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CDSCO ISSUES FINAL GUIDANCE DOCUMENT ON MEDICAL DEVICE SOFTWARE UNDER THE MEDICAL DEVICES RULES, 2017

On July 21, 2026, the Central Drugs Standard Control Organisation ("**CDSCO**"), through its Medical Devices Division, issued a Circular bearing F. No. MED-16028/2/2025-eoffice, notifying the Guidance Document on Medical Device Software under MDR-2017, bearing Document No. CDSCO/MD/GD/MDSW/01/2026 ("**Guidance Document**"). The Guidance Document sets out the regulatory approvals applicable to medical device software ("**MDSW**"), including in-vitro diagnostic ("**IVD**") medical device software, regulated under the Medical Devices Rules, 2017 ("**MDR-2017**"), and is intended for reference by manufacturers, importers and innovators/researchers, etc. while making regulatory submissions to the licensing authority.

The Guidance Document, via Section 3.0 prescribes the mode of regulatory submissions for MDSW. It provides that all applications relating to the manufacture or import of MDSW, clinical investigations, and registration for sale or distribution are required to be submitted through designated online portals. Applications for Test Licences are to be filed through the National Single Window System **(NSWS)** portal, while all other applications, including those for regulatory permissions, manufacturing and import licences, and registration for sale and distribution, are required to be submitted through the CDSCO Online System for Medical Devices (MD Online) portal.

The key highlights of the Guidance Document are as follows:

- **Scope:** The Guidance Document applies to software products that fall within the definition of a medical device. Further, Section 4.11 of the Guidance Document, defines "Medical Device Software" as – 'software (as covered in Section 4.9) that is intended for a medical purpose (Refer Section 4.10), as under: i) software that are, either alone or in combination, intended to be used to perform one or more medical purposes without being part of a hardware medical device, wherein, "without being part of" means software does not necessarily require a hardware medical device to achieve its intended medical purpose. Such software may also be referred to as standalone medical device software; ii) software that are considered as a "part of" the medical device hardware and/or that drive or influence the use of that medical device," wherein the term "drive or influence the use of a medical device," indicates that it can: (a) operate, modify the state of, or control the device either through an interface or via the operator of the device, or (b) supply output related to the (hardware) functioning of that device.' We further observe that the Draft Guidance Document dated October 21, 2025, explicitly classified software into Software as a Medical Device **(SaMD)** and Software in a Medical Device **(SiMD)**. However, this classification has not been incorporated into the Final Guidance Document published by CDSCO.

- **Software:** Section 5.0 of the Guidance Document clarifies that not all healthcare software qualifies as MDSW and identifies four regulated categories, including software on general-purpose platforms such as PCs, smartphones and cloud, as well as software interconnected with other

systems and datasets. Section 5.2 of the Guidance Document further lists exclusions from MDSW, including hospital/clinical information systems, laboratory information systems and image management systems.

- **Artificial intelligence and machine learning:** Section 6.0 read with Section 12.4.2 of the Guidance Document requires applicants to disclose the analysis methodology of MDSW in the intended use statement, including whether it is rule-based or uses artificial intelligence ("**AI**") or machine learning ("**ML**"), and its degree of autonomy such as autonomous, supervised autonomy or non-autonomous. Section 12.4.2(D) of the Guidance Document identifies AI-specific risks such as bias, lack of explainability, model drift and poor generalizability, and contemplates an Algorithm Change Protocol ("**ACP**") covering data management, performance evaluation, retraining, updates and rollback. Section 12.4.2(G) of the Guidance Document requires disclosure of training, validation and testing datasets, including demographic, geographic and clinical diversity, along with evidence on bias, robustness and generalizability across Indian sub-populations. Where non-Indian datasets are used, justification and Indian validation are required. Section 12.5.3 and Table 8 of the Guidance Document further mandate post-market monitoring for drift, bias and hallucination, which is further defined as AI-generated factually false outputs with high confidence.

- **Risk-based classification:** Section 7.0 of the Guidance Document classifies all medical devices, including MDSW, into four risk classes under MDR-2017: Class A (low), Class B (low-moderate), Class C (moderate-high) and Class D (high). Classification is based on intended use derived from labelling, IFU, manuals, websites and promotional materials. For standalone MDSW, Section 7.1 of the Guidance Document provides a matrix based on clinical context and the software's role in treatment, diagnosis or clinical management. CDSCO, as Central Licensing Authority ("**CLA**"), confirms classification, and a dynamic list is maintained on CLA's Online System for Medical Devices.

