July 21, 2026

CDSCO

CDSCO publishes final guidance on medical device software

CDSCO's guidance CDSCO/MD/GD/MDSW/01/2026 sets out when software is a medical device under the MDR-2017, how it is classed A to D, and how it is licensed.

THE CENTRAL DRUGS Standard Control Organization (CDSCO), Medical Devices and IVD Division, issued its Guidance Document on Medical Device Software, Doc No. CDSCO/MD/GD/MDSW/01/2026, with a circular dated July 21, 2026 (F. No. MED-16028/2/2025-eoffice) signed by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India). The circular says a draft was published for comments on October 21, 2025. The guide covers software, IVD software included, that meets the medical device definition under the Drugs & Cosmetics Act, 1940 and the Medical Devices Rules, 2017 (MDR-2017). It says it reflects current practice and "should not be misconstrued as a new regulatory control", and is for public awareness, not for legal or professional purposes. It sets no start date, and it refers to the MDR-2017 for fees and processing timelines.

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Guidance Document on Medical Device Software, Doc No. CDSCO/MD/GD/MDSW/01/2026, with Circular F. No. MED-16028/2/2025-eoffice

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Software is a medical device when its maker intends it for a medical purpose under the MDR-2017 definition, such as diagnosis, prevention, monitoring or treatment of a disease; mitigation and prediction may also count. That covers standalone software, software embedded in or driving a hardware device, mobile apps, cloud or network-based software, AI/ML software and software for animals. Software, mobile apps and cloud software included, that can control or adjust a device over a physical or wireless link, such as Bluetooth or Wi-Fi, is a device. Embedded software sold separately from its hardware needs its own licence; when it is part of the device, it may be registered or licensed with the parent device. Its examples include CAD software that analyzes X-ray images or ECGs and an AI/ML tool for triage or screening of cancer lesions.

General wellness software is outside the rules, provided its intended use makes no reference to a disease, disorder or pathological condition. So is software with no medical purpose. The guide's examples are ERP and quality-system software, software that only transfers, stores, converts or encrypts data, teaching tools, general communication systems, and hospital, clinical, laboratory and image management systems that manage data. A hospital, clinical, laboratory or image management system may be a device if it has added functions for a medical purpose, such as image analysis as an aid in diagnosis or real-time patient monitoring. Software that measures or reports physiologic values for screening, diagnosis, monitoring, alerting or managing a disease is not general wellness software.

Classes run from A (low risk) to D (high risk), by intended use under the First Schedule of the MDR-2017. Software that drives or influences a hardware device takes that device's class. Standalone software may follow the guide's Table 2, by how serious the condition is and whether the output treats or diagnoses, drives or informs clinical management. Standalone software for non-clinical users in a serious condition, without specialist support, may be treated as used in a critical one. CDSCO's Central Licensing Authority (CLA) confirms the class and publishes a list of classified software; if the software is not listed, the applicant may apply for its class on the MD

Online portal. The quality system rests on the Fifth Schedule, IS/IEC 62304, IS/ISO 14971 and IS/IEC 82304-1. Makers should keep and periodically update a software bill of materials, ideally covering third-party, open-source and commercial components, and monitor, assess and mitigate their known vulnerabilities. Safeguards include encryption in transit and at rest, access control and audit trails.

Imports of every class are licensed by the CLA, on an application in Form MD-14. The import checklist includes a Power of Attorney with the authorized agent's undertaking, a notarized quality management system (QMS) certificate, and plant and device master files. Class A non-sterile, non-measuring devices need only registration. Test licences go through the National Single Window System (NSWS); all other applications go to the MD Online portal. Software with no suitable predicate may be treated as an investigational device or new IVD, needing CLA permission for clinical investigation and for import or manufacture. For AI-based software, applicants must disclose the make-up of their training, validation and test datasets, and justify how models trained or validated outside India apply to Indian clinical settings. Major changes, such as a version change that affects intended use or safety, need the licensing authority's approval; minor ones are notified.

Issued by	Central Drugs Standard Control Organization (CDSCO), Medical Devices & IVD Division, Directorate General of Health Services, Ministry of Health and Family Welfare
Document	Guidance Document on Medical Device Software, Doc No. CDSCO/MD/GD/MDSW/01/2026, with Circular F. No. MED-16028/2/2025-eoffice
Dated	July 21, 2026, the date stamped on the circular; the guide itself prints no date
Applies to	Software, including IVD software, that meets the medical device definition under the MDR-2017; manufacturers, importers and innovators or researchers
Takes effect	No date given; the guide reflects current practice under the MDR-2017 and is not a new regulatory control
Draft	Published for comments under File No. MED-16028/2/2024-eoffice dated October 21, 2025
Risk classes	A (low), B (low moderate), C (moderate high), D (high)
Import licence	Application in Form MD-14 to the Central Licensing Authority, for Classes A, B, C and D; Class A non-sterile, non-measuring devices need only registration

Where to apply	Test licences on NSWS (www.nsws.gov.in); all other applications on the MD Online portal (www.cdscomdonline.gov.in)
Quality system	Fifth Schedule, MDR-2017; IS/IEC 62304, IS/ISO 14971 and IS/IEC 82304-1; a software bill of materials kept up to date
SaaS	Applicants say whether the SaaS is hosted on a cloud server empanelled by MeitY; cloud hosting risk is assessed case by case
Adverse events	Suspected unexpected serious adverse events, and action taken, reported within 15 days
Length	92 pages: the circular, the guide (a cover, an index and 62 numbered pages) and its Annexure A document checklists
Signed by	Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India), on the circular

Risk class of standalone medical device software (the guide's Table 2)

State of healthcare situation or condition	Treatment or diagnosis	Drive clinical management	Inform clinical management
Critical	D	C	B
Serious	C	B	A
Non-serious	B	A	A

The guidance document (PDF, 1.6 MB)

Source: CDSCO's own copy.

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