MedTech Spectrum

EMPOWERING MEDTECH ECOSYSTEM

INDIA REGULATORY REFERENCE SERIES

CDSCO GUIDANCE DOCUMENT · JULY 2026

Software Becomes a Device

India has published its first full rulebook for Medical Device Software. What it covers, how it classifies risk, what the AI and digital health clauses actually demand, and the decisions every manufacturer now has to make.

INSTRUMENT	ISSUED	AUTHORITY
CDSCO/MD/GD/MDSW/01/2026	21 July 2026	DCG(I), CDSCO

REFERENCE EDITION

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A working guide to the Central Drugs Standard Control Organization's guidance on Medical Device Software, written for people who have to act on it.

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HOW TO USE THIS DOCUMENT

This is an independent editorial reference prepared by MedTech Spectrum. It summarises and interprets a public guidance document; it is not the guidance itself and it is not legal or regulatory advice. Every submission decision should be taken against the statutory text of the Drugs and Cosmetics Act, 1940, the Medical Devices Rules, 2017, and the current guidance published by CDSCO. Where this document paraphrases, the source guidance governs.

SECTION 01

The moment the rulebook arrived

India has regulated software as a medical device since 2020. What it did not have, until now, was a manual.

On 21 July 2026, the Drugs Controller General of India signed a short circular with long consequences. Under file number MED-16028/2/2025-eoffice, CDSCO's Medical Devices Division released the final **Guidance Document on Medical Device Software**, catalogued as CDSCO/MD/GD/MDSW/01/2026 and addressed to every State and Union Territory licensing authority, plus all stakeholders through the CDSCO website.

The legal hook is not new. Gazette Notification S.O. 648(E) of 11 February 2020 pulled all medical devices under the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017. Software intended for medical purposes was inside that net from the start. What has been missing for six years is the operating manual: how CDSCO reads the definition, where the boundary sits between a clinical tool and a hospital utility, which risk class a diagnostic algorithm lands in, and what a dossier for a cloud-hosted product is supposed to contain.

That gap is now closed. A draft went out for public comment on 21 October 2025 under file MED-16028/2/2024-eoffice. Comments were reviewed with experts, and the final text runs to 62 pages plus a full annexure of application checklists. CDSCO is explicit that this reflects current practice under MDR-2017 rather than a new layer of control. In practice, though, a great deal that was previously negotiated case by case is now written down.

62
pages of guidance, plus fifteen application checklists in Annexure A

4
risk classes, from Class A low risk to Class D high risk

2
submission portals: NSWS for test licences, MD Online for everything else

15
days to report a suspected unexpected serious adverse event

Four things that changed on the ground

Qualification became testable. The guidance sets out worked examples on both sides of the line, from pacemaker firmware to behaviour change platforms to hospital information systems. Companies that have been arguing they sit outside MDR-2017 now have to argue against a published list.

Standalone software got its own risk grid. Rather than reasoning by analogy to hardware, CDSCO has adopted a matrix that reads the significance of the information a product provides against the seriousness of the healthcare situation it is used in. It resolves cleanly to Class A, B, C or D.

AI moved from footnote to framework. Algorithm change protocols, model drift, dataset composition disclosure, bias evidence across Indian sub populations, and a named requirement to monitor for AI hallucination in post market surveillance. These are not general gestures at good practice; they sit inside the documentation expectations.

India specificity became a submission requirement. Alignment with the Ayushman Bharat Digital Mission, compliance with the Digital Personal Data Protection Act, 2023, disclosure of whether a cloud product sits on a MeitY empanelled server, usability validation that reflects Indian clinical workflows, and justification when a model was trained or validated somewhere else. This is the part global players will feel most.

The change is not that software is regulated. It is that the regulator has now said, in writing, exactly how it will be read.

WHERE THE APPLICATIONS GO

Test licences are filed through the National Single Window System at nsws.gov.in. **Everything else**, meaning commercial permissions, manufacturing and import licences, and registration for sale and distribution, goes through the Online System for Medical Devices at cdscomdonline.gov.in. Getting this wrong costs weeks.

SECTION 02

Does your software count?

Not everything running in a hospital is a medical device. The guidance is unusually clear about where the line falls, and unusually clear about how easily it moves.

Medical Device Software, abbreviated MDSW throughout the guidance and inclusive of in vitro diagnostic software unless stated otherwise, is software intended by its manufacturer for a medical purpose. Those purposes are the ones already written into the definition of a medical device: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation or assistance for injury or disability; investigation, replacement, modification or support of anatomy or a physiological process; supporting or sustaining life; disinfection of medical devices; and control of conception. CDSCO adds a note that mitigation, prediction and alleviation of a disease or pathological condition may also count.

Two shapes qualify. **Standalone software** performs one or more medical purposes without needing a hardware device to achieve them. **Embedded or driving software** is part of the device hardware, or operates, modifies the state of, or controls it, or supplies output relating to how it functions. Firmware sold separately from its parent device needs its own licence. Firmware supplied with the device can usually be registered or licensed alongside it as a component or accessory.

Three clarifications matter commercially. Software written for veterinary medical purposes is MDSW. Mobile apps, AI and machine learning software, and cloud or network based software all qualify if they meet the definition. And all MDSW is treated as an active medical device, because it depends on an energy source other than the human or animal body or gravity.

