

# CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

(Medical Devices and Diagnostic Division)

## Frequently Asked Questions on Registration and Import of Medical Devices in India

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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION  
DIRECTORATE GENERAL OF HEALTH SERVICES  
MINISTRY OF HEALTH & FAMILY WELFARE  
GOVT. OF INDIA

**CDSCO**

**Notice:**

*The replies to the FAQs are aimed only for creating public awareness about In-Vitro Diagnostic 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 time to time for all their professional needs.*

## MEDICAL DEVICE REGULATIONS

### 1. What is a medical device in India?

**Ans:** such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.

### 2. Whether medical devices are regulated in India?

**Ans:** Yes, import, manufacture, sale and distribution of medical devices are regulated in India under the provisions of the Drugs & Cosmetic Act 1940 & Rules 1945.

### 3. Where can we get a copy of the Drugs & Cosmetic Act 1940 & Rules 1945?

**Ans:** The copy of the Drugs & Cosmetic Act 1940 & Rules 1945 is available in Link: <http://cdsco.nic.in/Drugs&CosmeticAct.pdf>

### 4. Whether all medical devices are regulated in India?

**Ans:** No, however only notified medical devices are regulated in India. The following medical devices are notified under the Drugs and Cosmetics Act.

<b>Name of the Device</b>	<b>Notification Number</b>	<b>Date of Notification</b>
Disposable Hypodermic Syringes	GSR 365 (E)	17-03-1989
Disposable Hypodermic Needles	GSR 365 (E)	17-03-1989
Disposable Perfusion Sets	GSR 365 (E)	17-03-1989
In-vitro Diagnostic Devices for HIV, HbsAg and HCV	GSR 601(E)	27-08-2002
Cardiac Stents	S.O. 1468 (E)	06-10-2005
Drug Eluting Stents	S.O. 1468 (E)	06-10-2005
Catheters	S.O. 1468 (E)	06-10-2005
Intra Ocular Lenses	S.O. 1468 (E)	06-10-2005
I.V. Cannulae	S.O. 1468 (E)	06-10-2005
Bone Cements	S.O. 1468 (E)	06-10-2005
Heart Valves	S.O. 1468 (E)	06-10-2005
Scalp Vein Set	S.O. 1468 (E)	06-10-2005
Orthopaedic Implants	S.O. 1468 (E)	06-10-2005
Internal Prosthetic Replacements	S.O. 1468 (E)	06-10-2005

**5. Which is the Regulatory Authority that governs the regulations of Import of medical devices in India?**

**Ans:**Drugs Controller General (India), 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 Phone: 91-11-23236965 / 23236975, Fax: 91-11-23236973, E-mail:- [dci@nb.nic.in](mailto:dci@nb.nic.in)

**6. Which division of CDSCO (HQ) is responsible for registration/import of Medical Devices in India?**

**Ans:** Medical Device & Diagnostics Division, 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 is responsible for registration/import of Medical Devices in India.

**7. What are the requirements for import of medical devices in India?**

**Ans:** For the import of medical devices in India, Registration Certificate in Form 41 and Import License in Form 10 are required as per provisions of the Drugs & Cosmetic Act & Rules. For import of medical device, the manufacturing site and products (medical devices) are required to be registered with Indian drug regulatory agency (i.e. Central Drugs Standards Control Organization).

**8. Whether Registration and import license is required for import of non-notified medical device in India?**

**Ans:**No, registration is not required for import of non-notified medical devices in India. However, the following devices are regulated as Drugs under Drugs and Cosmetics Act and Rules, hence registration and import license is required for import in India.

Blood Grouping Sera  
Ligatures, Sutures, Staples  
Intra Uterine Devices (Cu-T)  
Condoms  
Tubal Rings  
Surgical Dressing  
Umbilical Tapes  
Blood / Blood Component Bags

**9. Who can import medical devices into India?**

**Ans:** Any person/firm/enterprise etc. having wholesale license and/or manufacturing license issued under Drugs and Cosmetics Act, 1940 and Rules 1945 can be an applicant for Registration and import of medical devices into India.

**10. To whom shall the application be submitted for Registration/Import License for Medical Device in India?**

**Ans.** Applications for Registration/ Import License of Medical Device shall be submitted to the Drugs Controller General (India), Central Drugs Standard Control Organization (CDSCO), FDA Bhavan, ITO, Kotla Road, Delhi-110002. Phone: 91-11-23236965 / 23236975. Fax: 91-11-23236973.

