November 8, 2026

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

CDSCO: how India regulates drugs, medical devices and cosmetics

The Central Drugs Standard Control Organization (CDSCO) is India's central regulator for drugs, medical devices and cosmetics under the Drugs and Cosmetics Act, 1940. The Drugs Controller General (India), or DCGI, heads it. CDSCO decides device imports, Class C and D manufacture, new drugs, trials and cosmetic imports; state drugs controllers license Class A and B device making and sale.

ON NOVEMBER 8, 2026, CDSCO's rules rest on the Drugs and Cosmetics Act, 1940 and its rules. In 2026 European Union approvals joined the waiver for new devices, imported drugs began to need a year of shelf life, and CDSCO started rejecting long-pending applications left unanswered after three reminders.

KEY FACTS

LAW

Drugs and Cosmetics Act, 1940

DEVICES

Medical Devices Rules, 2017

COSMETICS

Cosmetics Rules, 2020

UPDATED

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Central Drugs Standard Control Organization · November 8, 2026

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Where do CDSCO's rules stand on November 8, 2026?

On November 8, 2026, CDSCO's rules rest on the Drugs and Cosmetics Act, 1940 and its rules. In 2026 European Union approvals joined the waiver for new devices, imported drugs began to need a year of shelf life, and CDSCO started rejecting long-pending applications left unanswered after three reminders.

As of November 8, 2026

We read 56 official texts on November 8, 2026. They include the Act, the rules, the 2024 to 2026 Gazette notifications, CDSCO's FAQs and notices, and a Central Board of Indirect Taxes and Customs (CBIC) circular. CDSCO's compilations lag, so we cite each later amendment.

Changes since September 2025:

- September 15, 2025: CDSCO says a later importer of an approved device has had its own portal route since September 11 (circular).
- October 7, 2025: CDSCO asks Customs to send bills of entry on ICEGATE, Customs' online system, to its port offices (letter).
- October 31, 2025: CDSCO lists the Class A non-sterile, non-measuring devices (list).
- November 2025: CDSCO asks buyers to require an Indian device licence (circular).
- December 4, 2025: CDSCO says a risk classification module has been open on the device portal since November 27, 2025 (circular).
- January 16, 2026: long-pending applications on SUGAM, CDSCO's online portal, are rejected after three unanswered reminders (notice).
- January 20, 2026: permission to make new drugs for trials or tests gets a forty-five working day limit, in force 45 days after publication (G.S.R. 46(E)).
- January 30, 2026: draft guidance for importers of in vitro diagnostic (IVD) devices (draft).
- July 21, 2026: final guidance on medical device software (guidance).

- July 30, 2026: applicants under the Drugs Rules who file misleading, fake or fabricated documents may face debarment (G.S.R. 706(E)).
- August 14, 2026: labels must name an outsourced sterilization site's licence from mid-February 2027 (G.S.R. 743(E)), and European Union approvals count for new devices (G.S.R. 744(E)).
- September 3, 2026: Customs checks CDSCO's checklists before clearing drugs, devices and cosmetics on "PGA facilitated" bills of entry (Circular No. 40/2026-Customs).
- October 16, 2026: imported drugs need one year of shelf life left, from the Gazette of October 28 (G.S.R. 951(E)).
- October 28, 2026: three drafts on drug import points, batch release and licence suspension (G.S.R. 954(E), 955(E), 956(E)).

CDSCO guides, and what each answers

Guide	What it answers
Medical device registration in India	Classes, licences and the Class A route
Medical device import licence	Forms MD-14 and MD-15
The Indian authorized agent	What foreign makers need
Medical device manufacturing licence	Forms MD-5 and MD-9
Medical device labeling	Labels, and what you report after approval
Drug import licence	Form 41 registration and Form 10
Clinical trial approval	Forms CT-04 and CT-06, and new drug permission
Cosmetics registration	Importing under COS-1 and COS-2

The CDSCO tracker: notices and Gazette notifications →

CDSCO notices, summarized →

What is CDSCO, and what do the state drugs controllers decide?

CDSCO is the central regulator under the Drugs and Cosmetics Act, 1940. Its head, the DCGI, licenses devices centrally: imports of every class, Class C and D manufacture, clinical

investigations and new IVDs. Each state's drugs controller licenses Class A and B device makers and cosmetic factories, and registers device sellers. CDSCO registers imported cosmetics.

