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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

Indian authorized agent for medical devices: what foreign makers need

A foreign maker sells in India through an Indian authorized agent for medical devices, appointed by power of attorney. The agent must hold a device manufacturing licence, a wholesale drug licence or an MD-42 registration. It files Form MD-14 with the Central Drugs Standard Control Organization (CDSCO) and holds the MD-15 licence. A new agent needs a fresh licence.

AN INDIAN authorized agent for medical devices is a person or firm that an overseas maker appoints through a power of attorney to import its device into India (Medical Devices Rules, 2017, rule 3(f)). The agent applies for the import licence, holds it, and answers for the maker's business in India in all respects (Form MD-15, item 4).

KEY FACTS

LAW

Drugs and Cosmetics Act, 1940

DEVICES

Medical Devices Rules, 2017

COSMETICS

Cosmetics Rules, 2020

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What is an Indian authorized agent for medical devices?

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The same rules cover in vitro diagnostic (IVD) devices (rule 2). See our guide to how CDSCO regulates drugs, devices and cosmetics.

Who can be an Indian authorized agent?

Only a person or firm holding one of three licences can be the agent (rule 34(1)). It needs a licence to make devices for sale, a wholesale drug licence in Forms 20B and 21B, or a Form MD-42 registration to sell devices (CDSCO device FAQ, addendum 02, question 30). A foreign maker with no Indian entity holds none.

Your Indian subsidiary can be the agent only if it holds one of these licences. Setting it up, under company law and India's foreign investment rules, is outside this guide. The application itself is on our guide to the medical device import licence.

What must the power of attorney contain, and how is it authenticated?

The power of attorney follows the format in Part I of the Fourth Schedule to the Medical Devices Rules, 2017. A first class magistrate in India, the Indian embassy or an apostille authenticates it (CDSCO device FAQ, question 102). The agent's undertaking is bound in as one document (addendum 03, question 3).

In the Fourth Schedule format, the maker states:

- its signatory, and its own and each factory's address
- the agent's name and address as on its licence or registration
- each device, with model, intended use, shelf life, sterility and class
- that CDSCO may inspect the factory and take samples
- that the agent stays responsible for any violation involving devices it imported, even after the power of attorney is withdrawn

The free sale certificate must name both the legal and the actual maker (question 108). CDSCO's draft guidance for IVD imports of January 30, 2026 lists common gaps (section 12). They include a missing undertaking, no authentication, and addresses or models that don't match the other documents.

Who holds the licence, and what does that mean for you?

The Indian agent holds the MD-15 import licence, not the overseas maker. Form MD-15 licenses the agent to import devices from the factories it lists. The agent pays the retention fee every five years and reports changes and actions abroad to CDSCO (rules 37 and 38). The licence has no end date while the fee is paid.

What the MD-15 holder must do (Medical Devices Rules, 2017)

Duty	Time limit	Rule
Pay the retention fee	Every five years; ninety days' grace with a late fee, then deemed canceled	Rule 37

Report a recall or other action abroad	Within fifteen days; stop dispatch at once	Rule 38(1)(ii), (iii)
Get approval for a major change	CDSCO answers within sixty days, or it is deemed approved	Rule 38(1)(v), (vi)
Report a minor change	Within thirty days	Rule 38(1)(vii)
Report a change in constitution of the maker or agent	Within thirty days, in writing	Rule 38(1)(viii)

CDSCO's 2024 device FAQ says forty-five days for a change in constitution (question 109). Rule 38(1)(viii) and its 2025 addendum 01 (question 6) say thirty, and the rule governs.

Can more than one Indian company import your device?

Yes. CDSCO allows several authorized agents to import the same device from the same legal and actual maker (CDSCO device FAQ, question 94). Since September 11, 2025, a later agent applies through a separate subsequent importer route on CDSCO's device portal, for devices CDSCO has already approved. Each agent applies for its own licence.

CDSCO's notices are on our CDSCO tracker.

What happens when you change the agent or your company changes?

A new Indian agent needs a fresh import licence, CDSCO says (CDSCO device FAQ, question 104). A change in the constitution of the maker or the agent needs a fresh application within 180 days, and the old licence holds meanwhile (rule 39). A new factory location needs a fresh licence too.

What follows each change

The change	What follows	Source
A new Indian agent	A fresh import licence	FAQ question 104

The maker that signed the power of attorney changes its constitution	Notice within thirty days; a fresh application within 180 days	Rules 38(1)(viii), 39
The agent changes its constitution, such as a partnership becoming a company	The same	Rules 38(1)(viii), 39; addendum 02, question 4
The factory moves	A fresh import licence	FAQ question 92
The factory is renamed, constitution unchanged	A post approval change	Addendum 03, question 4

Some guides say a letter to CDSCO is enough to switch distributors. CDSCO's own answer is a fresh import licence.

Should your distributor be your agent, or an independent firm?

The Medical Devices Rules, 2017 don't choose for you. Any firm holding a qualifying licence can be your agent, whether it also sells your device or not. What follows is the same either way: the licence and its duties sit with the agent, and moving to a new agent means a fresh licence.

