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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

Medical device manufacturing licence in India: MD-5 and MD-9

A medical device manufacturing licence in India comes from the state for Class A and B (Form MD-5) and from the Central Drugs Standard Control Organization (CDSCO) for Class C and D (MD-9). Every site must meet the Fifth Schedule quality system. Class B, C and D sites are checked first. The licence doesn't expire while you pay retention fees.

A MEDICAL DEVICE manufacturing licence comes from the State Licensing Authority, the drugs controller of the state where the plant is, for Class A and B devices. The Central Licensing Authority at CDSCO grants it for Class C and D (rule 8 of the Medical Devices Rules, 2017). Class A devices that are neither sterile nor measuring are registered instead.

KEY FACTS

LAW

Drugs and Cosmetics Act, 1940

DEVICES

Medical Devices Rules, 2017

COSMETICS

Cosmetics Rules, 2020

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Who grants a medical device manufacturing licence in India?

A medical device manufacturing licence comes from the State Licensing Authority, the drugs controller of the state where the plant is, for Class A and B devices. The Central Licensing Authority at CDSCO grants it for Class C and D (rule 8 of the Medical Devices Rules, 2017). Class A devices that are neither sterile nor measuring are registered instead.

Who grants a medical device manufacturing licence, by class

Device class	Apply on	Licence	Granted by	Rule
Class A, non-sterile and non-measuring	Online registration, no licence	A registration number	Generated on the Online System for Medical Devices	rules 19G to 19I
Class A, sterile or measuring	Form MD-3 (MD-4 for a loan licence)	Form MD-5 (MD-6)	State Licensing Authority	rule 20(2) and (4)
Class B	Form MD-3 (MD-4)	Form MD-5 (MD-6), after a Notified Body audit	State Licensing Authority	rule 20(5) and (6)
Class C and D	Form MD-7 (MD-8)	Form MD-9 (MD-10)	Central Licensing Authority (CDSCO)	rules 21(1) and 25(1)

Some registration pages say CDSCO grants Class A and B manufacturing licences. The state where the plant stands grants them (Medical Devices Rules, 2017, rules 8 and 20; CDSCO's device FAQ, question 80). A loan licence lets you make a device at another licensee's site that already makes it (question 82).

In vitro diagnostic (IVD) devices follow the same split (rule 20(1)), and CDSCO has drafted a guide to IVD manufacturing licences. See medical device registration in India for classes, and start with how CDSCO regulates drugs, medical devices and cosmetics.

Will your plant be audited or inspected before the licence?

Class B, C and D plants are checked before grant. For Class B, a state-assigned Notified Body audits the site. For Class C and D, at least two Medical Device Officers, or a Notified Body, inspect it within sixty days. A sterile or measuring Class A plant gets its licence first, then a Notified Body audit within 120 days.

A Notified Body is an audit body accredited by the National Accreditation Body and registered with CDSCO (rule 13). You can't choose one: the state assigns it after review (CDSCO's device FAQ, questions 23 and 83). A Class C or D loan licence needs no inspection at a site already licensed for the same device (rule 23(1), proviso).

After the licence, the state also inspects licensed Class A and B sites at random (rule 28).

What must a device plant have before it applies?

A device plant must meet the quality management system in the Fifth Schedule of the Medical Devices Rules (rule 22(i)). You file an undertaking saying so with the application (CDSCO's device FAQ, question 85). CDSCO says an ISO 13485 certificate is not required. The rules also set staff qualifications and batch testing.

- **Manufacturing staff:** a degree in engineering, pharmacy or science and two years in making or testing devices, or a diploma in engineering or pharmacy and four years (rule 22(ii)).
- **Testing staff:** a degree or diploma and two years testing devices (rule 22(iii)).
- **Batch testing:** every batch tested before release, in your own laboratory or a registered one (rule 26(v)).
- **Reference samples:** one unit from each batch of invasive devices and IVDs, kept 180 days past expiry (rule 26(viii)).

How long does a manufacturing licence take?

