Satori One Click SOLUTIONS LLP

Global Pharma, QA-QC Management, Legal and Regulatory Compliance Consultancy Services

Regulatory & Digital Health Compliance Partner

WHITE PAPER

Navigating India's SaMD Regulatory Landscape

A Practical Roadmap to CDSCO Compliance for Software as a Medical Device (SaMD)

Based on CDSCO Guidance Document on Medical Device Software
Doc No.: CDSCO/MD/GD/MDSW/01/2026

Prepared by Satori One Click Solutions | 2026

Executive Summary

India's healthcare sector is undergoing rapid digital transformation, and software is now central to diagnosis, monitoring, and treatment decisions. The Central Drugs Standard Control Organization (CDSCO) has formalized this shift through its Guidance Document on Medical Device Software (Doc No. CDSCO/MD/GD/MDSW/01/2026), which clarifies how Software as a Medical Device (SaMD) — including AI/ML-based tools, mobile health apps, and cloud-hosted diagnostic platforms — is classified, licensed, and monitored under the Medical Devices Rules, 2017 (MDR-2017).

For founders, product teams, and healthcare innovators, this regulatory clarity is an opportunity — but only for those who can translate dense compliance requirements into an executable go-to-market plan. This white paper distills the CDSCO framework into a practical roadmap and outlines how Satori One Click Solutions helps SaMD companies move from concept to compliant commercial launch with a single point of accountability.

1. What Counts as Medical Device Software Under CDSCO?

CDSCO defines Medical Device Software (MDSW) broadly: any software, used alone or with hardware, that is intended for a medical purpose — diagnosis, prevention, monitoring, treatment, alleviation of disease or injury, or control of conception — falls within the ambit of MDR-2017. This includes standalone software that does not require hardware to achieve its purpose, as well as embedded software that drives or influences a hardware device.

Illustrative examples that ARE regulated as MDSW include:

- AI/ML-based tools for triage or screening of disease (e.g., cancer lesion detection)
- Computer-Aided Detection (CAD) software analyzing X-rays or ECGs
- Bluetooth-connected apps that read vitals from a paired medical device
- Digital therapeutics platforms for chronic disease management
- Cloud/IoT platforms offering real-time AI-driven clinical interventions

Software that generally falls OUTSIDE MDR-2017 includes:

- General wellness and fitness-tracking apps with no disease-specific claim
- Hospital/Clinical Information Systems limited to scheduling, billing, and records
- Laboratory Information Systems limited to workflow and result communication
- Software used purely for teaching, training, or data transfer/storage

Source: CDSCO Guidance Document on Medical Device Software, Sections 4.9–5.2.

2. Risk-Based Classification: Why It Determines Your Entire Strategy

Under Rule 4 of the MDR-2017, every MDSW is placed into one of four risk classes — A, B, C, or D — based on its intended use, the criticality of the health condition addressed, and whether the software's output drives, informs, or merely supports clinical decision-making. This classification is the single most important early decision in a SaMD program: it determines the licensing authority, the documentation burden, the timeline, and the cost of market entry.

Degree of Risk	Class	Typical SaMD Example	Licensing Authority
Low risk	Class A	Wellness tracking with a borderline clinical claim	SLA (registration only, non-sterile)
Low-moderate risk	Class B	Symptom checker / triage support app	SLA
Moderate-high risk	Class C	AI-based radiology CAD tool	CLA
High risk	Class D	Software driving insulin dosing / therapy delivery	CLA

Simplified illustration derived from Table 1 & Table 2 of the CDSCO Guidance Document (Sections 7.0–7.1).

Standalone MDSW is further assessed on two axes — the significance of the information it provides (treatment/diagnosis vs. driving vs. informing clinical management) and the criticality of the underlying health situation (critical, serious, or non-serious). Getting this classification wrong at the outset is the most common — and most expensive — mistake SaMD companies make.

3. The Regulatory Pathway, End to End

CDSCO has established two dedicated digital portals: the National Single Window System (NSWS) for Test Licences, and the CDSCO MD Online Portal for all other permissions, including clinical investigations, manufacturing/import licences, and post-approval changes. The pathway below summarizes the journey from early-stage testing to full commercialization.

Stage	Portal / Form	Purpose
Test Licence	NSWS Portal – Form MD-12 / MD-16	Clinical investigation, evaluation, demonstration or training
Clinical Investigation / Performance Evaluation	CDSCO MD Online – Form MD-22/23, MD-24/25	Establish safety, performance & effectiveness in humans
Investigational Device Permission	Form MD-26/27 (IMD), MD-28/29 (new IVD)	Permit manufacture/import prior to full licensing
Manufacturing / Import Licence	Form MD-3, MD-7, MD-14 (class-dependent)	Commercial sale & distribution in India
Post-Market Surveillance	PMS Plan, PSUR, ACP, Vigilance (MvPI)	Ongoing safety, drift & adverse-event monitoring

Simplified from Sections 10.0–12.5 of the CDSCO Guidance Document.