Who decides what (MDR: the Medical Devices Rules, 2017)

Activity	Authority	Form	Rule
Import any class of device	CDSCO	MD-14 for an MD-15 licence	MDR rules 8(1), 34 and 36
Make Class A or B devices	The state's drugs controller	MD-3 for an MD-5 licence	MDR rules 8(2) and 20
Make Class C or D devices	CDSCO	MD-7 for an MD-9 licence	MDR rules 21 and 25
Sell devices	The state's drugs controller	MD-41 for an MD-42 registration	MDR rule 87A
Register imported cosmetics	CDSCO	COS-1 for a COS-2 certificate	Cosmetics Rules, 2020, rules 4(1), 12 and 13
License cosmetic factories and oversee cosmetics on sale	The state's licensing authority	A state licence to manufacture	Cosmetics Rules, 2020, rule 4(2)
Register and license drug imports	A licensing authority the central government appoints	Form 40 for a Form 41 certificate; Form 8 for a Form 10 licence	Drugs Rules, 1945, rules 21 to 24A
Approve clinical trials and new drugs	CDSCO, the DCGI	CT-04 for a CT-06 trial permission	New Drugs and Clinical Trials Rules, 2019, rules 21 and 22

Since 2020 every medical device is regulated under the Medical Devices Rules, 2017, which override the older Drugs Rules where the two conflict (rule 96; device FAQ, question 1). CDSCO runs a public relations cell in New Delhi for device startups, importers and makers (question 7).

Is your product a drug, a medical device or a cosmetic?

The Drugs and Cosmetics Act, 1940 decides it. A cosmetic is anything rubbed, poured, sprinkled or sprayed on the body to clean, beautify, add attractiveness or change appearance. A device counts as a drug once the government notifies it. A product given as an injection isn't a cosmetic, CDSCO said in May 2026.

- The definitions are in section 3 of the Act. No cosmetic may be used as an injection or for treatment (notice of May 18, 2026).

- A massager for soothing or wellness isn't regulated; one meant for a therapeutic purpose is a device (device FAQ, question 51).
- Only surgical, medical examination and other medical gloves are devices (addendum 02, question 32).
- Radiopharmaceuticals aren't devices; the Drugs Rules, 1945 license them (addendum 03, question 14).
- A microscope in a food plant, or other non-medical lab equipment, isn't a device (addendum 03, question 18).

Software that meets the device definition is a device, standalone software included: see medical device registration in India.

What are India's medical device risk classes?

Medical devices fall into four risk classes under rule 4 of the Medical Devices Rules, 2017: A (low), B (low moderate), C (moderate high) and D (high). In vitro diagnostic devices use the same four classes under their own parameters. Only CDSCO's Central Licensing Authority classifies a device; a maker can't set its own class.

Device risk classes, and who licenses their manufacture

Class	Risk	Manufacturing licence from
Class A	Low	The state; registration only, if non-sterile and non-measuring
Class B	Low moderate	The state
Class C	Moderate high	CDSCO
Class D	High	CDSCO

CDSCO classifies by intended use (rule 4(3)) and, where another country classes a device differently, may apply the higher class (device FAQ, question 93); see medical device registration in India.

Which approval does a medical device need?

A medical device needs the approval that matches what you do with it. Class A non-sterile, non-measuring devices are registered on CDSCO's portal. Every other import needs an MD-15 licence, making a device needs a state or central manufacturing licence by class, and a shop selling only devices needs an MD-42 registration.

Device approvals by activity, under the Medical Devices Rules, 2017

What you do	Application	Approval	Rule
Make or import a Class A non-sterile, non-measuring device	Details on the online portal	A registration number	Rules 19G to 19K
Import any other device	Form MD-14	Licence in Form MD-15	Rules 34 and 36
Make Class A or B devices	Form MD-3 (MD-4 for a loan licence)	Form MD-5 or MD-6	Rule 20
Make Class C or D devices	Form MD-7 (MD-8 for a loan licence)	Form MD-9 or MD-10	Rules 21 and 25
Sell devices only	Form MD-41	Registration in Form MD-42	Rule 87A
Make devices to test, demonstrate or train	Form MD-12	Test licence in Form MD-13, for three years	Rule 31
Import devices to test, demonstrate or train	Form MD-16	Test licence in Form MD-17, for three years	Rules 40 and 41

What does a new device with no predicate need?

