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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

Medical device import licence in India: Form MD-14 and MD-15

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ANYONE IMPORTING A medical device or an in vitro diagnostic (IVD) device for sale in India needs an MD-15 licence from the Central Licensing Authority, whatever its risk class. The one exception is a Class A device that is neither sterile nor measuring. Its importer registers it on the device portal and gets a registration number instead.

KEY FACTS

LAW

Drugs and Cosmetics Act, 1940

DEVICES

Medical Devices Rules, 2017

COSMETICS

Cosmetics Rules, 2020

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Who needs an MD-15 import licence?

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Some guides call MD-14 the licence for Class A and B and MD-15 the one for Class C and D. In fact MD-14 is the application and MD-15 the licence, for every class (Medical Devices Rules, 2017, rules 34(1) and 36(1)). The Central Licensing Authority is the Drugs Controller General (India), who heads the Central Drugs Standard Control Organization (CDSCO). Start with CDSCO and how India regulates drugs, medical devices and cosmetics.

An old registration number from before full licensing isn't an approval (device FAQ, question 2). The Class A route is in medical device registration in India.

Who files the MD-14 application?

The overseas maker's authorized agent in India files Form MD-14 on CDSCO's online device portal. The maker appoints that agent by power of attorney. The agent must already hold a device manufacturing licence, a wholesale drug licence or an MD-42 registration (rules 3(f) and 34(1) of the Medical Devices Rules, 2017).

Choosing and changing the agent are covered in the Indian authorized agent for medical devices.

What does the MD-14 file need?

An MD-14 file holds the maker's power of attorney and the agent's undertaking, the agent's licence, and the overseas site's registration and free sale certificate. It adds the site's quality certificate, any audit report from the last three years, a plant master file and, for Class B to D, a device master file (Fourth Schedule).

- **Power of attorney:** authenticated by a first class magistrate in India, or by the Indian embassy or apostille abroad (device FAQ, question 102). It's bound with the agent's undertaking as one document (addendum 03, question 3).
- **Free sale certificate:** it names both the legal and the actual maker (device FAQ, question 108).
- **One site per application:** each actual manufacturing site needs its own (addendum 01, question 8).
- **Brands:** a brand goes on MD-14 only if the free sale certificate shows it, and each brand carries its own fee (addendum 01, question 16; device FAQ, question 15). A brand added later goes through the portal's brand approval (addendum 02, question 8).
- **Quality certificate:** a notarized quality management system certificate for the manufacturing site (Fourth Schedule, Part II). CDSCO's draft IVD guidance names ISO 13485.

Master file contents (Fourth Schedule, Appendices I to III) aren't covered here. A file built on fake documents is summarily rejected, and the applicant may be debarred (rules 92 and 93).

Do CE, FDA or other approvals count?

CE marks and FDA clearances count through the free sale certificate. With a certificate from the regulator of Australia, Canada, Japan, a European Union country, the United Kingdom or the United States, MD-15 needs no clinical investigation (rule 36(3)). Other countries follow rules 36(4) and 36(5) of the Medical Devices Rules.

What the free sale certificate's country means for MD-15 (rule 36)

Where the free sale certificate is from	Device class	What the rule asks	Rule
Australia, Canada, Japan, a European Union country, the United Kingdom or the United States	Any class	The licence is granted without a clinical investigation	Rule 36(3)
Any other country	Class A (other than non-sterile, non-measuring) and Class B	Published safety and performance data, or a clinical investigation in the country of origin, plus that country's free sale certificate	Rule 36(5)
Any other country	Class C and Class D	A clinical investigation in India (Chapter VII)	Rule 36(4)

A CE mark or an FDA clearance isn't itself the document: the country's regulator or competent authority issues the certificate. A certificate of exportability doesn't count (device FAQ, question 111).

An investigational device, such as one with no predicate in India, needs permission in Form MD-27 before any import licence, and a new IVD needs Form MD-29 (rule 36(6)). Rule 63(1) lets CDSCO waive clinical investigation results for a device approved and marketed two years in the United Kingdom, the United States, Australia, Canada or Japan. G.S.R. 744(E) of August 14, 2026 added European Union countries. More in our summary of G.S.R. 744(E).

Will CDSCO inspect the factory abroad?

CDSCO may inspect the factory. Rule 35 of the Medical Devices Rules lets the Central Licensing Authority inspect the overseas site once an MD-14 application arrives, itself or through a body it delegates. CDSCO's device FAQ says this can happen before or after the licence is granted. The applicant pays a fee for the visit's costs.