INSIDE MDR-2017

- Firmware embedded in a cardiac pacemaker, regulated as a component of that pacemaker
- Embedded software that drives an insulin pump to deliver a calculated dose
- Operating software built into a clinical analyser, point of care analyser or personal glucose meter
- Software supplied separately that operates or influences an IVD analyser, treated as a distinct IVD
- An app connecting by Bluetooth to a blood pressure cuff to track readings for medical purposes
- Image analysis of body fluid preparations or digital slides for cell count and morphology review
- Computer aided detection software analysing X ray images or ECGs to suggest or exclude conditions
- An AI or ML tool for triage or screening of cancer lesions
- An IoT platform working with connected devices such as smart glucometers, offering real time analytics and interventions
- Behaviour change and digital therapeutics platforms intended to mitigate progression of chronic disease
- Veterinary radiological image analysis and veterinary device operation software

OUTSIDE MDR-2017

- ERP and other software automating design, manufacturing, labelling, packaging, distribution or complaint handling
- Software using device data without a medical purpose, such as encryption for transmission
- Software monitoring device performance for servicing purposes
- Software altering data representation for cosmetic or compatibility reasons
- Software solely for medical teaching, training or education
- Transfer, storage, archiving, conversion, formatting, communication, simple search and compression
- HIS and CIS limited to admission, scheduling, insurance and billing, clinical communication, and storing or transferring patient information
- General purpose communication systems including email, telecom, video and paging
- LIS whose main use is managing and validating incoming information from connected IVD analysers
- Image Management Systems networked with digital pathology to access, display, annotate, store, archive and share images
- General wellness software, subject to the limits described below

THE CARVE OUTS ARE CONDITIONAL, NOT PERMANENT

If a hospital or laboratory information system, or an image management system, gains any function that serves a medical purpose, it can become a medical device. CDSCO names the triggers: image analysis or modification as an aid to diagnosis, quantification of physiological parameters for clinical decision making, and real time patient monitoring. A single feature release can move a product across the line.

Wellness software has a similar trapdoor. It may claim to sustain or improve functions associated with a general state of health, but it must not refer to diseases, disorders or pathological conditions. Software intended to measure, estimate or report physiologic values for medical or clinical purposes, including screening, diagnosis, monitoring, alerting or management of a disease, is not general wellness software.

Commercial off the shelf components and non device functions

Commercial off the shelf software that meets the definition is MDSW. If it has no medical purpose it may sit outside MDR-2017, but where it forms part of a larger MDSW framework the manufacturer should submit a justification covering its role and its impact on the safety and efficacy of the MDSW function. The same logic applies to systems that mix regulated and unregulated features: the non device functions may not be subject to regulatory review, yet the manufacturer still has to clarify their impact on the safety and effectiveness of the regulated function.

SECTION 03

The sentence that decides everything

The intended use statement is the single highest leverage paragraph in the entire dossier. It sets the risk class, and the risk class sets the authority, the evidence and the timeline.

CDSCO asks for an intended use statement that is clinically meaningful and that defines the clinical role of the software plainly, whether it is decision support, whether it drives a device, or whether it delivers a definitive diagnosis or treatment recommendation. The statement is drawn from what the manufacturer says in labelling, instructions for use and promotional material, which means marketing copy and regulatory filings have to agree with each other.

Eight elements are named. Not all apply to every product, and some information, contraindications for instance, may sit elsewhere in the file.

ELEMENT	WHAT IT HAS TO ESTABLISH
Medical purpose	Diagnosis, prevention, screening or triage, monitoring, mitigation, prediction, treatment
Disease or condition	Which condition is targeted, and whether the situation is critical, serious or non serious. The state of the condition, chronic or acute, should be considered
Patient population	General population, or a specific subgroup such as paediatric or geriatric, a specific age group, or a specific ethnicity
Intended users	Non clinical users without medical qualification, or named professional categories from nurses and radiologists to specialist physicians
Use environment	Home use, primary or virtual primary care, hospital, specialty clinic
Contraindications	Conditions and comorbidities where the software should not be used, or may return erroneous results
Software function	Inputs and their sources, outputs and their formats, and an explanation of how both fit the clinical workflow. Output limitations must be stated explicitly, including how much clinical decision making stays with the professional
Software platform	General purpose consumer devices such as smartphones and watches, cloud based networks, or an interface with hardware

Additional elements for IVD software

Diagnostic software carries six further requirements: the analyte or parameter being analysed; the specimen type; the intended diagnostic level, whether screening, diagnosis aid, disease staging, prognosis or monitoring; limitations on intended use, including conditions, comorbidities, medications or analyte variants that may produce erroneous results; whether results are quantitative, semi quantitative or qualitative; and whether the software is intended for self testing or near patient testing.

WHY THIS IS THE LEVERAGE POINT

The risk class of an MDSW is fundamentally based on its intended use. That single fact determines whether a manufacturing licence comes from a State authority or the Central authority, how much clinical evidence is expected, whether a clinical investigation is required at all, and how heavy the post market obligations become. Two products with near identical code can sit in different classes because their intended use statements are written differently. Draft that paragraph last, after the regulatory strategy is settled, not first.

Proving substantial equivalence

Where a predicate exists, the applicant submits a structured comparison in tabular form between the proposed software and the predicate MDSW. CDSCO lists eleven minimum parameters, and requires a scientific justification wherever differences appear, demonstrating that those differences do not adversely affect safety, performance or effectiveness.

COMPARATIVE PARAMETER	REQUIRED INFORMATION, PREDICATE VERSUS PROPOSED
Intended use	Clinical purpose, indications and scope of use
Risk classification	Class under the First Schedule of MDR-2017, with justification
Design characteristics	Software architecture, AI or ML versus rule based system, algorithm type
Platform	Cloud, on premise, mobile, embedded
Input data	Type, source and format of inputs required
Output characteristics	Diagnostic, predictive, decision support
Target intended user	Clinicians, technicians, patients, general population, with age groups where available
Use environment	Hospital, primary health care, tertiary care, homecare
Training methodology	AI or ML training models and datasets used, where applicable
Standards compliance	National and international standards followed
Performance metrics	Sensitivity, specificity, accuracy, robustness

NO PREDICATE MEANS A DIFFERENT ROUTE ENTIRELY

Where no suitable predicate exists because the technology is novel, the product may be treated as an investigational medical device or a new IVD. That triggers prior permission from the Central Licensing Authority for clinical investigation or clinical performance evaluation, and for import or manufacture ahead of marketing. Companies bringing genuinely first in class algorithms into India should plan for this pathway from the outset rather than discovering it at filing.