A new medical device with no predicate needs a clinical investigation permitted in Form MD-23, then MD-27 permission before any import or manufacturing licence. The authority may waive the investigation for a device approved and marketed for at least two years in the UK, the US, Australia, Canada, Japan or, since August 2026, the EU.

- A licensed device claimed for a new use, population or material, or with a major design change, is investigational too (device FAQ, question 112).
- The applicant files Form MD-26 after the investigation, and CDSCO decides within 120 days, extendable by thirty (rule 63).
- European Union countries joined the waiver under G.S.R. 744(E), paragraph 5, of August 14, 2026, in force from its Gazette of August 19.
- Once approved and sold in India, it becomes a predicate for later applicants (question 116).

How do you import medical devices into India?

To import a medical device, an authorized agent in India files Form MD-14 online, and CDSCO decides on the import licence, Form MD-15, within nine months under rule 36(1). Every class needs it, except Class A non-sterile, non-measuring devices. The licence has no end date while a retention fee is paid every five years.

1. Appoint an Indian authorized agent by power of attorney.

2. Get a free sale certificate; one from Australia, Canada, Japan, the European Union, the UK or the US needs no clinical investigation (rule 36(3)).

3. From any other country, Class C and D need a clinical investigation in India (rule 36(4)). Class A and B need published data or an investigation abroad, plus a home-country free sale certificate (rule 36(5)).

4. File Form MD-14 on the portal, through the agent, and answer CDSCO's questions until it decides on Form MD-15.

The medical device import licence guide covers the dossier, inspection and later importers.

What does a foreign maker need in India?

A foreign device maker sells in India through an Indian authorized agent, appointed by power of attorney, who holds the MD-15 import licence. Changing that agent needs a fresh import licence. For cosmetics, the foreign maker may apply itself or through its agent, an importer or an Indian subsidiary it authorizes.

Sources: Medical Devices Rules, rule 3(f), CDSCO's device FAQ, question 104 and Cosmetics Rules, rule 12(2). The Indian authorized agent covers what the agent holds and signs.

How is making medical devices in India licensed?

Making medical devices in India needs a licence by class. The state licenses Class A and B makers in Form MD-5, after a Notified Body audit for Class B. CDSCO licenses Class C and D makers in Form MD-9. The licences have no end date while a retention fee is paid.

- A Class A licence needs no audit first; a Notified Body audits the site within 120 days after the grant (rule 20(4)).
- For Class B, the state, not the maker, assigns the Notified Body (device FAQ, question 83).
- A missed retention fee may be paid late for 180 days. After that the licence is deemed canceled (rule 29).
- A June 2026 draft, not yet law, proposes shorter timelines for Class B, C and D licences (G.S.R. 515(E)).

The medical device manufacturing licence guide covers the quality system, staff and audits.

What do device labels and post-market rules require?

Chapter VI of the Medical Devices Rules, 2017 sets what a device label shows: the name, the maker and factory address, the quantity, dates, batch number, sterility and warnings. After approval, an importer gets a major change approved, or deemed approved after sixty days, and reports a minor change within thirty days.

See rule 44 for labels and rule 38(1)(v) to (vii) for changes. Medical device labeling in India covers stickers, shelf life, recalls and change lists.

How do devices reach hospitals and buyers?

Devices reach buyers through sellers the state has registered. A shop or distributor dealing only in devices needs a Form MD-42 registration from the state; a wholesale drug licence also covers devices. CDSCO asked buyers, hospitals included, in November 2025 to require a CDSCO or state licence when they buy devices.

- The seller applies on Form MD-41 (rule 87A): see medical device registration in India.
- Any other certificate a buyer wants, such as a US FDA approval or a CE mark, is over and above that licence (November 2025 circular).
- The licensing authority may issue free sale and market standing certificates for tenders or export; a market standing certificate lasts a year (device FAQ, questions 41 to 43).

How do you import drugs into India?

Importing a drug for sale takes two approvals under the Drugs Rules, 1945: a registration certificate in Form 41 for the foreign factory and its drugs, and an import licence in Form 10. Each lasts three years. Since October 2026, an imported drug needs a year of shelf life left.