**11. What is the procedure to apply for the "Registration certificate" in Form-41 for Medical Devices in India?**

**Ans:** Following steps may be adopted for Registration application

**STEP 1.** Pay the required Registration fee through TR-6 Challan (in triplicate) in Bank of Baroda, Kasturba Gandhi Marg, New Delhi.

A fee of one thousand and five hundred US dollars [or its equivalent in Indian rupees] shall be paid along with the application in Form 40 as registration fee for the manufacturing premises meant for manufacturing of medical device intended for import into and use in India.

A fee of one thousand US dollars [or its equivalent in Indian rupees] shall be paid along with the application in Form 40 for the registration of a single medical device meant for import into and use in India and an additional fee at the rate of one thousand US dollars for each additional medical device:

**STEP 2.** Compilation of Registration dossier as per the guidance documents available at the link: [http://cdsco.nic.in/Medical\\_div/guidance.htm](http://cdsco.nic.in/Medical_div/guidance.htm)

**STEP 3.** Submit Product Registration application at CDSCO (HQ), New Delhi

**12. Whether Device manufacturing site required to be inspected before grant of Registration Certificate in Form 41? If yes, how much fees for the inspection or visit of the manufacturing premises of Medical Devices?**

**Ans:** No, however if required the applicant shall be liable for the payment of a fee of five thousand US dollars [or its equivalent in Indian rupees] for expenditure as may be required for inspection or visit of the manufacturing premises.

**13. How the fees shall be paid in India?**

**Ans:** The fees shall be paid through a Challan in the Bank of Baroda, Kasturba Gandhi Marg, New Delhi-110001 or any other branch or branches of Bank of Baroda, or any other bank, as notified, from time to time, by the Central Government, to be credited under the Head of Account 0210-Medical and Public Health, 04-Public Health, 104-Fees and Fines:

Provided that in the case of any direct payment of fees by a manufacturer in the country of origin, the fees shall be paid through Electronic Clearance System (ECS) from any bank in the country of origin to the Bank of Baroda, Kasturba Gandhi Marg, New Delhi, through the Electronic Code of the bank in the Head of Account 0210-Medical and Public Health, 04- Public Health, 104-Fee and Fines+, and the original receipt of the said transfer shall be treated as an equivalent to the bank challan, subject to the approval by the Bank of Baroda that they have received the payment.

**14. Is there any system of prescreening of applications for issue of grant of Registration Certificate/ Import Licence at the time of submission at CDSCO (HQ) New Delhi?**

**Ans:** Yes, application will be prescreened as per checklist available under link: [http://cdsco.nic.in/Medical\\_div/medical\\_device\\_division.htm](http://cdsco.nic.in/Medical_div/medical_device_division.htm)

**15. What is the time period for Grant of Registration Certificate?**

**Ans:** If the application is complete in all respects and informations specified in Schedules D-I and D-II are in order, the licensing authority shall, within nine months from the date of receipt of an application, issue such Registration Certificate in Form 41.

**16. What is the Duration/Validity of "Registration certificate" in Form-41 for Medical Devices in India?**

**Ans:** A Registration Certificate, unless, it is sooner suspended or cancelled, shall be valid for a period of three years from the date of its issue

**17. How to register additional device(s) in the already approved/valid Registration Certificate?**

**Ans.** Importer has to apply for endorsement to the existing Registration Certificate along with the requisite documents provided that the additional device(s) is being manufactured at the same manufacturing site as stated in the Registration Certificate for each additional device 1000 USD is to be paid as a Registration fee. The requirements for endorsement of additional Device(s) to the valid Registration Certificate are remains same to the fresh Registration Certificate except Site Registration Fees (1500 USD) and Plant Master File.

**18. When should an application for Re-Registration of devices be submitted?**

**Ans.** Applications for Re-Registration should be submitted minimum Nine months ahead of the expiry of the registration certificate.

**19. What are the requirements for Re-Registration of devices?**

**Ans.** The requirements for Re-registration of Devices are remains same as fresh Registration requirements except requirement of hard copy of Plant Master File (PMF) and Device Master File (DMF) provided there are no changes in the PMF and DMF, However soft copy of PMF and DMF in the form of compact disc shall be provided along with the application.

**20. Is it possible for an applicant to submit their applications for Registration Certificate (Form 41) and Import License (Form 10) together?**

**Ans.** Yes, an applicant can apply for both Registration Certificate (Form 41) and Import License (Form 10) together, provided Indian agent and importer remain same

**21. How much fees for issuance of duplicate copy of "Registration certificate" in Form-41 for Medical Devices in India?**

**Ans:** A fee of three hundred US dollars [or its equivalent in Indian rupees] shall be paid for a duplicate copy of the Registration Certificate, if the original is defaced, damaged or lost.

