November 8, 2026

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

Medical device registration in India: classes, licences, Class A

Medical device registration in India runs under the Medical Devices Rules, 2017, which cover every device since S.O. 648(E) of February 11, 2020. The Central Drugs Standard Control Organization (CDSCO) sets each device's risk class, and the class decides your route. Class A non-sterile, non-measuring devices are registered online, free and mandatory. Every other device needs a licence.

YOUR PRODUCT IS A medical device in India if it fits the device definition notified under section 3(b)(iv) of the Drugs and Cosmetics Act, 1940. That covers products for "the diagnosis, treatment, mitigation or prevention of disease". Since S.O. 648(E) of February 11, 2020, every such device falls under the Medical Devices Rules, 2017. The maker's stated purpose often decides.

KEY FACTS

LAW

Drugs and Cosmetics Act, 1940

DEVICES

Medical Devices Rules, 2017

COSMETICS

Cosmetics Rules, 2020

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Is your product a medical device in India?

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Borderline products, as CDSCO's device FAQ answers them

Product	A regulated device?	Source
Massager	Only if meant for a therapeutic purpose, not for soothing or general wellness	Device FAQ, question 51
Disinfectant	Only one meant for disinfecting medical devices	Device FAQ, question 57
Gloves	Only surgical, medical examination and other medical gloves	Addendum 02, question 32
Laboratory or factory equipment	No, when meant for non-medical use, such as a microscope in a food plant	Addendum 03, question 18
Component or accessory	Yes, when it meets the definition and is packed or labeled for sale. It needs its own licence	Addendum 02, question 35
Spare part	Only when it changes the device's performance, safety or intended use	Device FAQ, question 62
Device for animals	Yes, with its own licence for veterinary use, separate from any licence for human use	Device FAQ, question 4; Addendum 02, question 22

CDSCO and each state's drugs controller split the work. Who decides what is in our guide to CDSCO and how India regulates medical devices.

Is software a medical device in India?

Software is a medical device in India when it meets the device definition, and that includes standalone software. CDSCO's final guidance of July 21, 2026 leaves out software meant only for general wellness or fitness tracking, with no medical purpose. Software that measures or reports body values to screen, diagnose, monitor or manage a condition is not wellness software.

Under CDSCO's software guidance (CDSCO/MD/GD/MDSW/01/2026), intended use decides the class. Software that drives or influences the use of a hardware device takes that device's class. Standalone software follows this table, and CDSCO confirms the class on review (section 7.1). Software for untrained users in a serious condition may be treated as critical (the note to Table 2).

Risk class of standalone medical device software (CDSCO's guidance, Table 2)

State of the healthcare situation or condition	Information used to treat or diagnose	Information that drives clinical management	Information that informs clinical management
Critical	Class D	Class C	Class B
Serious	Class C	Class B	Class A
Non-serious	Class B	Class A	Class A

Software gets no exemption from the labeling rules (device FAQ, question 54), and a new version is filed as a post approval change (question 135). See our guide to medical device labeling and our insight on the software guidance.

How are medical devices classified in India?

Rule 4 of the Medical Devices Rules, 2017 sorts medical devices into four risk classes: A (low), B (low moderate), C (moderate high) and D (high). In vitro diagnostic devices (IVDs) use the same four classes, under Part II of the First Schedule. Only the Central Licensing Authority classifies a device.

The four classes and who licenses their manufacture (rules 4 and 8)

Class	Risk	Who licenses manufacture
Class A	Low risk	The state. Non-sterile, non-measuring Class A devices are registered instead
Class B	Low moderate risk	The state
Class C	Moderate high risk	CDSCO
Class D	High risk	CDSCO

The Central Licensing Authority, the Drugs Controller General (India), classifies devices by intended use and publishes class-wise lists (rule 4(3) and (4)). A maker can't set its own class (device FAQ, question 77).

The lists change: the authority may add, delete or reclass devices at any time (rule 4(4)). Recent ones cover Class A non-sterile, non-measuring devices (October 31, 2025) and oncology devices (January 2, 2026). New lists appear on our CDSCO tracker and in our CDSCO insights.

The class on a test licence (MD-13 or MD-17) is only the class the applicant proposed. It isn't the class for marketing (Addendum 02, question 39).

What if your device is not on a list, or is classed differently abroad?

