India

Latest Updates

Software	
Embedded Software	The CDSCO, in Feb 2020, released a notification to extend the scope of the devices regulated under the Drugs and Cosmetics Act. Under the new scope, software is also considered as medical devices if it is used for; • Diagnosis, prevention, monitoring, treatment, or alleviation of any disease or disorder • Assistance for any injury or disability • Investigation, replacement or modification, or support of the anatomy or a physiological process • Supporting or sustaining life • Disinfection of medical devices • Control of conception
Software as Medical Device (SaMD)	In September 2021, CDSCO released official guidelines on the classification of SaMD in harmony with IMDRF's risk-based classification. It is categorized into low-risk (Class A), low-moderate risk (Class B), moderate risk (Class C), and high-risk (Class D) devices.
Clinical Decision Support Software (CDS)	No updates at present.
Change Management Requirements for Software/SaMD	No updates at present.
Quality Management System (QMS)	As per MDR2017 product registration checklist, the manufacturing premises needs to be ISO13485 certified in order to pursue product commercialization in India
Post-Market Management	Per MDR2017, there is no consolidated section providing insight into PMS activities to be carried out by manufacturer. The information is

	staggered and placed under various sections or places. Please refer below: 1. Rule 89 of MDR2017 provides direction about recall of medical devices. 2. The conditions of license issued by the Indian HA provides guidance about adverse reaction. 3. The Indian HA has issued forms to report FSCA and adverse event to the authority.

Real World Data/Evidence

No updates at present.

Artificial Intelligence (SiMD & SaMD)

Machine Learning	No updates at present.
Deep Learning	No updates at present.
Best Ethical Practices	The document "Ethical guidelines for application of Artificial Intelligence in Biomedical Research and Healthcare 2023" was prepared by DHR-ICMR Artificial Intelligence Cell in 2023. The purpose of these guidelines is to ensure ethical conduct and address emerging ethical challenges in the field of Artificial Intelligence (AI) in biomedical research and healthcare. These guidelines are also meant to provide a framework for ethical decision-making in medical AI during the development, deployment, and adoption of AI-based solutions. The guidelines are intended for all stakeholders involved in research on AI in biomedical research and healthcare, including creators, developers, researchers, clinicians, ethics committees, institutions, sponsors, and funding organizations. The guidelines include sections on ethical principles, guiding principles for stakeholders, an ethics review process, governance of AI use, and informed consent.
Generative AI	No updates at present.

Cybersecurity

India does not have a dedicated cybersecurity law.

The Information Technology Act 2000 (the IT Act) read with the rules and regulations framed thereunder deal with cybersecurity and the cybercrimes associated therewith.

https://www.meity.gov.in/writereaddata/files/The%20Information%20Technology%20Act%2C%202000%283%29.pdf (I1)

Data Privacy

In early August 2023, the Indian Parliament passed the Digital Personal Data Protection (DPDP) Act, 2023. An Act to provide for the processing of digital personal data in a manner that recognises both the right of individuals to protect their personal data and the need to process

such personal data for lawful purposes and for matters connected therewith or incidental thereto.

Labelling	
UDI	No updates at present.
Specific Market Requirements	Below local label information is required on product: • Generic Name of Product • Name and Address of Actual Manufacturer • Local Customer Care Details (Address, Number and Email ID) • MRP (Unit Sale Price)