1. Apply on Form 40 for the registration certificate, through the maker's authorized agent in India, or as the maker with an Indian wholesale licence (rule 24A(1)).

2. Apply on Form 8 for the import licence, with the Form 41 certificate and the maker's undertaking in Form 9 (rule 24).

3. Ship drugs with a year of shelf life left, or 60% for biologicals and radiopharmaceuticals (G.S.R. 951(E)).

4. Apply for fresh ones before the three years end (rules 28 and 28A).

The drug import licence guide covers Schedule X drugs, test licences and renewal.

How are new drugs and clinical trials approved?

A clinical trial of a new drug needs permission from the Central Licensing Authority: you apply on Form CT-04 and receive Form CT-06. The authority decides within ninety working days, or the permission is deemed granted. Importing a new drug for sale needs permission on Form CT-18, granted in Form CT-19 or CT-20.

A local trial may be waived for a drug approved and marketed in countries named under rule 101, with no major unexpected serious adverse events (New Drugs and Clinical Trials Rules, 2019, rule 75(7)).

The clinical trial approval guide covers ethics committees, bioavailability and bioequivalence (BA/BE) studies, and the 2026 routes.

How are imported cosmetics registered in India?

No cosmetic may be imported into India unless CDSCO has registered it. The maker, its authorized agent, the importer or an Indian subsidiary applies online on Form COS-1, and CDSCO grants a COS-2 certificate, or rejects it, within six months. COS-2 has no end date while a retention fee is paid.

See rules 12 to 14 of the Cosmetics Rules, 2020. No cosmetic tested on animals after November 12, 2014 may be imported (rule 18(4)). The cosmetics registration guide covers labels, COS-4A numbers and the 2026 cancellations.

How do CDSCO applications work, and when are they rejected?

Device applications go online through CDSCO's medical devices portal or the National Single Window System (NSWS). Drug, trial and cosmetic applications go on CDSCO's SUGAM portal. Since January 2026, a long-pending SUGAM application left waiting on the applicant gets three reminders thirty days apart, then a fourth notice rejects it and forfeits the fee.

- Device fees aren't refunded (device FAQ, question 14). An incomplete application to make Class C or D devices is rejected, but fixable gaps restart its scrutiny clock (rule 21(7)).
- The January 16, 2026 notice covered drug, cosmetic and device files pending since 2016 or 2018; the May 4, 2026 notice added trial, BA/BE, ethics committee and veterinary files.
- A device application resting on fake or fabricated documents is rejected after a hearing, and the applicant may face debarment (rules 92 and 93).
- A retention application filed on time with the fee keeps a device licence deemed valid while it is processed (device FAQ, question 141).

CDSCO's cosmetics FAQ still says there is no time limit to answer on a cosmetics application; the 2026 notices are the later word.

What do CDSCO and Customs check at the port?

At the port, CDSCO's port office gives a no objection and Customs clears the goods. Drugs, devices and cosmetics enter India only through the places listed in rule 43A of the Drugs Rules, 1945. Since September 2026, Customs officers check CDSCO's checklists on "PGA facilitated" bills of entry before release.

- Rule 43A applies to cosmetics too (Cosmetics Rules, rule 22). Cochin and Thiruvananthapuram airports joined it in May 2024 (G.S.R. 293(E)) and Navi Mumbai in July 2026 (G.S.R. 561(E)).
- CDSCO's 2021 port notice sets two to three hours for a no objection on documents alone, 24 to 48 hours with a physical check, and 48 to 72 hours when a lab tests samples. That's CDSCO's own figure, not a promise for any shipment.
- Shelf life left on import: devices 40%, 50% or 60%, by total shelf life (Medical Devices Rules, rule 47); drugs one year (G.S.R. 951(E)); cosmetics a use-before date over six months away (Cosmetics Rules, rule 18(2)).

Duty and the bill of entry are on customs in India, and import restrictions on India import policy.

What enforcement and quality rules apply?

The Drugs and Cosmetics Act bars importing misbranded, adulterated or spurious drugs and misbranded or spurious cosmetics, and lets the central government ban a drug or cosmetic in the public interest. It banned 16 fixed dose combinations in June 2026. Some offenses may be compounded under section 32B.

