Medical Devices

Definition of Medical Devices

- Under the Drugs and Cosmetics Act, 1940 (amended), and the Medical Devices Rules, 2017, a medical device refers to any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or other similar article intended by the manufacturer to be used alone or in combination for human beings or animals for purposes such as:
    - Diagnosis, prevention, monitoring, treatment or alleviation of disease
    - Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury or disability
    - Investigation, replacement or modification or support of the anatomy or a physiological process
    - Supporting or sustaining life
    - Control of conception
    - Disinfection of medical devices
    - Providing information via in vitro examination of specimens from the human body
- **Examples:**
    - Thermometers, syringes
    - Blood glucose monitors
    - Stents, pacemakers
    - MRI machines
    - Pregnancy test kits

Regulatory Framework (India)

Governing Authority:

- Central Drugs Standard Control Organization (CDSCO)
- Drugs Controller General of India (DCGI)
- State Licensing Authorities (for Class A and B)

Key Legislations:

1. Drugs and Cosmetics Act, 1940
2. Drugs and Cosmetics Rules, 1945
3. Medical Device Rules, 2017

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4. New Drugs and Clinical Trials Rules, 2019 (for clinical investigation)
5. Indian Standards (BIS guidelines)
6. Import and Export Control Laws

Categorization of Medical Devices

Medical devices are categorized based on risk to the human body:

Class	Risk Level	Examples	Regulatory Oversight
Class A	Low Risk	Surgical dressings, thermometers	Self-certification / State Licensing Authority
Class B	Low-Moderate Risk	Hypodermic needles, suction equipment	State Licensing Authority
Class C	Moderate-High Risk	Blood bags, infusion pumps	CDSCO
Class D	High Risk	Heart valves, implantable devices	CDSCO

Risk-Based Classification Factors:

- **Invasiveness**
- **Duration of use** (transient, short-term, long-term)
- **Part of body** in contact (external vs. internal, central circulatory system, CNS, etc.)
- **Sterility or need for electricity**
- **Software involvement**

This classification affects:

- Licensing procedure
- Clinical evaluation requirements
- Post-market surveillance
- Manufacturing site inspection

Basic Aspects Related to Manufacture of Medical Devices

A. Licensing and Registration

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- Manufacturers must obtain a Manufacturing License from the appropriate Licensing Authority (SLA or CDSCO).
- Device classification determines the type of license and application route.

B. Quality Management System (QMS)

- Mandatory implementation of **ISO 13485** (QMS specific to medical devices).
- Ensure consistency, traceability, safety, and effectiveness in manufacturing.

C. Site Inspection

- For Class C and D, site audits are conducted by CDSCO-appointed inspectors.
- Good Manufacturing Practices (GMP) must be followed under the Medical Device Rules.

D. Labeling Requirements (as per MDR 2017)

- Every device must be labeled with:
  - Name of device and manufacturer
  - Batch/lot number
  - Manufacturing and expiry date
  - Instructions for use
  - Warnings and precautions
  - Sterility, if applicable

E. Clinical Evaluation

- Necessary for moderate to high-risk devices.
- May involve clinical investigations under controlled conditions.
- Data must demonstrate safety and performance of the device.

Basic Aspects Related to Sale of Medical Devices

A. Registration of Importers and Distributors

- All importers and distributors must be registered with CDSCO.
- They must comply with proper storage, labeling, and supply chain integrity.

B. Retail and Wholesale Sale Licensing

- Devices listed as notified medical devices are treated as “drugs”.
- Sales require:

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- **Retail license (Form 20/21)**
- **Wholesale license (Form 20B/21B)**

➢ Only qualified people (e.g., registered pharmacists) can manage sales where required.

C. Ethical Obligations in Sale

➢ No misleading claims or unauthorized promotional activities

➢ Truthful labeling and genuine warranty

➢ Post-market vigilance to report adverse events or device malfunction

➢ Avoid sale of unapproved or counterfeit devices

D. Prohibition and Penalties

➢ Sale of unlicensed, misbranded, or substandard devices attract penalties:

- Imprisonment and/or fines under the Drugs and Cosmetics Act
- Product seizure and license suspension

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