
October 9, 2026

CDSCO

CDSCO drafts a guide to IVD manufacturing licences

A CDSCO draft guidance sets out the documents, fees, timelines and inspections for licences to manufacture in-vitro diagnostic medical devices in India.

THE CENTRAL DRUGS Standard Control Organisation (In-Vitro Diagnostic Division), under the Directorate General of Health Services, has placed a draft guidance document for manufacturers of in-vitro diagnostic (IVD) medical devices in the public domain, No. CDSCO/IVD/GD/DRAFT/MFG/01/2026. The 59-page document explains what to furnish in each section of a

manufacturing licence application made through the Online System for Medical Devices (cdscomonline) and the National Single Window System (NSWS) portal. Stakeholders are asked to send comments and suggestions within 15 days from the date of publication, through a Google Form linked in the document. CDSCO published the draft on October 9, 2026, so comments are due by October 24, 2026.

KEY FACTS**AUTHORITY****CDSCO**

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The draft is aimed at domestic manufacturers of IVD medical devices and explains their obligations under the Medical Devices Rules, 2017 and the Drugs and Cosmetics Act, 1940. It gives 57 key definitions and the four risk classes: Class A (low risk), Class B (low moderate risk), Class C (moderate high risk) and Class D (high risk). The Central Licensing Authority, through CDSCO, grants manufacturing licences for Class C and Class D devices; the State Licensing Authority grants them for Class A and Class B. A notice states that the document is meant for public awareness and not for legal or professional purposes.

The draft lists the licence types. Applications for Class A and B devices are made in Form MD-3 (manufacturing licence) or Form MD-4 (loan licence) to the State Licensing Authority; for Class C and D devices in Form MD-7 or Form MD-8 to the Central Licensing Authority; and for a test licence, for all classes, in Form MD-12 to the Central Licensing Authority. Forms MD-3, MD-4, MD-7 and MD-8 go through cdscomdonline, and Form MD-12 through NSWS. A manufacturing licence remains valid in perpetuity if the retention fee is paid before five years from its date of issue.

Most of the draft explains the documents for each application. For Forms MD-7 and MD-8 these include a covering letter with a breakup of the fee, constitution details, a site or plant master file, the quality management system under the Fifth Schedule, an undertaking of compliance, regulatory certificates such as a valid ISO 13485 certificate, if any, and a device master file in 18 parts. The parts cover, among others, the essential principles checklist, risk analysis, analytical performance, stability studies on at least three lots, clinical evidence, labeling and performance evaluation reports for three batches.

The draft gives processing timelines of 45 days for Forms MD-3/4 and 105 days for Forms MD-7/8. For Class A devices, no audit is needed before the licence is granted, and a registered Notified Body audits the site within 120 days of the grant. For Class B, the Notified Body audit is carried out within 90 days from the date of application. For Class C and D, the site is inspected within 60 days from the date of application under Rule 23, by a team of at least two Medical Device Officers. Licensed sites may also be inspected after the grant.

Issued by	Central Drugs Standard Control Organisation, In-Vitro Diagnostic Division
Document	Draft guidance document, No. CDSCO/IVD/GD/DRAFT/MFG/01/2026
Length	59 pages, with checklists in an annexure
Comments	By October 24, 2026 (15 days from publication on October 9, 2026), through a Google Form
Applies to	Manufacturers of IVD medical devices applying for manufacturing, loan and test licences
Legal basis	Medical Devices Rules, 2017 and Drugs and Cosmetics Act, 1940
Timeline, Form MD-3/4	45 days
Timeline, Form MD-7/8	105 days
Licence validity	In perpetuity, if the retention fee is paid before five years from the date of issue

Fees under the Medical Devices Rules, 2017, as listed in the draft

Rule	Subject	In rupees (INR)
20(2)	Manufacturing Licence or Loan Licence, Class A or Class B IVD: one site	500/-
20(2)	Manufacturing Licence or Loan Licence, Class A or Class B IVD: each distinct medical device	500/-
21(2)	Manufacturing Licence or Loan Licence, Class C or Class D IVD: one site	50000/-
21(2)	Manufacturing Licence or Loan Licence, Class C or Class D IVD: each distinct IVD medical device	1000/-
29(1)	Retention fee: one site manufacturing Class A or Class B IVD	5000/-
29(1)	Retention fee: one site manufacturing Class C or Class D IVD	50000/-
29(1)	Retention fee: each distinct IVD of Class A or Class B	500/-
29(1)	Retention fee: each distinct IVD of Class C or Class D	1000/-
31(1)	Test Licence, for each distinct IVD medical device	500/-

[The draft guidance document](#) (PDF, 1.5 MB)

Source: [CDSCO's own copy](#).

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