- Bans: sections 10, 10A and 26A of the Act; the June 2026 combinations (S.O. 3068(E) to 3083(E)).
- The compounding rules were notified on April 24, 2025 (notice); it's at the authority's discretion (FAQ, question 20).
- The Jan Vishwas (Amendment of Provisions) Act, 2026 changes to the Act take effect on June 30, 2027 (S.O. 3286(E)).

- Drug makers must test every batch of raw material and finished product, CDSCO told states in October 2026 (letter).
- Two drafts of October 28, 2026 would require an authorized person to release each drug batch (G.S.R. 955(E)) and suspend a manufacturing licence on a not of standard quality report until corrective action (G.S.R. 956(E)). Both are drafts.
- CDSCO may order a whole device batch withdrawn or recalled, from hospitals too (Medical Devices Rules, rule 38(2)).

What time limits do CDSCO's rules set?

CDSCO's rules set their own time limits. An MD-15 import licence is decided within nine months, a COS-2 cosmetic registration within six, and trial permission within ninety working days. These are the government's own limits, counted as each rule counts them, not a promise of a decision by a date.

Time limits in CDSCO's rules, as of November 8, 2026

What is decided	Limit	Counted from	Rule
MD-15 device import licence	9 months	Application	Medical Devices Rules, rule 36(1)
IVD import and test licences	Draft only: 270 days for MD-14, 30 days for MD-16	Application	Draft IVD guidance, section 11
Class C or D manufacturing licence	Scrutiny 45 days; inspection 60 days; decision 45 days	The application; then the inspection report	Rules 21(4), 23(1), 25(1)
Class B manufacturing licence	Audit 90 days; report 30 days; decision 20 days	The application; the audit; its report	Rule 20(6)
Device test licence, MD-13 or MD-17	30 days	Application	Rules 31(3) and 41(1)
Device with no predicate, MD-27	120 days, plus up to 30	Application	Rule 63(2)
Personal use permit for a device	7 days	Application	Rule 43(3)
Appeal against most device refusals	45 days to file	The order	Rules 20(7), 25(2), 30(2), 36(2)
Form 41 drug registration certificate	9 months, plus up to 3	A complete application	Drugs Rules, rule 27A(1)

COS-2 registration or COS-4A number	6 months	Application	Cosmetics Rules, rules 13(1), 17(2)
Clinical trial permission, CT-06	90 working days; 30 for a drug discovered, or researched and made, in India	Application	NDCT Rules, rules 22(2) and 23
New drug import permission	90 working days	The CT-18 application	NDCT Rules, rule 76(1)
Port office no objection	2 to 3 hours on documents; 24 to 48 with a physical check; 48 to 72 with lab testing	Not stated	CDSCO notice of September 10, 2021

Which CDSCO dates are coming up?

The next CDSCO date is mid-February 2027, when device labels must show the licence number of an outsourced sterilization site. The Jan Vishwas Act, 2026 changes to the Drugs and Cosmetics Act start on June 30, 2027, and Schedule H2 widens on July 1, 2027 and July 1, 2028.

CDSCO dates ahead, as of November 8, 2026

Date	What	Source
From mid-February 2027	Labels show an outsourced sterilization site's licence number	Worked out: six months from G.S.R. 743(E) of August 14, 2026
June 30, 2027	Jan Vishwas Act, 2026 changes to the Drugs and Cosmetics Act start	S.O. 3286(E)
July 1, 2027	Schedule H2 covers vaccines, narcotic and psychotropic drugs and anticancer drugs	G.S.R. 506(E)
July 1, 2028	Schedule H2 covers all antimicrobials	G.S.R. 506(E)

Drafts not yet final: G.S.R. 515(E) (device licence timelines), 509(E) (drug test licences), 790(E) (BA/BE studies) and 954(E), 955(E) and 956(E) of October 28, 2026.

What do pages online get wrong about CDSCO's rules?

Pages online often repeat CDSCO rules that changed or never existed: an MD-15 licence that expires after five years, Class A registration called voluntary, a trial approval time halved in 2026, and 60% shelf life for every imported drug. The table sets 13 such claims beside what the official documents say.