The maker agrees to inspection in the power of attorney. If CDSCO doubts a device's quality and sends it for testing, the agent pays the laboratory (rule 34(3)).

How long does a medical device import licence take in India?

Rule 36(1) of the Medical Devices Rules gives the Central Licensing Authority nine months from the date of application to grant MD-15 or reject it with reasons. That's an outer limit, not a promise. CDSCO's January 30, 2026 draft guidance for importing IVDs lists 270 days for MD-14 and thirty days for MD-16. It's still a draft.

Some pages say an import licence officially takes four to six months. No rule sets that; CDSCO's device FAQ repeats nine months (question 97).

A long-pending application waiting on your reply can be closed. Under CDSCO's notice of January 16, 2026, three reminders thirty days apart go out, then a fourth letter rejects the application and the fee is forfeited. Devices and IVDs are covered. More in how CDSCO applications work.

Rejected applicants may appeal to the central government within forty-five days (rule 36(2)).

How long is an MD-15 licence valid?

An MD-15 licence has no end date. Under rule 37 of the Medical Devices Rules, it stays valid until canceled or surrendered while the agent pays the retention fee every five years from issue. The fee is due for each overseas site and each licensed device. A late fee is allowed for ninety days, then the licence is deemed canceled.

Five years, often quoted as MD-15's validity, is only the retention cycle. A retention application filed on time with the fee keeps the licence valid while CDSCO processes it (device FAQ, question 141).

Can more than one importer bring in the same device?

Yes. Several Indian agents may import the same device from the same maker, each with its own MD-15 licence. Since September 11, 2025, a later agent applies through a separate subsequent importer route on CDSCO's device portal. A maker that changes its Indian agent needs a fresh import licence (device FAQ, questions 94 and 104).

The subsequent importer circular and the agent's duties are in our guide to the Indian authorized agent.

What about IVD kits?

IVD kits and reagents are licensed for import like other devices, on MD-14 and MD-15. They use the same four risk classes under their own parameters in Part II of the First Schedule (rule 4(2)). A kit missing from CDSCO's lists is classified through the IVD module on the device portal, open since February 2, 2026.

CDSCO's draft guidance for importing IVDs lists the gaps it finds most often in MD-14 files (section 12.2). Among them:

- A power of attorney that isn't authenticated, or whose addresses or model numbers differ from the application form.
- A free sale certificate naming only the legal maker, not the actual site.
- A quality certificate for the legal maker only, or one whose scope misses the products.
- Accelerated stability data only, or a batch test report for one lot instead of three.

Classes are explained in device classes and licences.

Can you import devices for tests, demos or a patient?

Yes, under separate permissions that never allow sale. A test licence, applied for on Form MD-16 and granted on MD-17, covers testing, evaluation, clinical investigation, demonstration or training. A Government hospital imports for a patient on Form MD-18, and a patient imports for personal use on Form MD-20, with permission on MD-21.

Imports outside an MD-15 licence (rules 40 to 43)

Purpose	Who applies	Forms	Time limit and validity	Conditions
Testing, evaluation, investigation, demonstration or training	The importer	MD-16, granted on MD-17	Decided within 30 days; valid 3 years (rule 41)	Only for that purpose and place; no sale; unused devices exported or destroyed after telling CDSCO (rules 41(2) and 41(6))
Treating a patient with a life-threatening disease, a disease causing serious permanent disability or an unmet medical need	A medical officer of a Government hospital or statutory medical institution	MD-18, granted on MD-19	No time limit in rule 42	A small quantity of an investigational device, approved in its country of origin, for that patient only (rule 42(1) and (3))
Personal use, not carried as baggage	The patient	MD-20, granted on MD-21	Decided within 7 days (rule 43(3))	A small quantity, with a prescription (rule 43(2))

A prescribed device in a passenger's own baggage needs no permit (rule 43(1)). The class on a test licence is only the class proposed, not the class for marketing (addendum 02, question 39).

What happens when imported devices reach the port?

Imported devices may enter only through ports notified under rule 43A of the Drugs Rules, 1945 (device FAQ, question 106). In October 2025, CDSCO asked Customs to send bills of entry on ICEGATE to its port offices and admit drugs, devices and cosmetics only at those ports. Some India-specific label details may be stickered after import.