The Medical Devices Rules set limits for the authorities, not a promise. For Class C and D, CDSCO scrutinizes the application within 45 days, inspects the site within sixty days, and decides within 45 days of the report. For Class B, the Notified Body audits within ninety days, reports within thirty, and the state decides within twenty.

Time limits in the Medical Devices Rules, 2017 for a manufacturing licence

Class and step	Time limit in the rules	Rule
Class B audit	Within 90 days of the application	rule 20(6)(i)
Class B audit report	Within 30 days of the audit	rule 20(6)(ii)
Class B decision	Within 20 days of the report	rule 20(6)(iii)
Class C and D scrutiny	Within 45 days of online submission	rule 21(4)
Class C and D inspection	Within 60 days of the application	rule 23(1)
Class C and D decision	Within 45 days of the inspection report	rule 25(1)

A deficiency the authority points out restarts the Class C and D scrutiny period from the day you fix it (rule 21(7)). You can appeal a refusal within 45 days (rules 20(7) and 25(2)).

A draft, G.S.R. 515(E) of June 23, 2026, proposes shorter limits: for Class C and D, thirty days for scrutiny, fifty-five for inspection and twenty for the decision. The draft isn't law, and no final rule is in our CDSCO tracker as of November 8, 2026. More in our summary of the draft timelines.

How long is a medical device manufacturing licence valid?

A medical device manufacturing licence in Form MD-5, MD-6, MD-9 or MD-10 has no end date. It stays valid until suspended or canceled, as long as you pay the retention fee before each five years from issue run out (rule 29). A late fee applies for 180 days, then the licence is deemed canceled.

Many guides say a device licence lasts five years. That is the retention fee cycle, not an end date (CDSCO's device FAQ, question 55).

Do you need a test licence for prototypes?

Yes, for test batches. A test licence in Form MD-13 lets you make small quantities for clinical investigation, testing, evaluation, demonstration or training. You apply on Form MD-12 to the Central Licensing Authority, even for a Class B device. The rules give it thirty days to decide, and the licence lasts three years (rule 31).

CDSCO's device FAQ names it for prototypes built for feasibility, verification or validation testing (question 59). You use them only at the place the licence names, and keep records (rule 32).

An investigational device, such as one with no predicate device approved in India, needs permission in Form MD-27 (Form MD-29 for a new IVD) before any manufacturing licence (rule 25(4)).

What changes need a fresh manufacturing licence?

A change in constitution, such as a sale of more than half the voting shares, is reported within 45 days, with an application for a fresh licence within 180 days (rule 27). Moving the plant needs a fresh licence and a new audit. A major change needs approval first, and a minor one is reported within thirty days.

- **Change in constitution:** also a switch between proprietorship and partnership, or between private and public company (rule 3(j)). The old licence stays valid until the new one is decided (rule 27).
- **A new site:** a fresh licence and a new quality system audit (Addendum 01, question 9; Addendum 03, question 17).
- **A major change** in the Sixth Schedule: the authority answers within 45 days, or it is deemed approved (rule 26(iii) and (iv)).

Which label changes count as major is in our guide to medical device labeling.

What must you report after a device launches?

A licence holder reports any suspected unexpected serious adverse event, and any recall, to its licensing authority within fifteen days of learning of it (rule 26(ii)). If the authority finds part of a lot doesn't conform, you withdraw the rest of that lot from sale and recall what you can (rule 26(vi)).

For labels, shelf life and recalls, see medical device labeling and what you report after approval.

Do outsourced sterilization sites go on the label?

Yes, from mid-February 2027. G.S.R. 743(E) of August 14, 2026 added clause (p) to rule 44 of the Medical Devices Rules. A maker that outsources sterilization to another licensed site prints that site's licence number on the device label. Compliance is mandatory six months from the date of the notification.

The number goes after one of three prefixes set by G.S.R. 743(E), paragraph 4:

- "Sterilization sites Manufacturing License Number"
- "Ster. Mfg. Lic. No."
- "S.M. L."

