REGULATION OF MEDICAL DEVICES IN INDIA

Current Framework and Practical Considerations

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1. Medical Device Definition & Qualification Criteria

In India, medical devices are regulated under the Drugs and Cosmetics Act, 1940 and the Medical Device Rules (MDR), 2017 enforced by the Central Drugs Standard Control Organisation (CDSCO).

A product qualifies as a medical device primarily based on its:
1. Intended Medical Purpose: Diagnosis, prevention, monitoring, treatment or alleviation of disease, injury, handicap, or replacement of anatomy/physiological processes.
2. Mode of Action: It does NOT achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means (which defines a drug), though it may be assisted in its function by such means.

Note: Factors such as sales price, country of manufacture, or whether it has electronic parts do not determine medical device qualification.

2. Risk-Based Classification Framework (MDR 2017)

Under Rule 4 of the Medical Device Rules, 2017, all medical devices are grouped into Four Principal Risk Classes based on their intended use and risk to patient/user health:

* Class A (Low Risk): Non-invasive, non-measuring instruments, surgical dressings, cotton wool, tongue depressors.
* Class B (Low-Moderate Risk): Hypodermic needles, blood collection bags, surgical gloves, suction equipment.
* Class C (Moderate-High Risk): Mechanical ventilators, orthopaedic bone screws, infusion pumps, patient monitors.
* Class D (High Risk): Implantable cardiac pacemakers, heart valves, coronary stents, neurological implants.

Class A (non-sterile & non-measuring) devices follow an online self-certification registration route via the CDSCO portal without requiring an exhaustive manufacturing audit upfront.

3. Regulatory Licensing Authorities & Application Forms

The Indian regulatory system divides licensing duties between Central and State authorities:

1. Central Licensing Authority (CLA - CDSCO, Headed by DCGI):
- Responsible for commercial import licences for all classes of medical devices (Form MD-14 application, Form MD-15 licence).
- Responsible for domestic manufacture licences for Class C and Class D medical devices (Form MD-7 application, Form MD-9 licence).
- Approves Clinical Investigations and Overseas registrations.

2. State Licensing Authority (SLA):
- Responsible for domestic manufacture licences for Class A and Class B medical devices (Form MD-3 application, Form MD-5 licence).
- Loan licences and wholesale distribution registrations.

Overseas Approvals (US FDA 510(k), CE mark, Free Sale Certificate):
Overseas clearances provide supporting regulatory evidence and may streamline clinical evaluations, but they DO NOT replace an official Indian import licence issued by the CLA.

4. Quality Management System (QMS) & ISO 13485

A Quality Management System (QMS) is mandated under the Fifth Schedule of MDR 2017 (closely harmonized with ISO 13485:2016).
The purpose of a QMS is to ensure controlled and consistent design, risk management (ISO 14971), verification, validation, manufacturing, packaging, and traceability of medical devices.

Compliance to QMS is verified through regulatory inspections by Medical Device Officers and registered Notified Bodies.

5. Software as a Medical Device (SaMD)

Standalone software, mobile health applications, or cloud AI algorithms are classified as Software as a Medical Device (SaMD) when:
- Their intended purpose includes diagnosis, prediction, monitoring, or clinical decision support for a medical condition.
- Example: An app that records an ECG from an optical sensor or wearable and analyzes it to alert the user of possible cardiac arrhythmia. The app qualifies as a medical device because its primary function is diagnostic evaluation of a clinical condition.

6. Post-Market Surveillance (PMS) & Vigilance

Regulatory responsibility does NOT end upon grant of approval or commercial launch.
Manufacturers and importers have strict ongoing legal obligations:
1. Post-Market Surveillance (PMS) & Complaint Handling: Timely receipt, investigation, and root-cause analysis of customer complaints.
2. Materiovigilance Programme of India (MvPI): Serious adverse events (death or serious deterioration of health) must be reported to the CLA within 15 days of becoming aware.
3. Corrective and Preventive Action (CAPA): Addressing recurring safety defects and initiating Field Safety Corrective Actions (FSCA) or product recalls when patient safety is compromised.