D.PHARM • SECOND YEAR

Pharmacy Law & Ethics

CHAPTER 21

Medical Devices



ENGLISH CHAPTER NOTES

DIPLOMA IN PHARMACY

MEDICAL DEVICES

DEFINITION

A medical device is an instrument, apparatus, appliance, implant, material, software, in-vitro diagnostic reagent or related article intended for use in humans or animals for one or more specified medical purposes.

Its primary intended action is not achieved by pharmacological, immunological or metabolic means, although such means may assist its function.

INTENDED PURPOSES



- diagnosis, prevention, monitoring or treatment of disease
- diagnosis, monitoring, treatment, alleviation or assistance for injury or disability
- providing information by in-vitro examination of human specimens
- investigation, replacement, modification or support of anatomy or a physiological process
- disinfection of medical devices
- supporting or sustaining life
- control of conception

LEGAL TIMELINE

1. Drugs and Cosmetics Act, 1940 — enabling law.
2. Medical Devices Rules, 2017 — effective from 1 January 2018.
3. S.O. 648(E), 11 February 2020 — effective from 1 April 2020; all qualifying devices were notified as drugs under Section 3(b)(iv).
4. G.S.R. 744(E), 14 August 2026 — updated selected Class A non-sterile and non-measuring requirements.

EXAMPLES

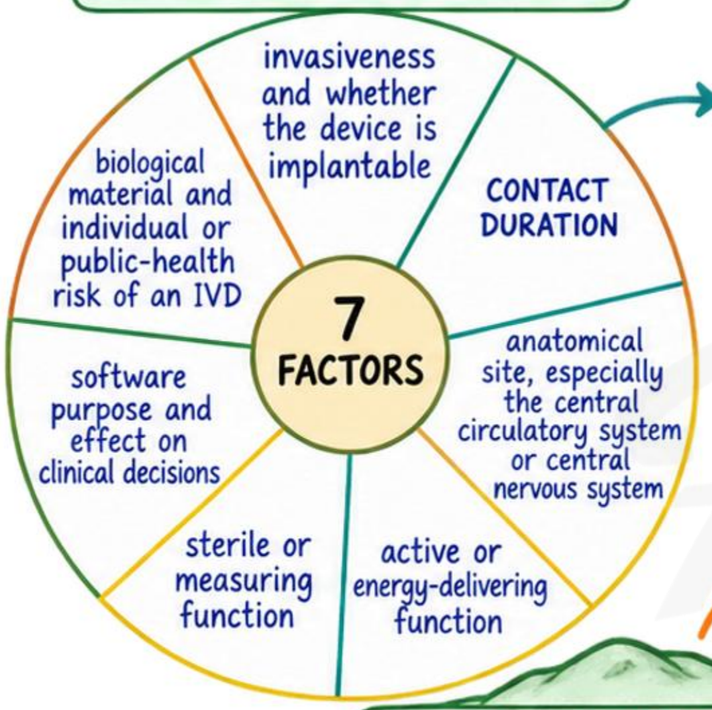
Syringe • thermometer • blood-pressure monitor • surgical instrument • implant • diagnostic software • IVD test kit

REGULATORY AUTHORITIES

CDSCO / DCGI acts as the Central Licensing Authority; State Licensing Authorities perform assigned State functions; registered Notified Bodies audit specified Class A and Class B manufacturers.
Clinical investigation of an investigational medical device is governed primarily by **Chapter VII** of the Medical Devices Rules, 2017.

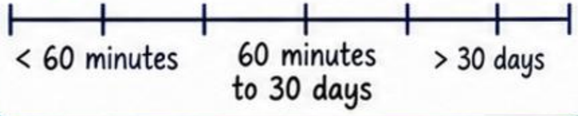
CATEGORIZATION OF MEDICAL DEVICES

CLASSIFICATION FACTORS



DURATION RULER

transient less than 60 minutes;
short-term 60 minutes to 30 days;
long-term more than 30 days



CLASS A — LOW RISK

Typical examples: reusable manual surgical scissors and some simple supports.

Class A other than NSNM is licensed by the State Licensing Authority.

CLASS B — LOW-MODERATE RISK

Typical examples: hypodermic needle and some thermometers.

Manufacture is licensed by the State Licensing Authority after a registered Notified Body audit.

CLASS C — MODERATE-HIGH RISK

Typical examples: infusion pump and blood bag.

Manufacture is licensed by the Central Licensing Authority after inspection or audit.

CLASS D — HIGH RISK

Typical examples: implantable pacemaker and prosthetic heart valve.

Manufacture is licensed by the Central Licensing Authority with the highest scrutiny.

CLASS A NSNM EXCEPTION

Class A non-sterile and non-measuring devices are exempt from licensing but require online registration under Chapter IIIB, with applicable standards and QMS undertakings.

Examples are only typical: exact class depends on intended use and the current official CDSCO classification list.

WHO CLASSIFIES?

The Central Licensing Authority classifies devices according to intended use and the First Schedule. The manufacturer must follow the published class, not choose a convenient class.

WHY THE CLASS MATTERS

It determines the licensing authority, audit intensity, technical and clinical evidence, post-market vigilance and level of regulatory control.

BASIC ASPECTS RELATED TO MANUFACTURE OF MEDICAL DEVICES

STEP 1 — CLASSIFY THE DEVICE

Fix intended use, risk class, manufacturing site and whether the application is a normal licence, loan licence or import licence.

MANUFACTURE AND IMPORT LICENCE ROUTES

- Class A other than NSNM and Class B — Form MD-3, or loan-licence Form MD-4, to the State Licensing Authority → Form MD-5 or MD-6.
- Class C and Class D — Form MD-7, or loan-licence Form MD-8, to the Central Licensing Authority → Form MD-9 or MD-10.
- Import of any class — Form MD-14 to the Central Licensing Authority → import licence in Form MD-15.

QUALITY MANAGEMENT SYSTEM

- Comply with the Fifth Schedule for design control, purchasing, production, validation, cleanliness, complaint handling, CAPA, records and traceability.
- The statutory requirement is Fifth Schedule compliance. It is based on ISO 13485 principles; an ISO certificate does not replace compliance with the Rules.

AUDIT / INSPECTION

- Class A other than NSNM — no pre-grant audit; a registered Notified Body audits within 120 days after grant.
- Class B — registered Notified Body audit before grant.
- Class C and Class D — pre-grant inspection or audit under Central Licensing Authority arrangements.

RELEASE

Device may be released for supply after complying with licence conditions, QMS requirements and any other applicable regulatory requirements.

CLASS A NSNM REGISTRATION BYPASS

Class A NSNM — online registration under Chapter IIIB; no manufacturing licence. Applicable standards and QMS compliance undertakings are required.

CLINICAL INVESTIGATION — CHAPTER VII

Clinical investigation is governed primarily by the Medical Devices Rules, 2017, not by treating the NDCTR 2019 as the main device rule.

Investigational medical device: sponsor applies in Form MD-22 → permission in Form MD-23.

New IVD clinical performance evaluation: Form MD-24 → permission in Form MD-25.

Before enrolment: registered Ethics Committee approval, CTRI registration and informed consent.

Follow GCP and the Seventh Schedule.

A serious adverse event must be reported to the Central Licensing Authority within 14 days, with required follow-up and compensation processes.

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