The clause doesn't mention imported devices, and no CDSCO document we read clarifies it. More in the sterilization site section of our labeling guide and our summary of the rule.

How do you get a free sale certificate to export?

A free sale certificate for export comes from the licensing authority that granted your manufacturing licence: the state for Class A and B devices, the Central Licensing Authority for Class C and D. You apply online, and the same authority issues market standing certificates for tenders (CDSCO device FAQ, question 41).

1. Apply on the Online System for Medical Devices to the authority that licensed your device (CDSCO's free sale certificate guidance, paragraphs 3 and 4).

2. List the licensed products to be covered, and attach your manufacturing licence and the fee receipt (paragraphs 4.2 to 4.4).

3. Add a notarized undertaking that no action or conviction stands against you over adverse events, market complaints or not of standard quality reports (paragraph 4.5).

The guidance says a certificate may not be granted for products made only for export (note 1). Rule 91 also lets an exporter ask the Central Licensing Authority for a quality, safety and performance certificate an importing country requires.

How IndusDesk helps with a medical device manufacturing licence

We help device makers work out which authority and form apply, prepare the application and replies for you to file, and track retention fees and changes. We also help industry groups comment on draft rules such as G.S.R. 515(E). Whether a licence is granted is for the licensing authority to decide.

Public policy & advocacy →

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Industry coalitions →

Talk to our desk about a medical device manufacturing licence

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Frequently asked questions

Does CDSCO or the state license Class B devices?

The state does. The State Licensing Authority where the plant stands grants Class A and B licences (Medical Devices Rules, 2017, rule 8(2)).

Is ISO 13485 required for a device licence?

No. CDSCO says an ISO 13485:2016 certificate isn't required for a manufacturing licence (Addendum 01, question 15). The site must still meet the Fifth Schedule quality system.

Can I sell devices made under a test licence?

No. CDSCO says devices made under a test licence can't be sold, and unused ones are destroyed after telling the Central Licensing Authority (Addendum 02, question 38).

How long is a free sale certificate valid?

As long as the manufacturing licence, if no regulatory action has started on the products (CDSCO's free sale certificate guidance, note 3). A market standing certificate lasts one year (device FAQ, question 42).

Do I need a new licence if I move my factory?

Yes. CDSCO says a new manufacturing site needs a fresh licence and a new quality system audit (Addenda 01 and 03, questions 9 and 17).

Sources

- Medical Devices Rules, 2017 (G.S.R. 78(E)), CDSCO compilation as amended to G.S.R. 777(E) of October 14, 2022: rules 3(j), 8, 13, 19G to 19I, 20 to 33 and 91, and the Fifth and Sixth Schedules (PDF, 1.6 MB)
- G.S.R. 743(E), August 14, 2026 (Gazette, August 19, 2026): Medical Devices (Second Amendment) Rules, 2026, paragraphs 4 and 5, rule 44(p) (PDF, 799 KB)
- G.S.R. 515(E), June 23, 2026 (Gazette, June 24, 2026): draft amendment of the Medical Devices Rules, 2017, timelines for manufacturing licences (a draft, not law) (PDF, 698 KB)
- CDSCO, Medical Devices Frequently Asked Questions, CDSCO/FAQ/MD/01/2024: questions 21 to 23, 41 to 43, 55, 59, 80 and 82 to 85 (PDF, 507 KB)
- CDSCO, Addendum No. 01 to the Medical Devices FAQ, April 3, 2025: questions 9 and 15 (PDF, 363 KB)
- CDSCO, Addendum No. 02 to the Medical Devices FAQ, July 9, 2025: questions 38 and 39 (PDF, 318 KB)
- CDSCO, Addendum No. 03 to the Medical Devices FAQ, November 3, 2025: question 17 (PDF, 374 KB)
- CDSCO, Guidance Document for obtaining Free Sale Certificate (FSC) for licensed medical devices in India, CDSCO/MD/GD/FSC/02/2024: paragraph 4, notes 1 and 3, Annexure A (PDF, 386 KB)

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