SECTION 04

Risk classification, decoded

Rule 4 of MDR-2017 gives four classes. For standalone software, a three by three matrix does the work.

All medical devices, software included, are classified by degree of risk: Class A is low risk, Class B low moderate, Class C moderate high and Class D high. Classification follows the parameters in the First Schedule of MDR-2017, and where several rules apply to the same device, the strictest rule and the higher classification prevail.

Software that drives or influences a hardware device takes the same class as that hardware. Device operation software and image output generation and processing software are the examples given. Standalone software is where the new matrix applies. Two questions decide it: how significant is the information the software provides to a healthcare decision, and how serious is the situation it is used in.

RISK CLASSIFICATION OF STANDALONE MDSW

HEALTHCARE SITUATION	TREATMENT OR DIAGNOSIS	DRIVE CLINICAL MANAGEMENT	INFORM CLINICAL MANAGEMENT
Critical Accurate or timely action is vital to avoid death, long term disability or serious deterioration	D	C	B
Serious Accuracy matters to avoid unnecessary intervention or long term irreversible consequences	C	B	A
Non serious Accurate diagnosis and treatment are important but not critical to avoiding irreversible harm	B	A	A

Reading the columns

Treatment or diagnosis means the information will be used for an immediate or near term action: treating, preventing or mitigating by connecting to other devices, medicinal products or actuators; or diagnosing, screening or detecting a disease or condition using sensors and data.

Drive clinical management means the information aids treatment or diagnosis, triages, identifies early signs, or guides the next diagnostic step or treatment intervention. It includes aiding diagnosis by analysing information to predict risk or support a definitive diagnosis.

Inform clinical management means no immediate or near term action is triggered. The software informs on options for treating, diagnosing, preventing or mitigating a condition, or provides clinical information by aggregating relevant data.

Reading the rows

A **critical** situation involves a life threatening condition, including incurable states, one requiring major therapeutic intervention, or one that is time critical, meaning progression may affect the user's ability to reflect on the output. The population is fragile with respect to the condition, and the software is intended for specialised trained users.

A **serious** situation involves a condition that is moderate in progression and often curable, does not need major therapeutic intervention, and is not time critical, so the user can detect an erroneous recommendation. The population is not fragile, and users may be specialists or non clinical.

A **non serious** situation involves slow, predictable progression, manageable if not curable, needing only minor and mostly non invasive intervention, with users again either specialised or non clinical.

THE ESCALATION CLAUSE WORTH READING TWICE

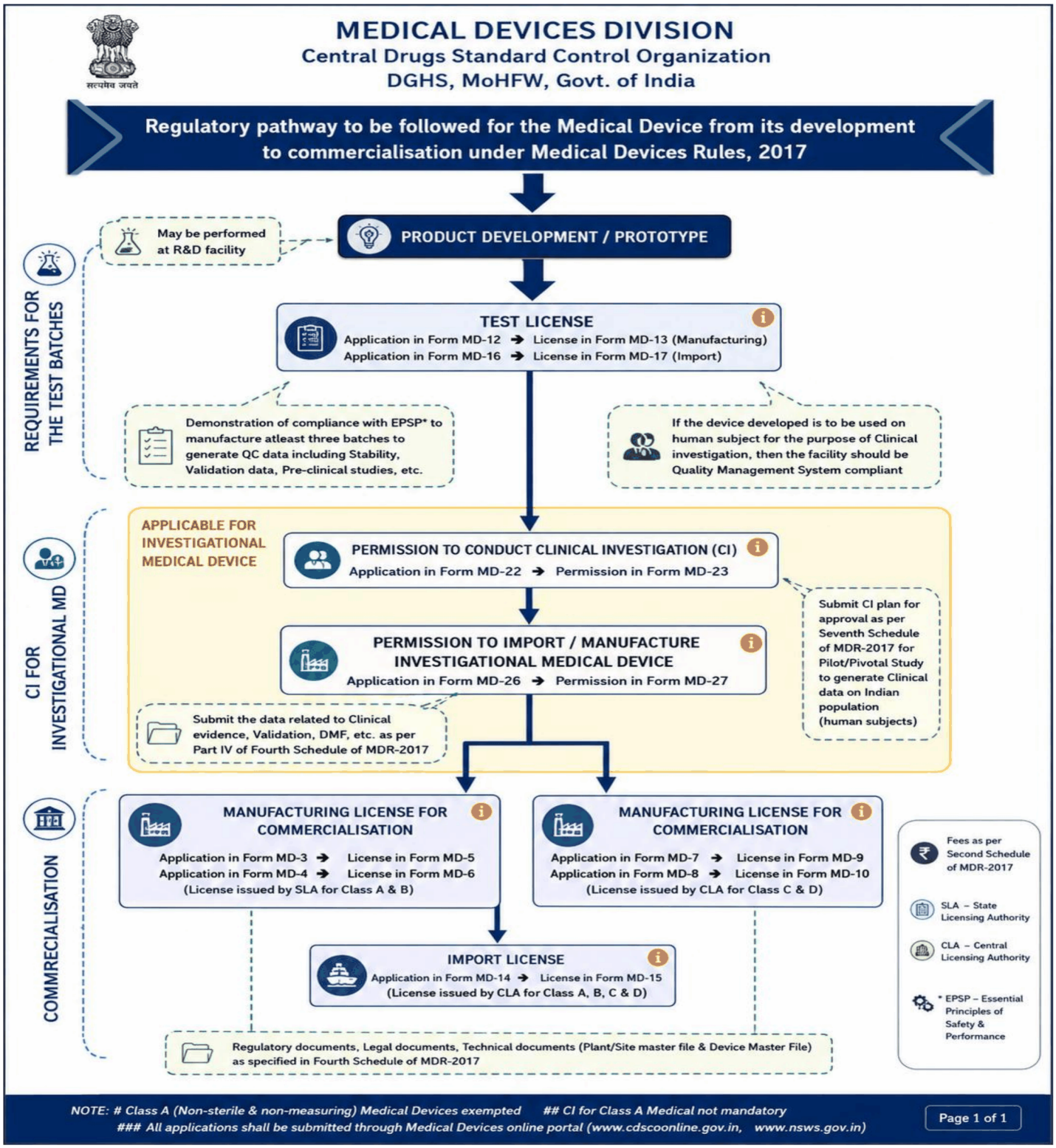
Standalone software intended for non clinical users in a serious situation, without support from specialised professionals, may be treated as software used in a critical situation. That single note can push a consumer facing product from Class C to Class D, or from Class B to Class C, and with it move the licence from a State authority to the Central authority. Any product whose route to market is direct to patient should model both outcomes before committing to a launch plan.