**22. What are the requirements for grant of Import license in Form 10 of Medical Devices?**

**Ans.** The requirements for grant of import license in Form 10 are available in the CDSCO web page under link [i.e. http://cdsco.nic.in/Medical div/medical device division.htm](http://cdsco.nic.in/Medical_div/medical_device_division.htm)

**23. What is the Duration/Validity of "Import Licence" in Form-10 for Medical Devices in India?**

**Ans:** Import Licence, unless, it is sooner suspended or cancelled, shall be valid for a period of three years (Till Registration Certificate is valid).

**24. When should an application for renewal of Import Licence be submitted?**

**Ans.** Applications for Import Licence should be submitted along with the application for Re-Registration provided importer and Indian Agent are remain same or minimum three months ahead of the expiry of the Import Licence.

**25. Whether Devices, having valid Import Licence, can be imported from any notified ports of India?**

**Ans.** Yes,

**26. Whether multiple Import Licences are required for devices that are registered under one Registration Certificate by the same Indian Agent/ Importer in case he wants to import from different notified ports?**

**Ans.** No. Single license may be issued, in respect of the import of more than one drug or class of drugs manufactured by the same manufacturer to the Importer through which importer can import the products thorough any notified port under Drugs and Cosmetics Act and Rules.

**27. Whether devices imported under valid import Licence can stocked in any other wholesale licence premises other than stated in the Import Licence?**

**Ans.** Yes

**28. What is the time period for Grant of Import licence?**

**Ans:** If the application is complete in all respects and informations are in order, the licensing authority may within three months from the date of receipt of an application, issue an import licence in Form 10.

**29. Whether Notified Medical Devices can be imported only for demo purpose into India?**

**Ans.** No, there is no provision to import demo samples in India.

**30. What is the Test license in Form 11?**

**Ans:** The Test Licence in Form 11 is to import small quantities of drugs / Medical Devices/ Diagnostic kits, for the purpose of examination, test or analysis provided that Imported Medical Devices under Form 11 shall not be used for any commercial purposes.

**31. What are essential documents required for import of medical device for examination, test and analysis in Form 11?**

**Ans:** The essential documents required for Import of devices under test Licence are available in CDSCO website under Link: [http://cdsco.nic.in/Medical div/medical device division.htm](http://cdsco.nic.in/Medical_div/medical_device_division.htm)

**32. What is the Duration/validity of "Test License" in Form-11?**

**Ans:**A Test License unless, it is sooner suspended or cancelled, shall be valid for a period of one year from the date of its issue

**33. Whether Registration Certificate and Import Licence are required to import components of Medical Devices?**

**Ans.**Yes, Devices in assembled form ready for packaging and sterilization are regulated under the provision of Drugs and Cosmetic Act 1940 and Rules thereunder. Hence Registration Certificate and Import Licence are required to import into India.

**34. Whether both legal (if any) and actual manufacturer name and address should be stated in the Free Sale Certificate issued by the national Regulatory agency for the purpose of registration of devices in India?**

**Ans.**Yes.

**35. Any changes in name and/or address of Indian agent/ Importer or change in constitution after issue of Registration Certificate/ Import Licence are required to be communicated to the Licensing Authority?**

**Ans.**Yes, Indian agent/ Importer shall inform the licensing authority immediately in writing and shall submit fresh application as per Rules.

**36. Any changes in name and/or address of legal and/or actual manufacturer or change in constitution after issue of Registration Certificate/ Import Licence are required to be communicated to the Licensing Authority?**

**Ans.** Yes, the manufacturer or his authorized agent in India shall inform the licensing authority immediately in writing in the event of any change in the constitution of the firm and / or address of the registered office / factory premises operating under this Registration Certificate. Where any such change in the constitution of the firm and/or address takes place, the current Registration Certificate shall be deemed to be valid for a maximum period of three months from the date on which the change has taken place unless, in the meantime, a fresh Registration Certificate has been taken from the licensing authority in the name of the firm with the changed constitution of the firm and/or changed address of the registered office or factory premises

**37. Whether acquisition/merger of one company by another company is considered as change in constitution of the company?**

**Ans.**Yes.

**38. What are the changes that require an applicant to make a fresh Registration?**

**Ans.**The following changes require a fresh registration  
Any change with respect to manufacturer (legal/ actual) like change in constitution, change in name, change in address, etc.  
Any change with respect to importer/ Indian Agent like change in constitution, change in name, etc.

