017?

- **Yes.**

144. If the trader/distributor involved only for stock, sale and distribution of medical device only, whether the wholesale license (Form 20B & Form 21B or Form 21C) issued under the Drugs and Cosmetics Rules, 1945 is mandatory?

- **No. If the trader/distributor is involved exclusively for stock, sale and distribution of medical device only, then they are required to obtain Registration certificate in Form MD-42.**

145. Which authority grants the registration certificate in Form MD-42 to sell, stock, exhibit or offer for sale or distribute a medical device ?

- **The concerned State Licensing Authority.**

146. What is the mode of submission of application in Form MD-41 ?

- **The applicant may submit an application in Form MD-41 along with requisite documents and fees as per Second Schedule of MDR-2017 through online mode in the Medical Devices online portal to concerned State Licensing Authority.**

147. What is the timeline for grant of registration certificate in Form MD-42 ?

- **The State Licensing Authority may issue Form MD-42 within ten days from the date the application, provided the data found satisfactory.**

148. What is the validity period of Registration certificate granted in Form MD-42 ?

- **Registration certificate issued by the State Licensing Authority in Form MD-42 is in perpetuity, however, the registration certificate holder shall pay a registration certificate retention fee in every five years under the provisions of MDR- 2017.**

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