CHECK THE PUBLISHED LIST FIRST

Exercising powers under sub rule (3) of Rule 4, CDSCO has already classified a list of MDSW, published on the Online System for Medical Devices and revised from time to time. Applicants should check whether their product is listed, and if a listed product shares the same intended use, that classification may be followed. Where a product is not listed, an application can be filed on the MD Online portal to obtain a risk class determination. Risk class is confirmed by the Central Licensing Authority on review of intended use and design characteristics.

SECTION 05 · REGULATORY PATHWAY, PLATE ONE

Medical Device Software: development to commercialisation

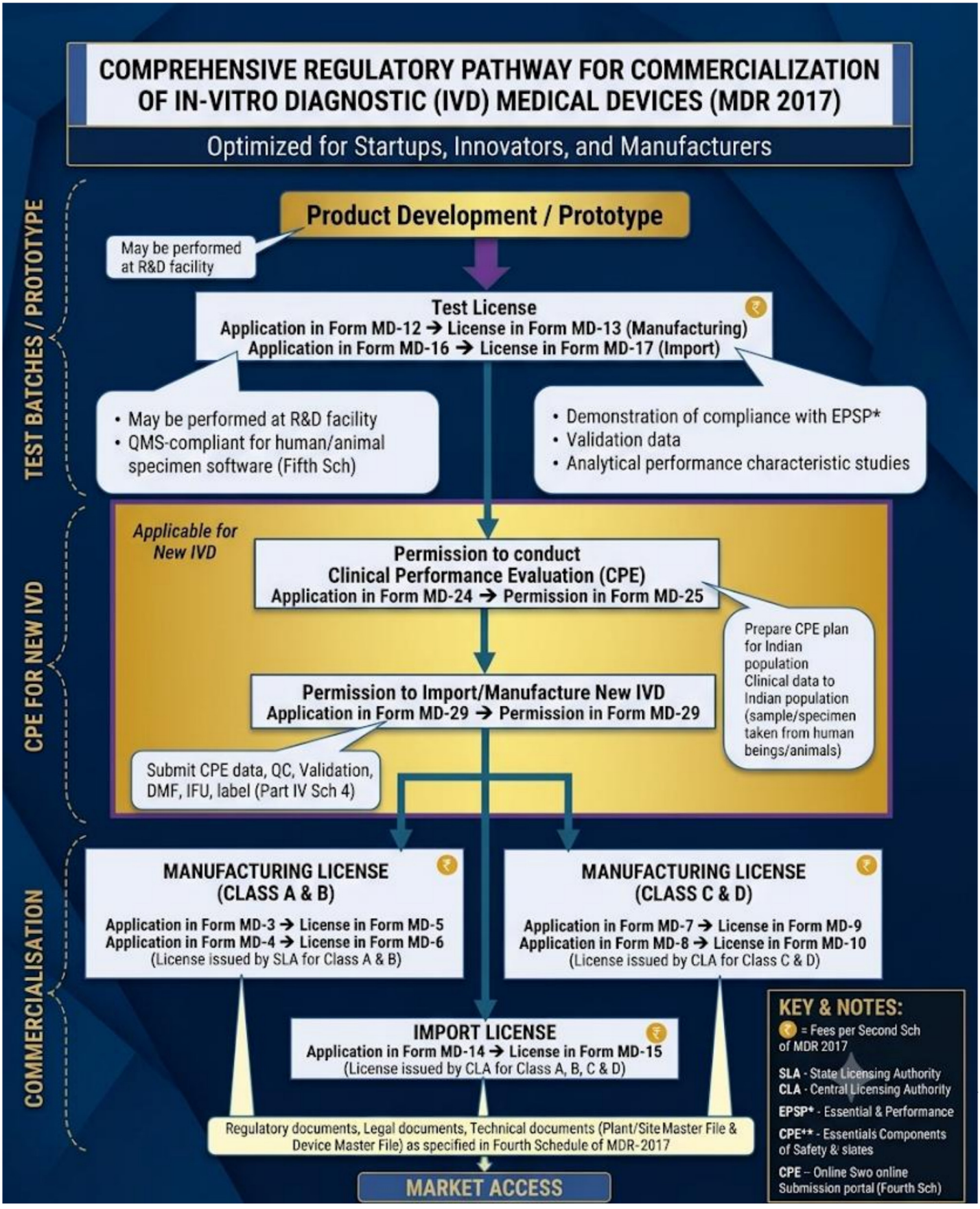


Reading the chart. Three bands, top to bottom. The first covers test batches, where a test licence is obtained in Form MD-13 for manufacturing or Form MD-17 for import, and where the facility must be quality management system compliant if the device will be used on human subjects in a clinical investigation.

The middle band applies only to investigational medical devices: clinical investigation permission in Form MD-23, then manufacture or import permission in Form MD-27. The bottom band is commercialisation, with Class A and B manufacturing licences from the State authority, Class C and D from the Central authority, and all import licences central in Form MD-15.

