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Review Article

Registration of Import License for IVD'S In India.

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A B S T R A C T

India is a huge market for medical devices and is constantly increasing last few years. The registration certificate and import license is mandatory for manufacturer of India who wishes to import any medical device in India. Indian Agent authorized by CDSCO is required for registering the medical device in India. Duly filled Form MD-14 is required to be submitted for import license registration and license obtained will be in Form MD-15. The review focuses on the regulations concerned to the registration procedures import for new medical device in India with latest amendments in the regulation concerned.

Keywords: Medical Device, Registration, Import License, Regulation

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INTRODUCTION:

India owning to its large population it attracts the manufacturer all over the world for import as having the capacity to be the world largest market in present scenario. The regulatory body of India which regulates and controls the registrations and regulations for medical devices Central Drug Standard Control Organization (CDSCO). All the actions related to medical device such as imports, manufacturing, sale, distribution and export are governed by Drugs and Cosmetic Act 1940 and Rules 1945. The medical devices are required to be registered in the Indian market for that the information of the device i.e is it the notified device or non-notified device needs to be checked.

In-Vitro Diagnostic Devices

In vitro diagnostic medical devices (IVD) are tests used on biological samples (such as tissues, blood, and urine) to determine the status of a person's health.

How IVDs differ from MDs?

The main difference is in the IVD space where clinical samples used may be excess samples from a clinical investigation or acquired by different clinical investigations.

Types of IVD Devices

- Laboratory based tests.
- Point-of-care tests.

Classification of Medical Devices

Medical devices are classified based on the increasing risk to the patients or the user.

Class A: Low Risk

E.g.: Absorbent cotton wools, surgical dressings, alcohol swabs etc.

Class B: Moderate Risk

E.g.: Thermometer, B.P monitoring device, disinfectants.

Class C: Moderate-High Risk

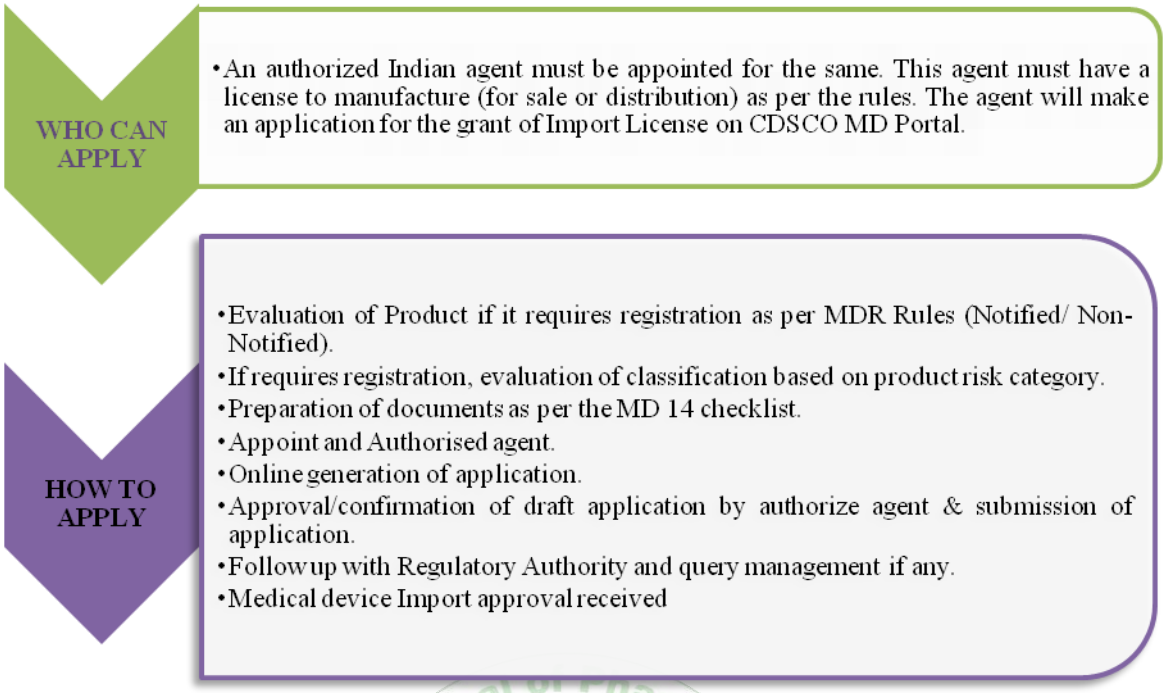
E.g.: Implants, Haemodialysis, Catheters etc.