Claims online, and what the documents say (MDR: Medical Devices Rules)

What some pages say	What the documents say	Rule
An MD-15 import licence is valid for five years	No end date while the retention fee is paid every five years	MDR rule 37
A COS-2 cosmetic registration is valid for three or five years	No end date while the retention fee is paid	Cosmetics Rules, rule 14(1)
Registering a Class A non-sterile, non-measuring device is voluntary	Mandatory and free; the portal issues the number	MDR rules 19G to 19K
MD-14 is the licence for Class A and B devices and MD-15 for Class C and D	MD-14 is the application and MD-15 the licence, for every class	MDR rules 34(1), 36(1)
CDSCO grants manufacturing licences for Class A and B devices	The state licenses Class A and B; CDSCO licenses C and D	MDR rules 8, 20, 21
An import licence officially takes four to six months	An outer limit of nine months; no rule sets four to six	MDR rule 36(1)
The January 2026 amendment halved the time to approve a clinical trial	Trial permission still has ninety working days	NDCT rule 22(2); G.S.R. 46(E)
Only five countries' approvals count for a device with no predicate	European Union approvals count too, since August 2026	G.S.R. 744(E)
Imported drugs need 60% of their shelf life left	One year since October 2026; 60% for biologicals	G.S.R. 951(E)
Changing your Indian distributor only needs a letter to CDSCO	A new Indian agent needs a fresh import licence	Device FAQ, question 104
Imported cosmetics are registered on Form 42 and Form 43	COS-1 and COS-2, since the Cosmetics Rules, 2020	Cosmetics Rules, rules 12(2), 13(1)
Only notified devices need a licence; the rest just register	All devices need a licence, except Class A non-sterile, non-measuring ones	Device FAQ, question 2
A device licence lets you import through any port	Only through ports notified under the Drugs Rules, 1945	Device FAQ, question 106

Where do BIS, DGFT, Customs, MoEFCC and NPPA come in?

Other agencies' rules sit beside CDSCO's. A device must meet the Bureau of Indian Standards (BIS) standard where one exists, and cosmetics on the Ninth Schedule, hair dyes included, must meet theirs. Import policy, customs duty, e-waste rules and drug prices belong to other bodies.

- Standards: without a BIS standard, a device meets an international (ISO or IEC) standard or a pharmacopoeia (rule 7). Hair dyes: CDSCO's June 2026 circular, BIS licence in India and quality control orders.
- Import policy (the Directorate General of Foreign Trade, DGFT): India import policy. Duty: customs in India.
- E-waste, battery and used equipment rules: Ministry of Environment, Forest and Climate Change (MoEFCC) rules for companies.
- Drug prices: National Pharmaceutical Pricing Authority (NPPA) notices. IndusDesk shows no prices.

How does IndusDesk help with CDSCO rules?

IndusDesk reads which class and approvals apply to your product, prepares applications, dossiers, replies to CDSCO's questions and post-approval changes for you or your authorized agent to file, and tracks retention fees, reminders and notices. CDSCO and the states decide, so we never promise a licence, a registration or a date.

We aren't anyone's authorized agent or importer, and we never appear before an appellate authority or a court. Every step stays on record in your workspace.

The CDSCO tracker: drug, device and cosmetic notices →

CDSCO notices, summarized →

- Public policy & advocacy: comments on draft rules →
- Regulatory & trade advisory →
- Industry coalitions →
- Data & analytics →
- Rule exposure audit →

Talk to our desk about CDSCO approvals Message us on WhatsApp

Frequently asked questions

What is the difference between CDSCO and the DCGI?

CDSCO is the organization; the Drugs Controller General (India), the DCGI, heads it. The DCGI is the Central Licensing Authority under the device rules and the trial rules.

Do I go to CDSCO or the state drugs controller?

It depends on the activity. Go to CDSCO for device imports, Class C and D manufacture, new drugs, trials and cosmetic imports, and to the state for Class A and B manufacture and device sales.

Can a consultant check my application status with CDSCO?

No. CDSCO says only an authorized person of the company may ask about a device application's status (device FAQ, question 11). A consultant prepares the papers; the company asks.

What happens if I don't answer CDSCO's questions on my application?

On a long-pending SUGAM application, CDSCO sends three reminders, thirty days apart, then a fourth notice rejects the application and the fee is forfeited. Its notice of January 16, 2026 set this out.

Which portal do I use for a CDSCO application?

Devices go through CDSCO's medical devices portal or the NSWS. Drugs, clinical trials and cosmetics go through SUGAM.

Can I appeal a CDSCO refusal?