Source: Guidance Document on Medical Device Software, Doc No. CDSCO/MD/GD/MDSW/01/2026, Figure 1. Central Drugs Standard Control Organization, Medical Devices and IVD Division, Ministry of Health and Family Welfare, Government of India. Reproduced for reference.

IVD Medical Device Software: development to market access



What differs here. Test batch work may be performed at an R and D facility, but software handling human or animal specimens must be quality management system compliant under the Fifth Schedule, and the evidence set includes analytical performance characteristic studies alongside validation data.

For a new IVD, permission to conduct a clinical performance evaluation is sought in Form MD-24 and granted in Form MD-25, with an evaluation plan built for the Indian population using specimens taken in India. Commercialisation then follows the same split as Figure 1.

Source: Guidance Document on Medical Device Software, Doc No. CDSCO/MD/GD/MDSW/01/2026, Figure 2. Central Drugs Standard Control Organization, Medical Devices and IVD Division, Ministry of Health and Family Welfare, Government of India. Reproduced for reference.

SECTION 07

Who licenses what

The split between Central and State authority is the most practical page in the guidance. It decides who you deal with, and for how long.

MDSW must be licensed for manufacture or import before it can be commercialised. Which authority issues that licence depends on the class, and the pattern is not uniform across permission types. Test licences and import licences always sit centrally. Manufacturing licences split at the B to C boundary. Sale and distribution always sits with the State.

LICENSING AUTHORITY BY PERMISSION TYPE AND CLASS

LICENCE OR PERMISSION UNDER MDR-2017	CLASS A	CLASS B	CLASS C	CLASS D
Test licence	CLA	CLA	CLA	CLA
Manufacturing licence	SLA	SLA	CLA	CLA
Import licence	CLA	CLA	CLA	CLA
Clinical investigation of investigational device, or clinical performance evaluation of new IVD	CLA	CLA	CLA	CLA
Permission to manufacture investigational device or new IVD	CLA	CLA	CLA	CLA
Sale and distribution	SLA	SLA	SLA	SLA
Market standing certificate or non conviction certificate, manufacturing	SLA	SLA	CLA	CLA
Market standing certificate or non conviction certificate, import	CLA	CLA	CLA	CLA
Free sale certificate, manufacturing only	SLA	SLA	CLA	CLA
Special code, neutral code or risk classification	CLA	CLA	CLA	CLA

CLA is the Central Licensing Authority; SLA is the State Licensing Authority. Processing timelines for each application type are set out in MDR-2017. Class A devices that are non sterile and non measuring are exempt from licensing and require registration only, under Chapter IIIB of MDR-2017.

The forms, in sequence

STEP	APPLY IN	RECEIVE
Test licence to manufacture, not for commercialisation	Form MD-12, NSWS portal, Rule 31	Form MD-13
Test licence to import, not for commercialisation	Form MD-16, NSWS portal, Rule 40	Form MD-17
Permission to conduct clinical investigation	Form MD-22, MD Online	Form MD-23
Permission to conduct clinical performance evaluation, new IVD	Form MD-24, MD Online	Form MD-25
	Form MD-26, MD Online	Form MD-27

Permission to manufacture or import an investigational device		
Permission to manufacture or import a new IVD	Form MD-28, MD Online	Form MD-29
Manufacturing licence, Class A and B	Form MD-3 or MD-4, State authority	Form MD-5 or MD-6
Manufacturing licence, Class C and D	Form MD-7 or MD-8, Central authority	Form MD-9 or MD-10
Import licence, all classes	Form MD-14, MD Online	Form MD-15

WHAT A SOFTWARE DOSSIER HAS TO CONTAIN

Beyond the legal documents, the technical file is built around a Device Master File and a Site or Plant Master File. For software, the site file describes infrastructure and work environment: equipment, information and communication networks, tools and physical facilities supporting development, production and maintenance, plus an organisation chart and personnel qualifications. The device file carries software architecture, software requirement specifications describing what the product is supposed to do, software design specifications describing how those requirements are implemented, source code management, version control, release management and lifecycle protocols. Where any checklist item is not applicable, a written rationale is required rather than a blank.

SECTION 08

The India layer

This is the part of the guidance with no international equivalent, and the part most likely to surprise a company arriving with a CE marked or FDA cleared product.

A global dossier will not simply transfer. The guidance embeds a set of requirements that are specific to India's digital health architecture, its data protection statute, its cloud procurement framework and its clinical realities. Taken together they form a distinct compliance layer that has to be built, not translated.

Alignment with the Ayushman Bharat Digital Mission

Where MDSW, including AI based systems, creates, processes, exchanges, analyses or displays patient health information, developers and implementers should align with the ABDM framework. That means interoperable, standards based data exchange, consent based access to health records, privacy and confidentiality protections, secure health information exchange, and integration with ABDM building blocks where applicable: the Ayushman Bharat Health Account, the Health Facility Registry and the Healthcare Professional Registry.

The guidance is more specific still for diagnostics. In vitro diagnostic systems, digital pathology solutions, radiology AI systems and diagnostic decision support software deployed inside healthcare facilities should be designed to support ABDM compliant health record generation and exchange, maintain patient consent controls, and enable traceability of diagnostic outputs to registered facilities and authorised healthcare professionals.

DIGITAL HEALTH ECOSYSTEM REQUIREMENTS

REQUIREMENT	EXPECTATION FOR MDSW, INCLUDING AI BASED SYSTEMS
Interoperability	Adopt standards based data exchange and integration mechanisms
Consent based data governance	Ensure transparent, consent driven access to and use of health data
Secure information exchange	Implement robust cybersecurity and secure data sharing controls
Privacy and confidentiality	Protect personal health information across the software and AI lifecycle
Digital traceability and accountability	Maintain auditable records and traceability of users, facilities and AI enabled clinical transactions

Data protection is now a device requirement

Consent driven access to health data must be authorised, transparent and compliant with the Digital Personal Data Protection Act, 2023, aligned with applicable regulatory, legal and ethical requirements. Manufacturers are required to implement encryption in transit and at rest, access control mechanisms, audit trails and traceability, and protection of patient data integrity and confidentiality. Privacy protection is expected across the whole AI lifecycle, from data collection through model development, deployment, monitoring and post market surveillance.