Class D: High Risk

E.g.: Angiographic guide wire, heart valves etc.

Medical devices coming to Class A and Class B are regulated under State Licensing Authority (SLA), whereas medical devices coming to class C and class D are regulated under Central Licensing Authority (CLA).

Registration for Import License



Documents required for Import License Registration.

- Covering Letter
- Power of Attorney (Original) 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 along with under taking from the authorized agent as specified in Part I of Forth Schedule.
- Self attested copy of valid wholesale license or manufacturing license if any.
- Regulatory certificates with previous import license if any.
- Notarized copies of overseas manufacturing license or establishment or plant registration by whatever name called, in the country of origin issued by competent authority.
- Notarized and valid copy of Free Sale Certificate issued by National Regulatory Authority or equivalent competent authority of the country of origin if any.
- Notarized and valid copy of Free Sale Certificate issued by National Regulatory Authority or equivalent competent authority of the any of the countries namely United States of America, Australia, Canada, Japan and European Union Countries.
- Copy of latest inspection report or audit report carried out by Notified bodies or National Regulatory Authority or Competent Authority within last 3 years, if any.
- Copy of NOC from Department of Animal Husbandry, Ministry of Agriculture, in case of Veterinary IVD Kits.
- Copy of NOC from Bhabha Atomic Research Center (BARC) Mumbai, In case of Radio Immuno Assay Kits.
- Quality Management System certificate in respect of legal and actual manufacturing sites (wherever applicable).
- Notarized and valid copy of Quality Management System Certificate (ISO 13485) certificate issued by the competent authority.
- Notarized and valid copy of Production Quality Assurance certificate or Full Quality Assurance certificate issued by competent authority.
- Notarized and valid copy of CE design certificate issued by competent authority (if any).
- Site or Plant master file as specified in Appendix 1 of Fourth Schedule of MDR 2017.
- Device master file for In-vitro Diagnostic Medical devices as per Appendix –III of Part III of Fourth schedule of Medical devices rules 2017.
- Part 1- Executive summary, Description and specification including variants and accessories and design and manufacturing of the in-vitro diagnostic medical device.
- Part 2- Regulatory status of the similar device in India. (new or approved device).
- Part 3- Essential principles checklist.
- Part 4- Risk analysis and control summary, Product validation and verification and clinical evidences.
- Part 5- Analytical studies , specimen type, analytical performance characteristics, analytical specificity, analytical sensitivity, Metrological traceability of calibrator, control material values, assays.
- Part 6- Claimed shelf life – Stability study report for the three consecutive batches including the protocol, acceptance criteria, testing intervals, conclusion.
- Part 7- Product Insert, Pack size, Label.

- Part 8- Specimen batch test report for at least 3 consecutive batches showing specification of each testing parameter.
- Part 9- Copy of performance evaluation report issued by the central medical device testing laboratory or medical device testing laboratory registered under sub-rule (3) of rule 83 of MDR 2017 for three batches/ Specific evaluation report, if done by any laboratory in India, showing the sensitivity and specificity of the in-vitro diagnostic medical device.
- Part 10-Post Marketing Surveillance dataand any other information of the product.
- Correlation chart with respect to products list mentioned in MD-14 and FSC submitted.
- Testing method, preferably in video.
- Fee Chalan
- Legal Form

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