- The agent stays answerable for violations involving its imports after the power of attorney ends.
- You can add a second agent as a subsequent importer.
- The rules give CDSCO up to nine months to grant or reject an import licence (rule 36(1)).

Which model suits you turns on your sales plans and contracts, which the rules don't address.

How does it work for drugs and cosmetics?

Drugs and cosmetics follow their own rules. For a drug, the foreign maker with an Indian wholesale licence, or its agent, applies on Form 40 for a registration certificate (Drugs Rules, 1945, rule 24A). For a cosmetic, the maker, its agent, the importer or its Indian subsidiary applies on Form COS-1 (Cosmetics Rules, 2020, rule 12(2)).

Authenticating the agent's authorization

Product	Authentication	Rule
Drugs	A first class magistrate in India, or an authority abroad with Indian embassy attestation	Drugs Rules, 24A(2)
Cosmetics	A first class magistrate in India, the competent authority abroad, the Indian embassy or an apostille	Cosmetics Rules, 12(3) and First Schedule

Drug registration certificates and import licences last three years (rules 28 and 28A). See our guides to the drug import licence and cosmetics registration.

What does Customs check?

Customs checks CDSCO's paperwork before it releases drugs, devices and cosmetics. Under Circular No. 40/2026-Customs of September 3, 2026, from the Central Board of Indirect Taxes and Customs (CBIC), officers verify a CDSCO checklist of documents for seven product types on "PGA facilitated" bills of entry. CBIC asks importers to upload those documents on e-SANCHIT, the Customs document portal.

See our guide to customs in India and India's import policy.

How IndusDesk helps foreign makers with their Indian agent

We watch the authorities, tell you what each change means for your products and plans, represent you while a decision is still open, and carry the work through, with every step on record in your workspace.

We prepare the power of attorney, applications and replies for your agent to file, and track retention fees, changes and CDSCO notices. We don't act as anyone's authorized agent or importer, and we never promise a licence: CDSCO decides.

Government affairs →

Regulatory & trade advisory →

Rule exposure audit →

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Frequently asked questions

Can a foreign maker apply to CDSCO directly for a device import licence?

No. Rule 34(1) gives the application to an authorized agent holding a qualifying Indian licence. For cosmetics, the maker may apply itself (Cosmetics Rules, 2020, rule 12(2)).

Can the import licence be transferred to a new distributor?

No. CDSCO says a change in Indian agent requires a fresh import licence (CDSCO device FAQ, question 104).

Does the power of attorney need an apostille?

For a device, an apostille is one of three routes, beside a first class magistrate in India and the Indian embassy. For drugs, rule 24A(2) of the Drugs Rules, 1945 names a magistrate or embassy attestation, not an apostille. For cosmetics, the First Schedule's form allows one.

What does a second importer of the same device file?

A shorter set than the first, including a copy of the first licence and the maker's undertaking that its master files haven't changed. Each importer holds its own licence (CDSCO device FAQ, question 95).

Can a foreign cosmetics brand register its own products?

Yes. The Cosmetics Rules, 2020 treat a brand owner that has its products made under authorization as a legal manufacturer, and a manufacturer may apply on Form COS-1 itself (rules 3(n), 3(q) and 12(2)).

Sources

- The Medical Devices Rules, 2017 (CDSCO compilation, as amended to October 14, 2022): rules 2, 3(f), 34(1), 36(1), 37, 38(1) and 39, the Fourth Schedule, Part I (power of attorney and undertaking) and Form MD-15 (PDF, 1.6 MB)
- Medical Devices Frequently Asked Questions, CDSCO/FAQ/MD/01/2024: questions 92, 94, 95, 102, 104, 108 and 109 (PDF, 507 KB)
- Addendum 01 to the Medical Devices FAQ, April 3, 2025: question 6 (PDF, 363 KB)
- Addendum 02 to the Medical Devices FAQ, July 9, 2025: questions 4 and 30 (PDF, 318 KB)
- Addendum 03 to the Medical Devices FAQ, November 3, 2025: questions 3 and 4 (PDF, 374 KB)
- Separate provision for subsequent importer in the Online System for Medical Devices, MED-13011/16/2025-eoffice, September 15, 2025 (PDF, 477 KB)
- Draft guidance for import of in vitro diagnostic medical devices, CDSCO/IVD/GD/DRAFT/IMP/01/2026, January 30, 2026 (for comments): section 12 (PDF, 2.1 MB)
- The Drugs Rules, 1945 (CDSCO compilation, as amended to July 1, 2024): rules 24A(1) and (2), 28 and 28A (PDF, 7.1 MB)
- The Cosmetics Rules, 2020, G.S.R. 763(E), December 15, 2020: rules 3(n), 3(q), 12(2) and 12(3), and the First Schedule (the authorization form) (PDF, 773 KB)
- Circular No. 40/2026-Customs, September 3, 2026: checklists for cosmetics, drugs and medical devices before out-of-charge (PDF, 3.3 MB)

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