Cloud hosting and the MeitY question

For Software as a Service, risk assessment relating to cloud hosting is conducted case by case, and the applicant should state whether the service is hosted on a cloud server empanelled by the Ministry of Electronics and Information Technology. Baseline security controls for hosted environments are expected, ensuring confidentiality, integrity and availability of safety relevant data and functions. On premises deployments carry their own case by case assessment

covering local hosting environment, infrastructure, network security, system maintenance, access controls, backup and recovery, and software updates.

Where models are trained or validated in non Indian settings, justification shall be provided for applicability to Indian clinical environments.

Evidence generated somewhere else

That sentence, taken from the verification and validation requirements, is the crux. Performance evidence generated outside India may be supplemented with validation in representative Indian populations, conducted in the intended clinical environments and demonstrating safety, effectiveness and robustness under local conditions of use. Manufacturers of AI enabled MDSW intended for use in India should show that device performance has been evaluated in at risk populations, healthcare settings and operational environments representative of the intended use. Where relevant, they should assess and mitigate clinically significant differences in performance across demographic, geographic, linguistic and healthcare system contexts.

Usability, on Indian terms

Usability validation should reflect Indian clinical workflows and operational conditions. Three factors are named: language and interface accessibility, variability in operator training and expertise, and infrastructure constraints in healthcare facilities. Manufacturers are also required to evaluate device performance across relevant populations, healthcare settings and operational environments to support safe and equitable use in the Indian healthcare ecosystem.

> **THE PRACTICAL READ**
>
> For an international manufacturer, three work streams are now unavoidable and none of them is quick. An ABDM integration and consent architecture assessment. A DPDP-2023 gap analysis covering the full data lifecycle, not just storage. And an India validation plan with real specimens, real sites and real users, designed early enough that it runs alongside the dossier rather than after a query letter. Companies that treat these as post approval commitments will find them raised at review.

SECTION 09

Rules written for AI

The guidance does not treat machine learning as an edge case. It builds explicit machinery for models that change after they ship.

CDSCO opens by acknowledging what makes software different: direct patient benefit and risk are not always present; products deploy across many hardware platforms; they interconnect with other systems and datasets; development cycles are rapid and changes frequent; updates are often left to the user to install; deployment happens at scale and pace outside the manufacturer's control; and information security has direct safety consequences. Risk management, built on IS/ISO 14971 and its software companions, has to run across the total product lifecycle rather than at a point in time.

The Algorithm Change Protocol

Where the nature and risks of the product warrant it, an Algorithm Change Protocol may be devised and submitted as part of the Risk Management File. The ACP sets out the procedures that ensure changes do not compromise safety or intended use, and CDSCO names five components.

ACP COMPONENT	CONTENTS
Data management plan	Data management protocol, risk assessment plan, new data collection protocols and quality assurance process
Performance evaluation and monitoring plan	Assessment metrics, statistical analysis plan, assessment frequency, performance targets and post market monitoring overview
Algorithm retraining plan	Retraining objectives, methods to improve performance, approach to evaluation, and potential impact on intended purpose
Software update plan	Version tracking, verification and validation methods, update triggers, update procedures and transparent communication to end users
Rollback plan	Triggers, backup and recovery procedures, and communication to users

What has to be disclosed about the model

For AI based MDSW, the applicant discloses dataset composition used for training, validation and testing, including demographic distribution, geographic origin and clinical diversity, and provides evidence addressing model bias, generalizability and robustness across sub populations relevant to India. Manufacturers must also state whether training datasets are real world data drawn from public databases or published literature, or artificially generated synthetic data. Decisions about why specific datasets, reference standards, parameters and metrics were selected for training, external validation and post deployment retraining are expected to be documented.

Risk domains for software

HOW CDSCO MAPS SOFTWARE RISK

RISK DOMAIN	MDSW OTHER THAN IVD SOFTWARE	IVD SOFTWARE
Clinical	Incorrect diagnosis, treatment recommendation errors, decision support errors, malfunction leading to patient harm	False positives and false negatives affecting diagnosis and treatment

Algorithmic	Bias, lack of explainability, model drift, poor generalizability, embedded software errors, updates affecting performance	Bias in interpretation algorithms, population specific performance limits, drift and hallucination in AI and ML based systems
Data related	Poor quality training data, privacy breaches, representativeness issues, sensor data integrity, corruption	Sample quality, laboratory data integrity, demographic bias in datasets
Operational	User misuse, inadequate training, workflow disruption, incorrect installation, maintenance failures, interface and interoperability errors	Laboratory workflow errors, operator training gaps, interface, interoperability and cross platform risk
System infrastructure	Cybersecurity vulnerabilities, cloud outages, interoperability failures, hardware and software integration failures	Laboratory information system integration failures, connectivity issues
Environmental and contextual	Performance degradation across settings, unintended societal impacts, variability in clinical environments	Variation in laboratory settings, population characteristics, resource constraints

INDIRECT HARM IS NOW A NAMED CATEGORY

The guidance defines indirect harm as patient injury or health damage caused by erroneous, delayed or misleading software information, or by a reduction in device effectiveness, rather than by direct physical failure. It gives a pointed example: the introduction of unintended bias into clinical decision making because of an MDSW output may be considered an indirect harm to the patient. Surveillance and monitoring mechanisms are expected for indirect harm, not only for device malfunction.

Security by design, and the software bill of materials

Manufacturers should implement secure by design principles at architecture stage, ideally performing formal threat modelling to identify and mitigate cybersecurity risk, particularly for network connected, cloud based and interoperable products. Products should ship with secure default configurations, with unnecessary services, ports, interfaces and debug functions disabled by default, and should be designed to keep operating safely during cybersecurity incidents including partial loss of connectivity, denial of service conditions and integrity compromise. A security focused architecture review should cover attack surfaces, trust boundaries, external interfaces, application programming interfaces and interoperability points.

