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FAQs
Medical Equipment Regulations

An APACMed RA India CoE Initiative

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FREQUENTLY ASKED QUESTIONS (FAQ's)

Medical Equipment Regulations

SECTION -1: MANDATORY REGISTRATION IN PHASE WISE MANNER UNDER THE PROVISIONS OF MEDICAL DEVICES RULES,2017

1. What is the approval timeline for equipment and software registration?

The approval timeline is same as mentioned in MDR 2017, rule 36 i.e 09 months from date of application to CDSCO. In case we are unable to issue the licence on time for those applications which have been filed within 3 months of the implementation date, CDSCO shall allow those member companies whose submitted applications are under review during the transition period continue importing their products beyond 1st Oct 2022 (provided applicant has VRN) until the application has been approved or rejected.

2. In case of Import license for medical devices and IVD's that are regulated first time in the market what would be the requirement?

The requirement of medical devices registration for the first time should have the FSC / CFG from any of the countries i.e US, EU, Japan, Canada and Australia and UK, other regulatory certificates mentioned in MDR and all other requirements for the registration dossier in the Class it falls as per Schedule IV of MDR,2017. Apart from this, VRN issued via SUGAM portal shall be considered as predicate information.

3. What information to be provided under predicate device section?

The applicant shall leverage approvals from any of the countries like EU, US, Japan, Canada, Australia & UK. Along with this import/sales data for India, global Post Market Surveillance data shall be submitted. Apart from this, VRN issued via SUGAM portal shall be considered as predicate information. Any product having registration under GSR 102(E) will be eligible for grand fathering.

4. Whether the products which have obtained registration before 01 Oct 2022, to import or manufacture for sale in India shall be considered as a predicate device when the application for the same products is made as per GSR 102(E) Amendment Medical Device Rules 2020?

Yes, all the medical devices, including IVD instruments, analyzers and software which are issued with registration number shall be considered as the predicate device under the import license regime. However, medical devices and IVD instruments, analyzers, softwares falling under Class A, the requirement of Predicate device shall not be applicable as per the Schedule IV of MDR 2017. Any product having registration under GSR 102(E) will be eligible for grand fathering.

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

   No. Only the initial software version shall be registered by CDSCO. Any change in the software as mentioned in sixth schedule, MDR 2017 need to be notified as post approval change application. CDSCO to consider issuing separate guidance document on Software regulations including change management and applicant will have to follow the respective guidance.

6. **Does Standalone Software require registration/import license?**

   Yes, in case the standalone software is used for patient's results interpretation and falls under the definition of medical device as per MDR,2017

7. **Does software function such as data storage, administrative support, electronic patient record or middle ware (where there is no interpretation of patient results) required registration?**

   No, such software does not require import license. The medical devices utilized under laboratory conditions (Laboratory Information Management System) for electronic transfer, data storage are exempt from registration

8. **Do we need to register software meant for monitoring of fitness, health or wellbeing as medical device under the purview of Medical Device Rule, 2017?**

   Yes

9. **What is the provision for change of model number in already approved accessories, components, and spare parts?**

   Change of model numbers for already registered devices should be done through the post approval process with new model details provided in online portal. Additional dropdown menu for incorporating changes with respect to the accessories, components, spare parts etc will be developed and implemented.

10. **For MD/IVD instruments that are already available in the market, but due to any reason the importer is not importing any new units in India. Under this Scenario do these kinds of instruments are required to be licensed as per MDR under MD-15?**

    No. For any instrument already existing in the market or available with the manufacturer as inventory, the import license will not be required.

11. **Whether equipment / analyzer/accessories/spares/consumables used for Food, beverages, pharmaceuticals sterility testing & life science equipment / software for research purposes or quality control testing are regulated under Medical Devices rules?**

No, equipment's / analyzers /accessories/spares/consumables used for Food, beverages, pharmaceuticals sterility testing & life science equipment's / software's for research purposes or quality control testing are not regulated under Medical Devices rules equipments / analyzers used for Clinical patient's testing are regulated under MDR 2017.

12. Are there any requirements for exporting Instruments /software /analyzers/ accessories already imported into the country vide MDR license?

No, CDSCO does not restrict export of regulated devices and exporters needs to be complying to the requirements of importing countries.

13. Do we need to get test license for prototype medical devices or IVD analyzers and software as medical device prototype, that are manufactured/ imported for the purpose of techno-commercial feasibility testing, verification & validation testing?

The Test License(s) in Form MD-13/ Form MD-17 are for manufacture or import small quantities of IVDs, for the purposes of feasibility testing, verification & validation testing or Evaluation or Demonstration or Training.

SECTION – 2: ACCESSORY; COMPONENT; SPARE PART; CONSUMABLES

14. Are Accessory; component; spare part; consumables used with Analyzers, Instruments covered in the scope of license issued under Medical Devices Rules, 2017?