If your device isn't on a published list, ask the Central Licensing Authority to classify it. Send its label, instructions for use and its regulatory status in other countries (device FAQ, question 78). Since November 27, 2025, the request goes through a risk classification module on CDSCO's device portal. IVDs got the module on February 2, 2026.

- **Another country classes it differently.** Where an IMDRF (GHTF) country's class differs from India's, "the higher risk class of Medical device may be considered" for approval here (device FAQ, question 93).
- **Your intended use differs from the list.** The wording needn't match, but if its essence differs, the class may change (Addendum 02, question 37).
- **Several rules fit one device.** The strictest rule, giving the higher class, applies (First Schedule, as CDSCO's software guidance restates it).

Medical device registration in India: which licence does each class need?

The class and what you do with the device decide the form: Class A non-sterile, non-measuring devices are registered, not licensed. Factories making other Class A and Class B devices are licensed by the state, and Class C and D factories by CDSCO. Importing any other device for sale needs CDSCO's MD-15 licence. Device-only sellers need the state's MD-42.

Forms by activity and class (Medical Devices Rules, 2017)

What you do	Apply on	What you get	Who decides	Rule
Make or import a Class A non-sterile, non-measuring device	The device portal	A registration number, no fee	The portal issues it	Rules 19G to 19K
Make another Class A device, or a Class B device	MD-3, or MD-4 for a loan licence	MD-5, or MD-6	The state	Rule 20
Make a Class C or D device	MD-7, or MD-8 for a loan licence	MD-9, or MD-10	CDSCO	Rules 21 and 25
Import any other device	MD-14, filed by the Indian authorized agent	MD-15	CDSCO	Rules 34 and 36
Make small test or trial quantities	MD-12	MD-13, valid three years	CDSCO	Rule 31
Import small test or trial quantities	MD-16	MD-17, valid three years	CDSCO	Rules 40 and 41
Sell, stock or distribute devices only	MD-41	MD-42	The state	Rules 87A to 87C

A device with no predicate (no approved device like it in India) needs Form MD-27 permission before any import or manufacturing licence. A new IVD needs Form MD-29 (rules 25(4) and 36(6)).

Imports and the authorized agent are in our medical device import licence guide; factories and audits in our medical device manufacturing licence guide.

How do you register a Class A non-sterile, non-measuring device?

You register a Class A non-sterile, non-measuring device on CDSCO's Online System for Medical Devices. Registration is mandatory, no fee is charged, and the portal generates the number once you file. These devices are exempt from the chapters on manufacture, import, clinical studies, devices with no predicate and sale, but labels, standards and records still apply.

A device measures if it measures a body parameter, or energy or a substance delivered to or removed from the body, and shows the result in units (device FAQ, question 72).

1. Confirm the class

Check the device is on CDSCO's Class A list of October 31, 2025, and neither sterile nor measuring.

2. Enter the device details

Give the factory's address and each device's generic name, brand, model, intended use, material, dimensions and shelf life (rules 19H(2) and 19J(2)).

3. Self-certify

Undertake that it's Class A non-sterile and non-measuring. Self-certify the essential principles checklist, the standards and, since G.S.R. 744(E) took effect on August 19, 2026, the quality management system.

4. Importers: add the overseas proof

Upload the foreign factory's home registration or a free sale certificate from its national regulator (rule 19J(2)(vi)).

5. Get the number

The portal generates it once you file (rules 19I and 19K). No fee is charged (device FAQ, question 71).

6. Keep labels and records

Follow the Chapter VI labeling rules and the standards. Keep manufacturing or import and sales records, and show them on request (rule 19L).

7. Import through a notified port

Use only ports notified under the Drugs Rules, 1945 (Addendum 03, question 31).

Selling these devices needs no wholesale drug licence and no MD-42 (Addendum 01, question 13). The QMS change is in our insight on G.S.R. 744(E).

Do you need MD-42 to sell medical devices?

A shop or distributor that deals only in medical devices needs a registration certificate in Form MD-42 from the state, applied for on Form MD-41 (rules 87(1A) and 87A). A wholesale drug licence already covers devices. The state decides an MD-41 application within ten days. MD-42 has no end date while you pay a retention fee every five years.

- Buy only from an importer, a licensed maker or a registered or licensed entity (rule 87B(4)).
- Keep purchase and sale records, with maker or importer, batch and expiry, for two years from the last entry (rule 87B(5) and (7)).
- Pay the retention fee before each five-year mark. After six months unpaid, the certificate is deemed canceled (rule 87C).
- Supply implants to a hospital on a delivery challan, with a cash or credit memo after surgery (rule 88).

CDSCO's November 2025 procurement circular asks buyers, hospitals included, to require a CDSCO or state licence. Any other certificate a buyer wants, such as US FDA or CE, "should be over and above" that licence.

Is the notified and non-notified device split still used?

No. All medical devices have been regulated under the Medical Devices Rules, 2017 since S.O. 648(E) of February 11, 2020. Today all are under licensing except Class A non-sterile, non-measuring devices. CDSCO's device FAQ says a registration number taken under G.S.R. 102(E) of the same date "shall not be considered as a regulatory approval".

How IndusDesk helps with medical device registration

We work out whether each product is a regulated device and which class and route apply. We prepare classification requests, registrations and licence applications for you or your authorized agent to file, and track retention fees and changes. CDSCO and the states decide, so we can't promise a class, registration or licence.

Regulatory & trade advisory →

Rule exposure audit →

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

Frequently asked questions

Is registering a Class A medical device voluntary?

No. Registering a Class A non-sterile, non-measuring device is mandatory under rules 19G to 19K (device FAQ, question 69). It's free, and the portal issues the number.

Is a fitness app a medical device in India?

Not if it's meant only for general wellness or fitness tracking, under CDSCO's July 21, 2026 software guidance. An app that measures or reports body values to screen, diagnose, monitor or manage a condition is a device.

Who decides my medical device's class?

The Central Licensing Authority, the Drugs Controller General (India), under rule 4(3). You can't set your own class.

Do I need a drug licence to sell medical devices?

No. A device-only seller needs the state's MD-42 instead (rules 87(1A) and 87A). A wholesale drug licence you already hold covers devices too (device FAQ, question 143).

How long does MD-42 take?

The state has ten days from your MD-41 application to grant MD-42 or refuse it with reasons (rule 87A(4)). You can appeal a refusal to the state government within 45 days.

Sources

- The Drugs and Cosmetics Act, 1940, section 3(b)(iv) (CDSCO's copy) (PDF, 686 KB)
- The Medical Devices Rules, 2017 (CDSCO's compilation, as amended to G.S.R. 777(E) of October 14, 2022): rules 3(x), 4, 8, 19G to 19M, 20, 21, 25, 31, 34, 36, 40, 41, 87 to 88 (PDF, 1.6 MB)
- G.S.R. 744(E), Medical Devices (Third Amendment) Rules, 2026, August 14, 2026, in force on publication, August 19, 2026: quality management system for Class A non-sterile, non-measuring devices (paragraphs 2 and 3) (PDF, 740 KB)
- CDSCO, Medical Devices Frequently Asked Questions, CDSCO/FAQ/MD/01/2024: questions 1, 2, 4, 51, 54, 57, 62, 69, 71, 72, 77, 78, 93, 135 and 143 (PDF, 507 KB)
- CDSCO, Addendum 01 to the device FAQ, April 3, 2025: question 13 (PDF, 363 KB)
- CDSCO, Addendum 02 to the device FAQ, July 9, 2025: questions 22, 32, 35, 37 and 39 (PDF, 318 KB)
- CDSCO, Addendum 03 to the device FAQ, November 3, 2025: questions 18 and 31 (PDF, 374 KB)
- CDSCO, Guidance Document on Medical Device Software under MDR-2017, CDSCO/MD/GD/MDSW/01/2026, July 21, 2026: sections 2.0, 5.0 and 7.1, Table 2 (PDF, 1.6 MB)
- CDSCO, Risk based classification list of Class A (non-sterile and non-measuring) medical devices, F. No. MED-16014(12)/1/2024-eoffice-Part(2), October 31, 2025 (PDF, 1.0 MB)
- CDSCO, risk classification list of oncology medical devices, January 2, 2026 (PDF, 307 KB)
- CDSCO circular MED-16035/14/2025-eoffice, December 2025: risk classification module for devices, from November 27, 2025 (PDF, 251 KB)
- CDSCO circular IVD-19011(11)/32/2024-eoffice, February 2026: risk classification module for IVD devices, from February 2, 2026 (PDF, 131 KB)

- CDSCO circular MED-13/87/2025-eoffice, November 2025: a CDSCO or state licence in procurement of medical devices (PDF, 467 KB)

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