Alongside this, manufacturers should maintain and periodically update a bill of materials including a Software Bill of Materials, ideally covering third party, open source and commercial components, with processes for monitoring, assessing and mitigating known vulnerabilities in those components across the software lifecycle.

The standards stack

Products conform to Bureau of Indian Standards specifications, or to standards notified by the Ministry of Health and Family Welfare. Where none exist, ISO, IEC or other pharmacopoeial standards apply, and failing that, validated manufacturer standards. The QMS expectation rests primarily on three: IS/IEC 62304 for software lifecycle, IS/ISO 14971 for risk management and IS/IEC 82304-1 for health software safety. Around them sit IS/ISO 13485, IEC/TR 80002-1, IS 16124, IEC 81001-5-1 for security activities in the product lifecycle, IEC 62366-1 for usability engineering, IS/ISO/IEC 23894 and IS/ISO/IEC 42001 for artificial intelligence risk and management systems, ISO 24291 for machine learning in imaging, IS/ISO/IEC 27001 for information security, IS/ISO/IEEE 11073 for point of care communication, and the IS/ISO 15223 series for labelling symbols.

SECTION 10

Life after approval

For software, the licence is the beginning of the obligation, not the end of it. Every release now sits inside a change control framework.

Changes to MDSW mean any modification made across its lifecycle, including maintenance. They may correct faults, improve functionality and performance, keep the product usable in a changed environment, or protect safety and effectiveness through a security patch. Major and minor changes are specified in the Sixth Schedule of MDR-2017, and the licence holder submits a post approval change notification or request through the Online System for Medical Devices, to the Central or State authority as applicable, for any change including a software version update.

MAJOR CHANGES: APPROVAL REQUIRED

- Design characteristics affecting quality in respect of specifications, indications for use, or performance of the software or connected hardware
- Modifications to software design or system requirements, including a new clinical claim or a new data input type
- The intended use or indications for use
- Name and address of the domestic manufacturer or site, the overseas manufacturer or site for imports, or the authorised agent
- Label changes, excluding font size, font type, colour and label design
- Manufacturing process, equipment or testing that affects quality
- A version change that affects intended use, safety, effectiveness or risk control measures

MINOR CHANGES: NOTIFICATION REQUIRED

- Design changes that do not affect quality in respect of specifications, indications, performance or stability
- Manufacturing process, equipment or testing changes that do not affect quality
- Revisions for bug fixes and security patches that do not affect intended use, safety or performance
- A version change that does not affect intended use, safety or effectiveness
- Performance re tuning within validated ranges

Where changes are made under an approved Algorithm Change Protocol, approval remains mandatory for major changes and notification is required for minor ones. A change in the constitution of the firm counts as a major change and requires a fresh licence application.

Post market surveillance for a product that keeps changing

Applicants submit a post market surveillance plan proportionate to the risk class. Named activities are complaint handling, adverse event reporting, software patch tracking, drift monitoring for AI, cybersecurity monitoring and field corrective actions. For AI, ML and adaptive systems the plan should include mechanisms to monitor model performance drift, error rates and false outputs, clinical safety signals and user feedback integration. Licence holders should also implement mechanisms to collect real world evidence from Indian healthcare settings as part of surveillance.

POST MARKET SURVEILLANCE ACTIVITIES TO DOCUMENT

ACTIVITY	MANUFACTURER EXPECTATION
Continuous performance monitoring	Monitor safety, effectiveness, accuracy and clinical performance throughout deployment
Algorithm change management	Maintain documented procedures for software updates, model modifications, retraining and version control
Performance drift and AI hallucination detection	Identify and address clinically significant degradation over time, and continuously monitor for AI hallucination, meaning the creation of factually false or fabricated data by a model with high confidence

Real world performance evidence	Periodically assess performance using real world operational data where feasible
Population and setting validation	Evaluate performance across the patient groups and healthcare settings intended for use in India
Transparency and traceability	Maintain records of updates, performance assessments, corrective actions and significant modifications

The reporting clocks

The licence holder must inform the State or Central authority of any suspected unexpected serious adverse event, and the action taken including any product recall, within **15 days** of the event coming to notice. An importer must inform the Licensing Authority within **15 days** of any administrative action taken abroad on account of an adverse reaction, including market withdrawal, regulatory restriction, cancellation of authorisation, or a declaration that the product is not of standard quality by the regulator of the country of origin or any other country where it is marketed.

Beyond that, the manufacturer or importer must immediately inform the authority where there is reason to believe a marketed product may be unsafe. For software, unsafe is defined broadly: erroneous results with a negative direct or indirect impact on patient health, or the introduction of bias into clinical decision making to an extent that may negatively affect the health of the user. Adverse events may also be reported to the Materiovigilance Programme of India, run by the Indian Pharmacopoeia Commission.

> **WHAT A RECALL MEANS WHEN THERE IS NOTHING TO RECALL**
>
> The guidance settles a question that has troubled software companies everywhere. A product recall for MDSW may mean a complete or partial halt in distribution of the software from some or all channels and domains, and it may mean uninstalling or decommissioning the software from some or all available networks and hardware devices. The ability to execute that, technically and contractually, needs to exist before it is needed.

Where a product was approved after clinical investigation, for instance a device with no predicate, clinical safety must be monitored closely once marketed and Periodic Safety Update Reports furnished under the conditions in MDR-2017. Those reports must present relevant new information from appropriate sources, relate it to patient exposure, summarise market authorisation status and safety variations in other countries, and indicate whether product information will change as a result.

SECTION 11

What this means for the market

The MedTech Spectrum read on who gains, who has work to do, and what to fix first.

The immediate effect of this guidance is clarity, and clarity tends to favour the prepared. Companies that have been building against IEC 62304 and ISO 14971 already hold most of the technical file. What they now need is the India layer on top, and that layer is not documentation alone; parts of it are engineering.