Yes, accessories, components, spare parts, consumables (Non-reagents or Plastic components) which are the part of medical devices including IVDs shall be under the scope. However, no separate import license shall be required for accessories and components if used along with the parent medical device to support, supplement or augment the performance but can't be utilized standalone to provide any diagnostic or clinical outcome.
All Accessories, spare parts, consumables, components of the Medical devices including IVD equipment shall be captured in the MD-14 under the Accessories and component section. The same shall be annexed as part of MD-15.
Also, to clarify that IVD labelled reagents should be separately applied under MD-14 for the grant of import license in MD-15.

15. Can we import accessories, components, spare parts covered under Medical devices including IVD analyzers separately?

Yes, accessories mentioned in the Licence can be imported along with the main equipment or imported separately. Kindly note to include all accessories, spare parts, consumables, components of the medical devices including IVD equipment in the MD-

14 under the Accessories and component section. The same shall be annexed as part of MD-15.

16. **Can Accessory; component; spare part; consumables having different manufacturing sites, but used in conjunction with a device, be covered under the license issued to parent device?**

Yes. All Accessories, spare parts, consumables, components of medical devices including IVDs shall be captured in the MD-14 of the parent medical device including IVD instruments/analyzers under the Accessories and components section.
The information about the accessories, components etc. shall be incorporated under the executive summary of DMF

17. **Is Chapter VI of MDR, 2017 on labelling of medical devices be applicable for accessories, components, spare parts and consumables that are registered as part of the main system.**

No, only the main system should be labelled as per the provisions of Chapter VI of MDR, 2017.

18. **Is labelling requirement mandatory for such Accessory; component; spare part; consumables covered under the parent device license? e.g mobile phone that is used as a general platform for applications that include mobile medical applications that are medical devices, or an off-the-shelf computer monitor used to display medical data as accessories unless they are specifically intended for use with such medical devices.**

India specific labelling as per clause 44 of MDR 2017 shall only be applicable for parent medical device and not for the accessories, components, spare parts etc.

19. **For an already issued Import license, what is the provision to include additional Accessory; component; spare part; consumables accessories & components under Post approval category?**

The application for post approval change can be made under section- Line extension of additional model number and model name.
There shall be a separate drop-down menu in the post approval change tab to add accessory/component/spare as a post approval option for accessory/component/spare. After review of the list of components, spares and accessories, an Annexure to the already issued licence will be issued for the Accessories/Spares/Components to be annexed to main license. No regulatory certificates, documents or fees are required for these accessory /component/spare.

20. **Is approval certificate from CoO or any other IMDRF countries required to include additional accessory/component/spare to already issued license?**

No. Approval of main device/equipment shall suffice, and no additional regulatory certificates are required.

21. Any documentation required to include additional Accessory; component; spare part; consumables accessories & components under Post approval category?

No. Only list model number of the accessories/components/spare parts and a write up of its use shall be submitted.

22. Standalone/ Accessory; component; spare part; consumables required for service and upkeep of a machine/equipment and not regulated in country of origin as MD/IVD, do they fall under MDR,2017?

No

23. If spare parts, components, and accessories regulated as MD/IVDs are listed in the MD-15, will all provisions of MDR 2017 i.e., safety reporting, post approval changes, etc. be applicable on these products:

Yes, the safety reporting will be required in cases there is Serious Adverse event due to usage of accessories, instruments etc.
Provided that accessories, instruments etc have very short exposure to the patients (translating to minimum safety issues) and to be used for supporting the parent device only, therefore the PAC will be limited to model number change, addition of model number etc only. The other changes like design, specification, label etc will be out of scope.

24. If there are changes in the accessories/component/spare parts model numbers post approval in MD-15, will there be an option to add or remove accessories/component/spare parts?

Yes. This shall be possible under post approval change under section accessories/component/spares.

SECTION 3: REFURBISHED MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS

25. Whether the refurbished MD / IVD instruments/ analyzers and devices are allowed to import in India?

As per the Waste Management rule 2016, any device in the critical care equipment list published by MOHFW are not allowed to be imported into India. Other devices can be imported with a licence from CDSCO.

26. Do refurbished instruments require licence? If yes, what documentation is needed to completed registration?

As of now, a regulatory framework is being framed where in if the refurbishment is done by OEM or its authorized agent, we have proposed it as continuation of life cycle and if it is refurbished by a non-OEM, all documents required for fresh licence as per MDR need to be submitted.

About Asia Pacific Medical Technology Association (APACMed)

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed) is the only regional association to provide a unified voice for the medical technology industry in Asia Pacific, representing both multinational corporations as well as small and medium enterprises, together with several local industry associations across the region. Headquartered in Singapore, APACMed's mission is patient-centric, and we strive to continuously improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia Pacific.

We are committed to working with governments and other stakeholders to facilitate patient access to innovative and life-saving medical technologies, supporting strong and thriving healthcare systems across the region, and promoting a robust and sustainable regional ecosystem that encourages investment, trade and innovation.

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