For devices, yes: most refusals and cancellations under the Medical Devices Rules may be appealed to the State or Central Government within 45 days. A debarment for fake documents carries an appeal within thirty days.

Sources

- MED-13011/16/2025-eoffice: Separate provision for subsequent importer in the Online System for Medical Devices (CDSCO, September 15, 2025) (PDF, 477 KB)
- IMP-12018(19)/13/2025-eoffice: Mapping of ICEGATE with CDSCO-notified ports (letter to the National Customs Targeting Centre) (CDSCO, October 7, 2025) (PDF, 2.3 MB)
- F. No. MED-16014(12)/1/2024-eoffice-Part(2): Risk based classification list of Class A (non-sterile and non-measuring) medical devices (CDSCO, October 31, 2025) (PDF, 1.0 MB)
- MED-13/87/2025-eoffice: Requirement of a licence issued by CDSCO or State Licensing Authorities in procurement of medical devices (CDSCO, November 2025) (PDF, 467 KB)
- MED-16035/14/2025-eoffice: New provision for risk classification of medical devices on the CDSCO Online System for Medical Devices (CDSCO, December 4, 2025) (PDF, 251 KB)
- IT-11011(11)/1/2026: Disposal or rejection of long-pending applications on the SUGAM portal awaiting a reply (CDSCO, January 16, 2026) (PDF, 96 KB)
- G.S.R. 46(E): New Drugs and Clinical Trials (Amendment) Rules, 2026: prior intimation and 45 working days for test licences (Ministry of Health and Family Welfare, January 20, 2026) (PDF, 733 KB)
- CDSCO/IVD/GD/DRAFT/IMP/01/2026: Draft guidance for import of in-vitro diagnostic medical devices (for comments) (CDSCO, January 30, 2026) (PDF, 2.1 MB)
- CDSCO/MD/GD/MDSW/01/2026: Guidance Document on Medical Device Software under MDR-2017 (CDSCO, July 21, 2026) (PDF, 1.6 MB)
- G.S.R. 706(E): Drugs (Eleventh Amendment) Rules, 2026: debarment for misleading, fake or fabricated documents (Ministry of Health and Family Welfare, July 30, 2026) (PDF, 759 KB)
- G.S.R. 743(E): Medical Devices (Second Amendment) Rules, 2026: sterilization site licence number on labels and the Ninth Schedule (Ministry of Health and Family Welfare, August 14,

2026) (PDF, 799 KB)

- G.S.R. 744(E): Medical Devices (Third Amendment) Rules, 2026: European Union countries in rule 63, and QMS for Class A non-sterile, non-measuring devices (Ministry of Health and Family Welfare, August 14, 2026) (PDF, 740 KB)
- Circular No. 40/2026-Customs: Checklists for cosmetics, drugs and medical devices to be verified before out-of-charge (CBIC, September 3, 2026) (PDF, 3.3 MB)
- G.S.R. 951(E): Drugs (Thirteenth Amendment) Rules, 2026: one year of residual shelf life for imported drugs (Ministry of Health and Family Welfare, October 16, 2026) (PDF, 572 KB)
- G.S.R. 954(E): Draft amendment of rule 43A of the Drugs Rules, 1945: more inland container depots, an SEZ and an airport (Ministry of Health and Family Welfare, October 28, 2026) (PDF, 616 KB)
- G.S.R. 955(E): Draft amendment of the Drugs Rules, 1945: an authorized person for batch release (Ministry of Health and Family Welfare, October 28, 2026) (PDF, 706 KB)
- G.S.R. 956(E): Draft amendment of the Drugs Rules, 1945: suspension of product permission on a not of standard quality report until CAPA (Ministry of Health and Family Welfare, October 28, 2026) (PDF, 653 KB)
- G.S.R. 78(E): The Medical Devices Rules, 2017 (CDSCO compilation, as amended by G.S.R. 777(E) of October 14, 2022) (Ministry of Health and Family Welfare) (PDF, 1.6 MB)
- G.S.R. 763(E): The Cosmetics Rules, 2020 (Ministry of Health and Family Welfare, December 15, 2020) (PDF, 773 KB)
- The Drugs Rules, 1945 (CDSCO compilation, as amended by G.S.R. 360(E) of July 1, 2024) (Ministry of Health and Family Welfare) (PDF, 7.1 MB)
- G.S.R. 227(E): The New Drugs and Clinical Trials Rules, 2019 (CDSCO compilation, as amended by G.S.R. 778(E) of October 14, 2022) (Ministry of Health and Family Welfare) (PDF, 1.7 MB)
- CDSCO/FAQ/MD/01/2024: Medical Devices Frequently Asked Questions (CDSCO, 2024) (PDF, 507 KB)
- Act No. 23 of 1940: The Drugs and Cosmetics Act, 1940 (Parliament of India, April 10, 1940) (PDF, 686 KB)
- COS-12/1/2026-eoffice: Public notice on the use of cosmetics (injectables are not cosmetics) (CDSCO, May 18, 2026) (PDF, 335 KB)
- CDSCO/FAQ/MD/01/2024, Addendum No. 02: Addendum 02 to the Medical Devices FAQ (CDSCO, July 9, 2025) (PDF, 318 KB)
- CDSCO/FAQ/MD/01/2024, Addendum No. 03: Addendum 03 to the Medical Devices FAQ (CDSCO, November 3, 2025) (PDF, 374 KB)
- G.S.R. 515(E): Draft amendment of the Medical Devices Rules, 2017: shorter timelines for manufacturing licences (Ministry of Health and Family Welfare, June 23, 2026) (PDF, 698 KB)