- **Applicable standards:** Section 8.0 of the Guidance Document requires compliance with Bureau of Indian Standards or Ministry-notified standards, and in their absence, by the International Organization for Standardization (**ISO**), the International Electrotechnical Commission (**IEC**), or other recognized pharmacopeial standards.

- **Quality management system and Digital health ecosystem requirements:** Section 9.0 of the Guidance Document mandates a lifecycle-wide quality management system for all MDSW manufacturers. Domestic manufacturers must submit an undertaking of compliance with the Fifth Schedule of MDR-2017, while overseas manufacturers must provide a notarised Quality management system ("**QMS**") certificate from the relevant national authority for import licensing. Section 9.0 of the Guidance Document further requires MDSW, including AI-based systems handling patient data, to ensure interoperability, consent-based data access under the Digital Personal Data Protection Act, 2023, secure data exchange and auditable traceability. Where applicable, alignment with the Ayushman Bharat Digital Mission framework, including Ayushman

Bharat Health Account, the Health Facility Registry and the Healthcare Professional Registry, is required under Section 12.4.2 of the Guidance Document.

- **Licensing pathway:** Sections 11.0 and Table 5 of the Guidance Document assign CLA responsibility for test licences, import licences and clinical investigation permissions across all classes. Manufacturing licences for Class A and B MDSW are issued by the State Licensing Authority ("**SLA**"), and manufacturing licences for Class C and D by CLA, while sale and distribution licences are issued by SLA for all classes. Section 12.1 of the Guidance Document sets out the test licence process for non-commercial use such as testing, evaluation, demonstration or training.

- **Essential principles of safety and performance:** Section 12.4.2(C) of the Guidance Document requires reference to the CDSCO essential principles checklist and mandates that MDSW be developed and maintained in line with state-of-the-art practices, including lifecycle management, risk management, information security and safe updates.

- **Software labelling:** Section 12.4.2(I) of the Guidance Document requires identification of MDSW through version, revision level and build date. The software may be supplied in a physical form or without any physical form or packaging, with instructions for use provided electronically.

- **Post-marketing regulatory requirements:** Section 12.5.3 of the Guidance Document requires a risk-proportionate post-market surveillance plan covering complaints, adverse events, patching, cybersecurity, field corrective actions and AI drift monitoring. For AI/ML systems, this includes tracking model performance drift, error rates, false outputs, clinical safety signals and user feedback, supported by documentation and real-world evidence. A Field Safety Corrective Action may be initiated where risks are identified. Serious unexpected adverse events must be reported to the SLA or CLA within 15 days. Periodic Safety Update Reports are required where devices are approved without a predicate as prescribed under MDR-2017.

- **Post-approval change ("PAC") notification:** Section 12.5.2 of the Guidance Document classifies lifecycle changes as major or minor under the Sixth Schedule of MDR-2017. Major changes require prior approval from the licensing authority, while minor changes require only a notification. PAC submissions must be made via the Online System for Medical Devices, and ACP-linked changes still require approval for major changes and notification for minor ones.

Conclusion:

The issuance of the Guidance Document marks a significant step in the maturation of India's regulatory framework for medical device software under the MDR-2017. While the Guidance Document does not introduce new statutory obligations, it provides much-needed regulatory clarity by consolidating the applicable licensing pathways, risk classification principles, quality management requirements, software lifecycle expectations and post-market obligations specific to MDSW. It provides significant clarity on regulatory expectations and is among the first CDSCO instruments to explicitly address

AI/ML within medical device software, including requirements on transparency, dataset governance, bias and drift monitoring, explainability and post-market oversight. Although issued in the form of guidance, it signals an important shift towards the formal integration of AI-specific regulatory principles into India's medical device regime and is likely to serve as the foundation for future legislative and regulatory developments governing AI-enabled healthcare products.

Read more at:
https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTQ1MTM=

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This update is only for general informational purposes and shall not be construed to constitute legal advice (which can only be given after being formally engaged and familiarizing ourselves with all the relevant facts). Should you have any queries, or require any assistance or clarifications with regard to anything contained in this newsletter, please feel free to contact our partner, Mr. Pradnesh Warke

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