**39. What are the changes which do not require fresh registration and only notification or amendment may be obtained?**

**Ans.** Change in shelf life, change in the method of testing, minor change in manufacturing process not affecting the final product specifications, updation in IFU like warnings, precautions, additional instructions and safety etc., labels and packaging (provided proper justification should be provided for the above changes).

**40. If there is a change in the Indications and/ or Intended use of a registered notified medical device, does the applicant need to submit a fresh application including Power of Attorney incorporating the changed Indications and/ or Intended use of the registered notified medical device?**

**Ans.** Yes, revised Power of Attorney is required to be submitted, reflecting the changes/ modification to indications.

**41. What is the procedure for expanding/ modifying the currently registered indications?**

**Ans.** The process for change notification to CDSCO and approval will be followed in such case. Revised Power of Attorney including the expanded/ modified indication will need to be submitted to the CDSCO.

**42. Whether any minor change which is notified to the Regulatory Authority but CDSCO's response is awaited can be imported in India?**

**Ans.** NO.

**43. What is the time line for response to a change notification?**

**Ans.** 90 working days.

**44. At the time of submitting applications for registration/ re-registration of medical devices, are original labels as per Rule 96 to be submitted to the CDSCO?**

**Ans.** While original labels as per Rule 96 are required however applicants may submit coloured copy of original label incorporating all details as per Rule 96. Labels submitted should include all models for which registration is sought.

**45. What are mandatory addresses on the labels of registered notified medical devices being imported/ marketed in India?**

**Ans.** The label of registered notified medical devices being imported must include the names and addresses of the legal manufacturer, actual manufacturer and the name and address of importer on which the Import License in Form 10 has been issued.

**46. Can the importers of registered notified medical devices incorporate India-specific requirements on labels after/post landing in India at customs warehouse or place approved by the Licensing Authority?**

**Ans.** Yes, importers of registered notified medical devices are currently allowed to incorporate India-specific requirements like name and address of importer, import Licence Number on imported medical devices post landing in India at customs warehouse or place approved by the CDSCO prior to release into market.

**47. Can the Quality Manual as per ISO 13485 be submitted in lieu of the Plant Master File?**

**Ans.** Yes. Provided Quality Manual has same content as prescribed in Plant Master File.



**48. The numbers of employees in the manufacturing premise are required to be included in the Plant Master File? However, there may be a change in this number by the time the Plant Master File is collated and submitted?**

**Ans.** Yes, the number of employees as on the date of preparation of Plant Master File will be considered for the purpose of registration.

**49. 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?**

**Ans.** No

**50. Which manufacturing site is considered the manufacturing premise for the purpose of inclusion in the Form - 40?**

**Ans.** The actual site of final batch release of the medical device is considered the manufacturing premise for the purpose of inclusion in the Form . 40.

**51. If applicant has applied for Registration Certificate and still not issued but in between there is the change has happened in the constitution of either Manufacturer or Indian Agent, address of manufacturer whether fresh fees is required for plant registration and product registration?**

**Ans.** Yes. The applicant has to submit the Fresh application including fee.

**52. If applicant wants to apply for Registration Certificate but the product is not being sold in any of the following countries i.e. USA, Europe, Japan, Health Canada or Australia. Can he apply for Registration Certificate?**

**Ans.** No. However if safety and effectiveness of device is proven by conducting clinical trials in India can apply for registration certificate.

**53. If applicant wants to apply for Registration Certificate but the product is not sold in the country of origin but is registered and marketed in any one of the following countries i.e. USA, Europe, Japan, Health Canada or Australia. Can he apply for Registration Certificate?**

**Ans.** Yes.

**54. What is the generic name of the medical device?**

**Ans.** The generic name is the name as per the internationally accepted nomenclature for the medical device.

**55. What is a “new” medical device?**

**Ans.** A new medical device is one which does not have a predicate medical device registered / approved in India.

**56. What is a “predicate” medical device?**

**Ans.** A predicate medical device is one which is registered / approved in India and has the same indications/ intended use, material of construction and design characteristics as the device which is proposed for registration in India.

**57. How is the process for registration of a “new” medical device different from that of a medical device for which predicates exist?**

**Ans.** Notified medical devices for which predicate devices are not registered in India are classified as “new” medical devices. These medical devices are referred to the Medical Device Advisory Committees (MDAC) to comment on safety, effectiveness, essentiality and desirability of proposed New Devices.

