Ministry of Health & Family Welfare
(Government of India)

Medical Device Regulations In India

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Assistant Drugs Controller(I)
Central Drugs Standard Control Organisation
New Delhi

Objective of Drugs & Cosmetic Act 1940 & Rules 1945:

To ensure safety, efficacy and quality of products

Risks ***Benefits***

Preamble:

To regulate Manufacture, Sale, Distribution and Import of

1.Drugs

2.Cosmetics

3.Biologicals(Vaccines)

4.Medical Devices

Drug is in concurrent list of Indian Constitution

It is governed by both Centre and State Governments under the Drugs & Cosmetics Act, 1940

Functions of CDSCO

- Approval of new drugs and clinical trials
- Import Registration and Licensing
- Licensing of Blood Banks, LVPs, Vaccines, r-DNA products & some Medical Devices
- Amendment to D &C Act and Rules
- Banning of drugs and cosmetics
- Grant of Test License, Personal License, NOCs for Export
- Testing of Drugs

Functions of State Licensing Authorities

- Licensing of Manufacturing Site for Drugs including API and Finished Formulation
- Licensing of Establishment for sale or distribution of Drugs
- Approval of Drug Testing Laboratories
- Monitoring of Quality of Drugs and Cosmetics marketed in the country
- Investigation and prosecution in respect of contravention of legal provision
- Recall of sub-standard drugs

Central Drugs Standard Control Organization

Drugs Controller General (I)

HEAD QUARTER
- New Drugs
- Clinical Trials
- Imports
- Biological
- