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CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

Medical device labeling requirements in India, changes and recalls

Medical device labeling requirements in India are in Chapter VI of the Medical Devices Rules, 2017. An imported device may add its India details by sticker. After approval, a major change needs approval first and a minor one is reported within thirty days. Recalls, suspected unexpected serious adverse events and regulatory action abroad are reported within fifteen days.

A MEDICAL DEVICE label in India shows the device name and use, the maker and factory address, net quantity, the month and year of manufacture and expiry, a batch number, the sterile state and warnings. Rule 44 of the Medical Devices Rules, 2017 sets the list. An imported device also shows its import licence number and importer.

KEY FACTS

LAW

Drugs and Cosmetics Act, 1940

DEVICES

Medical Devices Rules, 2017

COSMETICS

Cosmetics Rules, 2020

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What are the medical device labeling requirements in India?

A medical device label in India shows the device name and use, the maker and factory address, net quantity, the month and year of manufacture and expiry, a batch number, the sterile state and warnings. Rule 44 of the Medical Devices Rules, 2017 sets the list. An imported device also shows its import licence number and importer.

Rule 44, one part of how CDSCO regulates medical devices in India, asks for these in indelible ink on the label and every outer covering (Medical Devices Rules, 2017):

- The device name and use, and the maker's name and factory address (clauses (a) to (c)).
- Net quantity in metric units (d).
- Month and year of manufacture and expiry, or the shelf life (e). Equipment, and non-sterile devices of stable materials such as titanium, may leave out expiry.
- A batch or lot number (g).
- Where they apply: storage conditions, the sterile state and method, warnings and a single-use mark ((h) to (k)).
- For a device made in India, its manufacturing licence number (m).

An imported device adds its import licence number, the importer's name and address, the actual factory address and the date of manufacture. Where these aren't printed, they may go on by sticker in India (rule 44(n); CDSCO device FAQ, question 99, and addendum 02, question 11). The licence is in our guide to the medical device import licence.

Standalone software gets no exemption (CDSCO device FAQ, question 54). The software guidance of the Central Drugs Standard Control Organization (CDSCO) says software with no physical form may let users reach its label in the software itself or through a web address. The label includes the version or build number (software guidance, 2026, section 12.4.2(l)).

Does the sterilization site's licence number go on the label?

A device maker that outsources sterilization to another licensed facility must show that site's licence number on the label. G.S.R. 743(E) of August 14, 2026 added this as clause (p) of rule 44. Compliance becomes mandatory six months from the notification's date, which we count as mid-February 2027.

The proviso to paragraph 5 of G.S.R. 743(E) says "six months from the date of this notification" and prints no calendar date, so mid-February 2027 is our count. Our summary of G.S.R. 743(E) covers the rest.

Open question: imported devices

Clause (p) speaks of a manufacturer that outsources sterilization. It doesn't mention imported devices, and the documents we read hold no CDSCO clarification.

How much shelf life must an imported device have left?

An imported medical device needs at least 40%, 50% or 60% of its shelf life left on the date of import, depending on its total shelf life. The provisos to rule 47 of the Medical Devices Rules, 2017 set these floors, and the licensing authority won't allow an import below them.

Shelf life an imported device must have left (rule 47)

Total shelf life the maker claims	Left on the date of import
Under 90 days	At least 40%
90 days to 1 year	At least 50%
Over 1 year	At least 60%

Rule 47 also caps shelf life at sixty months, unless the maker justifies more. The one-year rule of October 2026 (G.S.R. 951(E)) is for drugs, not devices.

Which changes after approval need approval first?

Major changes listed in the Sixth Schedule of the Medical Devices Rules, 2017 need approval before you make them. Minor changes are reported within thirty days after they happen. A label change counts as major unless it changes only font size, font type, color or label design.

Post approval changes under rules 26 and 38

Licence and change	What you do	Time limit in the rules
Import licence, major change	Get approval first	Answer within 60 days, or deemed approved (rule 38(1)(v) and (vi))
Import licence, minor change	Tell the authority	Within 30 days after the change (rule 38(1)(vii))
Manufacturing licence, major change	Get approval first	Answer within 45 days, or deemed approved (rule 26(iii))
Manufacturing licence, minor change	Tell the authority	Within 30 days after the change (rule 26(iv))

Major changes in the Sixth Schedule also include the material of construction, the intended use, the sterilization method, the approved shelf life and the primary packaging material. So does a new name or address for the maker, its site or the authorized agent. These time limits are the rules' own, not a promise of speed. See the medical device manufacturing licence.

A new software version is filed as a post approval change (device FAQ, question 135). It's major if it affects intended use, safety or effectiveness (software guidance, section 12.5.2).

What must you report about safety and recalls?

A device licence holder in India reports recalls and serious safety events within fifteen days. A maker reports a suspected unexpected serious adverse event and any recall. An importer reports action taken abroad, and its authorized agent stops dispatch at once. A maker or agent that thinks a device may be unsafe starts a withdrawal at once.

- Made in India: a suspected unexpected serious adverse event and any recall, within fifteen days (rule 26(ii)).
- Imported: any action abroad, such as a withdrawal or a canceled authorization, within fifteen days. The authorized agent stops dispatch at once (rule 38(1)(ii) and (iii)).
- Any maker or agent that thinks a device may be unsafe starts withdrawing it from the market and from patients at once, and tells the authority why (rule 89(1)).
- A device with no predicate, under Form MD-27: periodic safety update reports from launch, every six months for two years, then yearly for two more (rule 65(b); device FAQ, question 126).

The Central Licensing Authority may order a batch recalled, from hospitals too (rule 38(2)). The CDSCO tracker lists its notices. The reporting procedure of the materiovigilance program (MvPI) isn't covered here: the documents we read don't set it out.

Can a single-use device be reused in India?

A medical device the maker sells as single use may not be reused in India, CDSCO says, because the maker assessed its safety and performance for one use only. The label carries that limit: rule 44(k) of the Medical Devices Rules, 2017 asks for a single-use mark where it applies.

Source: device FAQ addendum 02 of July 9, 2025, question 9.

Is a unique device identification required in India?

The device rules provide for a unique device identification, but only from a date the central government sets by order. Rule 46 of the Medical Devices Rules, 2017 says every device approved for sale or import shall carry one, in the manner that order sets. The rule itself names no date.

Rule 46 once set January 1, 2022, until G.S.R. 918(E) of December 31, 2021 replaced it (CDSCO's compilation, note 22).

How IndusDesk helps with device labels and changes

We check your labels against rule 44, sort your changes into major and minor, and prepare change applications and reports for you or your authorized agent to file. We can't promise an approval or its timing. Registration is in our guide to medical device registration in India.

Regulatory & trade advisory →

Rule exposure audit →

Talk to our desk about medical device labels Message us on WhatsApp

Frequently asked questions

Can I sticker India-specific details on imported devices?

Yes, where they aren't already printed. CDSCO says the import licence holder may sticker the details rule 44(n) asks for, at its licensed or registered warehouse too (device FAQ addendum 02, question 11).

Is a label change a major change?

Yes, unless it changes only font size, font type, color or label design (CDSCO device FAQ, question 38).

How fast must a recall abroad be reported?

At once, and within fifteen days at the latest (rule 38(1)(ii)).

Sources

- Medical Devices Rules, 2017 (CDSCO compilation, as amended to G.S.R. 777(E) of October 14, 2022): rules 26, 38, 44, 46, 47, 65 and 89, the Sixth Schedule, and note 22 on G.S.R. 918(E) of December 31, 2021 (PDF, 1.6 MB)
- Medical Devices (Second Amendment) Rules, 2026, G.S.R. 743(E), August 14, 2026 (Gazette of August 19, 2026): paragraphs 4 and 5, rule 44(p) (PDF, 799 KB)
- CDSCO, Medical Devices Frequently Asked Questions, CDSCO/FAQ/MD/01/2024: questions 38, 54, 99, 126 and 135 (PDF, 507 KB)
- CDSCO, Addendum No. 02 to the Medical Devices FAQ, July 9, 2025: questions 9, 11 and 23 (PDF, 318 KB)
- CDSCO, Guidance Document on Medical Device Software, CDSCO/MD/GD/MDSW/01/2026, July 21, 2026: sections 12.4.2(l) and 12.5.2 (PDF, 1.6 MB)
- Drugs (Thirteenth Amendment) Rules, 2026, G.S.R. 951(E), October 16, 2026 (Gazette of October 28, 2026): residual shelf life of imported drugs (PDF, 572 KB)

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