- **Stickering:** the import licence number, the importer's name and address, the actual site's address and the date of manufacture, where not printed (rule 44(n)).
- **Shelf life left on import:** at least 40% if the total is under ninety days, 50% up to a year, and 60% if longer (rule 47). More in medical device labeling in India.
- **Ports:** the list is in rule 43A of the Drugs Rules, with Navi Mumbai airport added in July 2026. CDSCO's letter of October 7, 2025 maps them to its port offices.

Customs checks CDSCO's device checklists before clearance (CBIC Circular No. 40/2026-Customs). Clearance and duty are in our Customs guide, and whether goods are free to import is in the import policy of the Directorate General of Foreign Trade (DGFT). New CDSCO notices land in our CDSCO tracker.

How IndusDesk helps with a medical device import licence

We work out which rules and class apply to a device. We prepare the MD-14 file, replies to CDSCO and post approval changes for the authorized agent to file, and track retention fees and notices. CDSCO answers status requests only from an authorized person of the company, and it decides every licence.

Regulatory & trade advisory →

Rule exposure audit →

Talk to our desk about a medical device import licence Message us on WhatsApp

Frequently asked questions

Do I renew an MD-15 licence every five years?

No renewal is needed. You pay the licence retention fee every five years, and the licence stays valid while you do (rule 37 of the Medical Devices Rules, 2017).

Can I sticker the import licence number on devices in India?

Yes, where it isn't already printed (rule 44(n); device FAQ, question 99).

Does a CE certificate avoid a clinical investigation in India?

A free sale certificate from an EU country's regulator or competent authority does, under rule 36(3). A device with no predicate in India is the exception: it needs MD-27 permission first (rule 36(6)).

Can I sell devices imported under a test licence?

No. CDSCO says devices under a test licence can't be sold (addendum 02 to the device FAQ, question 38).

Must imported devices be stored at the address on the licence?

No. Any of the importer's registered warehouses will do (device FAQ, question 107).

Sources

- Medical Devices Rules, 2017 (G.S.R. 78(E)), CDSCO's compilation as amended to G.S.R. 777(E) of October 14, 2022: rules 3(f), 4(2), 34 to 37, 40 to 43, 44(n), 47, 63(1), 92 and 93, and the Fourth Schedule, Parts I and II (PDF, 1.6 MB)
- G.S.R. 744(E), August 14, 2026: Medical Devices (Third Amendment) Rules, 2026, paragraph 5 (European Union countries in rule 63) (PDF, 740 KB)

- CDSCO, Medical Devices Frequently Asked Questions (CDSCO/FAQ/MD/01/2024): questions 2, 15, 88, 94, 97 to 99, 102, 104, 106 to 108, 111 and 141 (PDF, 507 KB)
- CDSCO, Addendum 01 to the Medical Devices FAQ, April 3, 2025: questions 8 and 16 (PDF, 363 KB)
- CDSCO, Addendum 02 to the Medical Devices FAQ, July 9, 2025: questions 8, 38 and 39 (PDF, 318 KB)
- CDSCO, Addendum 03 to the Medical Devices FAQ, November 3, 2025: question 3 (PDF, 374 KB)
- CDSCO, draft guidance for import of in vitro diagnostic medical devices (CDSCO/IVD/GD/DRAFT/IMP/01/2026), January 30, 2026: sections 11 and 12.2 (a draft) (PDF, 2.1 MB)
- CDSCO, risk classification of IVD medical devices on the Online System for Medical Devices (IVD-19011(11)/32/2024-eoffice), February 6, 2026 (PDF, 131 KB)
- CDSCO, separate provision for the subsequent importer in the Online System for Medical Devices (MED-13011/16/2025-eoffice), September 15, 2025 (PDF, 477 KB)
- CDSCO public notice IT-11011(11)/1/2026, January 16, 2026: long-pending SUGAM applications awaiting replies (PDF, 96 KB)
- CDSCO letter IMP-12018(19)/13/2025-eoffice, October 7, 2025: mapping of ICEGATE with CDSCO-notified ports (PDF, 2.3 MB)
- Drugs Rules, 1945, rule 43A, CDSCO's compilation as amended by G.S.R. 360(E) of July 1, 2024 (airports it misses: G.S.R. 293(E) of May 28, 2024 and G.S.R. 561(E) of July 2, 2026) (PDF, 7.1 MB)
- CBIC Circular No. 40/2026-Customs, September 3, 2026: checklists for cosmetics, drugs and medical devices (PDF, 3.3 MB)

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