4. Quality Management, Cybersecurity & AI Governance Expectations

Beyond licensing, CDSCO expects a documented Quality Management System aligned to standards such as IS/ISO 13485, IS/ISO 14971, and IS/ISO/IEC 62304, along with a maintained Software Bill of Materials (SBOM) and continuous performance monitoring. For AI/ML-based MDSW specifically, the guidance introduces expectations that go beyond traditional device regulation:

- An Algorithm Change Protocol (ACP) governing retraining, versioning, and rollback
- Disclosure of training/validation dataset composition, including demographic and geographic diversity
- Monitoring for model drift, bias, and AI hallucination post-deployment
- Secure-by-design architecture with threat modelling for cloud-connected and interoperable software
- Alignment with the Ayushman Bharat Digital Mission (ABDM) — ABHA, HFR, HPR interoperability and consent-based data governance

These requirements mean that a SaMD compliance program can no longer be treated as a one-time filing exercise. It requires the same engineering discipline as the product itself — version control, traceability, and lifecycle documentation — built in from day one.

5. Common Pitfalls We See in the Market

- Treating the product as a "wellness app" to avoid regulation, then facing enforcement action after clinical claims creep into marketing material
- Under-classifying risk by ignoring the "drive vs. inform clinical management" distinction, leading to licence rejection or recall
- Incomplete technical documentation — missing SRS/SDS traceability, verification & validation evidence, or bias/robustness data for AI models
- No Post-Market Surveillance or Periodic Safety Update Report plan in place before launch
- Treating SaaS hosting and cybersecurity as an afterthought rather than a design-stage requirement

6. How Satori One Click Solutions Helps

Satori One Click Solutions works as an extension of your product and regulatory team — converting the CDSCO framework into a single, sequenced execution plan so you file once, correctly, and get to market faster.

- **Regulatory Classification & Strategy**
  We assess your intended use statement against MDR-2017's First Schedule and CDSCO's published risk classification lists to confirm Class A–D status before you invest further, and define the correct licensing pathway (SLA vs. CLA).
- **Test Licence & Clinical Pathway Management**

End-to-end preparation and filing of Form MD-12/MD-16 test licence applications and, where required, clinical investigation (MD-22/23) or clinical performance evaluation (MD-24/25) dossiers via NSWS and CDSCO MD Online.

- **Technical & Device Master File Assembly**
  SRS/SDS documentation, software architecture diagrams, risk management reports (IS/ISO 14971), essential principles checklists, and substantial equivalence comparisons with predicate MDSW.
- **AI/ML Governance & Algorithm Change Protocol**
  Design and documentation of your ACP, dataset bias/robustness evidence, and drift-monitoring framework to meet CDSCO's AI-specific expectations.
- **Cybersecurity & QMS Enablement**
  Gap assessment against IS/IEC 62304, IS/ISO 27001 and secure-by-design principles; SBOM setup; and QMS documentation aligned to the Fifth Schedule of MDR-2017.
- **Manufacturing/Import Licensing & Post-Market Compliance**
  Full licence application support (Form MD-3/MD-7/MD-14), plus ongoing PMS plans, PSUR preparation, PAC notifications, and Materiovigilance (MvPI) reporting after launch.

7. The Opportunity Ahead

India's digital health market is scaling fast, and the 2026 CDSCO guidance gives SaMD innovators the regulatory clarity to build with confidence. Companies that treat compliance as a strategic differentiator — not a bottleneck — will be the ones that earn clinician trust, secure institutional partnerships, and scale across India's evolving digital health ecosystem.

Satori One Click Solutions exists to make that journey a one-click experience: one partner, one roadmap, one point of accountability from classification to post-market surveillance.

About Satori One Click Solutions

Satori One Click Solutions is a regulatory and digital health compliance partner supporting medical device and SaMD innovators through classification, licensing, quality management, and post-market compliance under India's Medical Devices Rules, 2017. We work with startups, hospitals, and digital health platforms to turn complex CDSCO requirements into a clear, executable roadmap.

Get in touch to schedule a SaMD regulatory readiness assessment.

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Disclaimer: This white paper is for general informational and business-development purposes only. It summarizes and paraphrases the CDSCO Guidance Document on Medical Device Software (Doc No. CDSCO/MD/GD/MDSW/01/2026) and does not constitute legal or regulatory advice. Readers should refer to the Drugs and Cosmetics Act, 1940, the Medical Devices Rules, 2017, and official CDSCO notifications for authoritative requirements.