- IT-11011(11)/16/2026: Disposal or rejection of long-pending applications on the SUGAM portal awaiting a reply (more divisions) (CDSCO, May 4, 2026) (PDF, 779 KB)
- Cosmetics FAQ (Cosmetics Rules, 2020): Frequently Asked Questions on Registration and Import of Cosmetics into India (CDSCO) (PDF, 518 KB)
- G.S.R. 293(E): Drugs (Third Amendment) Rules, 2024: Cochin and Thiruvananthapuram airports added to rule 43A (Ministry of Health and Family Welfare, May 28, 2024) (PDF, 717 KB)
- G.S.R. 561(E): Drugs (Ninth Amendment) Rules, 2026: Navi Mumbai airport added to rule 43A (Ministry of Health and Family Welfare, July 2, 2026) (PDF, 1.1 MB)
- Import/Misc./39/2018-DC (Pt.-12): Timelines for cargo clearances at port offices of CDSCO (CDSCO, September 10, 2021) (PDF, 1.1 MB)
- S.O. 3068(E) to S.O. 3083(E): Prohibition of 16 fixed dose combinations under section 26A (Ministry of Health and Family Welfare, June 11, 2026) (PDF, 1.4 MB)
- DCG(I)/Legal/Misc.-160/2025-DC: Public notice on compounding of offences under the Drugs and Cosmetics (Compounding of Offences) Rules, 2025 (CDSCO, January 1, 2026) (PDF, 347 KB)
- CDSCO/FAQ/CA/01/2025: FAQs on the Drugs and Cosmetics (Compounding of Offences) Rules, 2025 (CDSCO, January 1, 2026) (PDF, 368 KB)
- S.O. 3286(E): Start date of the Jan Vishwas (Amendment of Provisions) Act, 2026 for the Drugs and Cosmetics Act, 1940 (Ministry of Health and Family Welfare, June 22, 2026) (PDF, 1.0 MB)
- DC-DT-15011(11)/144/2025-eoffice: Strict compliance with the Drugs Rules, 1945 for testing of raw materials and finished formulations (CDSCO, October 27, 2026) (PDF, 830 KB)
- G.S.R. 506(E): Drugs (Seventh Amendment) Rules, 2026: more categories under Schedule H2 (Ministry of Health and Family Welfare, June 22, 2026) (PDF, 664 KB)
- G.S.R. 509(E): Draft amendment of the Drugs Rules, 1945: prior intimation in place of some Form 11 test licences (Ministry of Health and Family Welfare, June 23, 2026) (PDF, 1.2 MB)
- G.S.R. 790(E): Draft amendment of the New Drugs and Clinical Trials Rules, 2019: prior intimation for some BA/BE studies beyond export (Ministry of Health and Family Welfare, September 3, 2026) (PDF, 681 KB)
- COS-13011/4/2026-eoffice: Compliance of imported and manufactured hair color products with the Cosmetics Rules, 2020 and BIS standards (CDSCO, June 10, 2026) (PDF, 349 KB)

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