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CDSCO releases guidance document on medical device software

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To improve regulatory clarity, strengthen patient safety, encourage responsible AI innovation



Software role in healthcare is becoming increasingly critical, as a diverse array of products serves various medical and administrative functions across clinical and private settings. Any software, whether alone or in combination, intended by the manufacturer for medical purposes and attracts the definition of medical device under the Drugs and Cosmetics Act, 1940 and

Medical Devices Rules, 2017 (MDR-2017) is regulated as ‘medical device.’

The Central Drugs Standard Control Organisation (CDSCO) has released a document to provide guidance to stakeholders (manufacturers, importers and innovators/researchers, etc.) for the submission of application to the Licensing Authority (LA) for obtaining regulatory approvals for Medical Device Software (Medical Device Software) (including In-vitro Diagnostic (IVD) Medical Device Software) under the MDR-2017.

This Guidance Document reflects current practices under the MDR-2017 and should not be misconstrued as a new regulatory control on MDSW (including In vitro Diagnostic (IVD) MDSW).

Manufacturers of AI-enabled MDSW intended for use in India should demonstrate that device performance has been evaluated in at risk populations, healthcare settings, and operational environments representative of the intended use.

As per the document, manufacturers should design MDSW to maintain safe operation during cybersecurity incidents, including partial loss of connectivity, denial of-service conditions, or integrity compromise. In-vitro diagnostic systems, digital pathology solutions, radiology AI systems, and diagnostic decision-support software deployed within healthcare facilities should be designed such that they support ABDM compliant health record generation and exchange, maintain patient consent controls, and enable traceability of diagnostic outputs to registered facilities and authorized healthcare professionals.