**58. Which are the Specialties for which Medical Device Advisory Committees exist?**

**Ans.** Currently, Medical Device Advisory Committees cover the following specialties . Cardiovascular, Dental, Ophthalmic, Orthopaedic, Reproductive and Urology and a miscellaneous devices committee. Further, the CDSCO has also formulated a “General Expert Pool” for Medical Device Advisory Committee to advise the Drugs Controller General of India in matters related to review and regulatory approval of new medical devices and clinical trials.

**59. Who will issue Form-9 the manufacturer or the Principle Indian Agent?**

**Ans.** Form-9 can be issued by either the manufacturer OR the Principle Indian Agent.

**60. How should the documents be notarized?**

**Ans.** The notary should ensure that documents are properly authenticated by signing each document/page or by providing notarization page (Declaration from notary) having name/number of certificate/documents along with pages eg.

This part includes certificate X (pages), Certificate Y (pages)+etc. and should be intact (Authorized by notary tamper proof) and stapling or pasting not accepted.

**61. What is the time limit for submission of Query Response?**

**Ans.** There is no time limit for submission of Query Response as per the provision of Drugs and Cosmetics Act and Rules, however, it should be reasonable and justifiable.

**62. Can Third party/Authorized Consultant ask the status of the application?**






**Ans.** No. Only either applicant or his authorized Regular employee may ask the status of their application if it is beyond the time limit prescribed under Drugs and Cosmetics Act and Rules.

**63. Who is authorized to make a Technical Presentation, on behalf of applicant, when asked by the CDSCO?**

**Ans.** Only Subject Expert or Technical Person of the company who is equally competent to make technical presentation.

**64. Whether the Importer who is having valid Form-10 license but there is some small change in the name of importer or address of Importer still can he import till another license is granted?**

**Ans.** No, at the time of import, the label of the product should comply with details as specified in the Form-10 for the product.

**65. Can ISO Symbols such as , , , ,  etc. be incorporated on the labels of registered notified medical devices being imported into India?**

**Ans.**Yes, the ISO Symbols are acceptable on labels of registered notified medical devices being imported into India.

**66. Whether shelf life of the device can be stated on the label instead of date of manufacture?**

**Ans.**Yes

**67. What are mandatory addresses on the labels of registered notified medical devices being imported/ marketed in India as per the Drugs and Cosmetics Act, 1940?**

**Ans.**Name and address of Legal Manufacturer, Actual manufacturer and importer as stated in Form-10.

**68. All certificates with minimum 6 months validity are being asked as per guidance document. Can the applicant provide the renewed certificates in case the certificate gets expired during the review process?**

**Ans.**As per the Guidance document for Registration/ Re-registration, all certificates with minimum 6 months validity are to be submitted. However, if the applicant has a valid reason for not being able to submit the same within stipulated validity, they can provide an undertaking to the CDSCO stating that fresh certificates will be submitted immediately after expiry of such certificates and such instances will be dealt on a case to case basis as per rationale of reason.

**69. If my medical device has an adverse event, do I need to report it to CDSCO?**

**Ans.** Yes, To find out more about the adverse event reporting criteria, procedure and timeline, please refer to our website on <http://cdsco.nic.in/pharmacovigilance.htm>

**70. If a recall or corrective action is required for my medical device, do I need to report it to the CDSCO?**

**Ans.**Yes

**71. Can import of the medical device with brand name be done in case the Import License (Form-10) reflecting the product (medical device) with generic name or vice versa?**

**Ans.** No

**72. Can an importer import a registered notified medical device having residual shelf life less than 60 % for Commercial or testing purpose?**

**Ans.** No.

**73. Can one time permission for import of regulated medical device be granted without having valid Import Licence in Form-10?**

**Ans.** No.

**74. What are the regulatory requirements for Import, Manufacture and labeling of Veterinary medical devices?**

**Ans.** Same as devices meant for human beings.

**75. Is there a need to register notified products that are imported and locally processed for 100% export only and which will not be marketed in India?**

**Ans.** No, However the importer shall comply with requirements specified by DGFT from time to time.

**76. Whether local manufacturer needs to obtain an import license for suture raw material that is used 100% for own manufacturing of final finished Sutures for which state FDA has already issued a manufacturing license.**

**Ans.** Yes.

**77. Where can I submit my enquiries related to registration, import and manufacture of medical devices?**

**Ans.** All enquiries regarding the submission and approvals can be sent to the Drugs Controller General India ([dcg@nb.nic.in](mailto:dcg@nb.nic.in)) - CDSCO, FDA Bhawan, ITO, Kotla Road, New Delhi - 110002. Phone: 91-11-23236965 / 23236975. Fax: 91-11-23236973.