Four shifts worth planning around

The digital health platforms are inside the regulatory perimeter now, or one feature away from it. India's hospital IT, laboratory information and image management vendors have largely operated outside MDR-2017. The exclusion list protects them only while their products stay administrative. The moment a module quantifies a physiological parameter for clinical decision making, performs image analysis as a diagnostic aid, or monitors a patient in real time, the classification question opens. Product roadmaps and regulatory strategy need to be reviewed in the same meeting.

Consumer facing health software faces the sharpest reclassification risk. The wellness carve out is narrower than most marketing teams assume, and the escalation clause for non clinical users in serious situations can lift a product two steps. Direct to patient models should be stress tested against both the wellness boundary and the escalation note before launch messaging is locked.

Global dossiers will need Indian evidence. Justification for applicability to Indian clinical environments, dataset composition disclosure, bias and generalizability evidence across Indian sub populations, and validation in representative Indian populations conducted in the intended settings. For AI diagnostics in particular, this is a real programme with real timelines, and it favours companies that build Indian site partnerships early.

ABDM alignment is becoming a commercial requirement as well as a regulatory one. Interoperability with ABHA, the Health Facility Registry and the Healthcare Professional Registry, plus consent controls and traceability of diagnostic outputs to registered facilities and authorised professionals, is written into the design expectations for diagnostics deployed inside healthcare facilities. Products that integrate cleanly will find procurement conversations easier.

The companies that move fastest will be the ones that treated intended use as a strategic decision rather than a drafting exercise.

A readiness checklist

- [ ] **Run the qualification test on every product in the portfolio**
  Including modules and features shipped since the last regulatory review, and anything on the next two roadmap releases
- [ ] **Rewrite the intended use statement deliberately**
  All eight elements, plus the six additional IVD elements where applicable, with labelling, instructions for use and promotional material aligned to it
- [ ] **Check the published CDSCO classification lists**
  On the MD Online portal, and file for a risk class determination where the product or an equivalent intended use is not listed

- [ ] **Model the classification twice for consumer facing products**
  Once on the base matrix, once with the non clinical user escalation applied, and plan for the higher outcome
- [ ] **Identify the predicate, or accept the investigational route**
  Build the eleven parameter comparison table, with scientific justification for every difference
- [ ] **Complete a DPDP-2023 gap analysis across the full data lifecycle**
  Collection, model development, deployment, monitoring and post market surveillance, not storage alone
- [ ] **Confirm the hosting position**
  Whether the service sits on a MeitY empanelled cloud, with baseline security controls documented, or the on premises risk assessment completed
- [ ] **Build the ABDM integration assessment**
  ABHA, Health Facility Registry, Healthcare Professional Registry, consent architecture and output traceability
- [ ] **Draft the Algorithm Change Protocol before the next model update**
  All five components, and decide which future changes are major and which are minor
- [ ] **Produce and maintain the Software Bill of Materials**
  Third party, open source and commercial components, with a live vulnerability monitoring process attached
- [ ] **Plan Indian validation as a programme, not an annex**
  Representative populations, intended clinical environments, and usability testing that reflects Indian workflows, languages, training variability and infrastructure
- [ ] **Rehearse the software recall**
  Confirm you can halt distribution across channels and uninstall or decommission across networks and devices, and that contracts permit it

ONE CLOSING OBSERVATION

It is worth noticing what CDSCO chose to name explicitly. Model drift. Algorithm retraining. Rollback plans. Bias as an indirect harm. AI hallucination as a monitored post market phenomenon. Very few regulators have put those words into a guidance document with this level of specificity. Whatever else it does, this text signals that India intends to regulate adaptive software as adaptive software, and not as a static product that happens to be written in code.

REFERENCE

Source, scope and contacts

Primary source

Guidance Document on Medical Device Software, Doc No. CDSCO/MD/GD/MDSW/01/2026, issued with circular F. No. MED-16028/2/2025-eoffice dated 21 July 2026, signed by Dr Rajeev Singh Raghuvanshi, Drugs Controller General (India). Central Drugs Standard Control Organization, Medical Devices and IVD Division, Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, FDA Bhawan, Kotla Road, New Delhi 110002. Circulated to all State and Union Territory Licensing Authorities and to all stakeholders through the CDSCO website.

Statutory instruments referenced

- Drugs and Cosmetics Act, 1940
- Medical Devices Rules, 2017, including the First, Second, Fourth, Fifth, Sixth and Seventh Schedules, and Chapters VI, VII, VIII and IIIB
- Gazette Notification S.O. 648(E) dated 11 February 2020
- Digital Personal Data Protection Act, 2023

Official portals and resources

- CDSCO: cdsco.gov.in
- Online System for Medical Devices: cdscomdonline.gov.in
- National Single Window System: nsws.gov.in
- Risk classification lists and approved device databases, published on the MD Online portal and revised from time to time
- Materiovigilance Programme of India, Indian Pharmacopoeia Commission: ipc.gov.in
- Ayushman Bharat Digital Mission: abdm.gov.in
- Bureau of Indian Standards: standards.bis.gov.in
- CDSCO Public Relations Office, FDA Bhawan, New Delhi 110002. Startup and innovator queries: startupinnov@cdsco.nic.in

Scope of this document

This is an independent editorial reference prepared by MedTech Spectrum. It summarises and interprets a public guidance document and does not reproduce it. The source guidance itself carries a notice that it is aimed at creating public awareness and is not meant to be used for legal or professional purposes, and it directs readers to the statutory provisions of the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules, 2017, together with the guidelines and clarifications issued by CDSCO from time to time. That direction applies equally here. Nothing in this document constitutes legal or regulatory advice, and readers should verify the current position with CDSCO or qualified counsel before acting.

MedTech Spectrum

EMPOWERING MEDTECH ECOSYSTEM

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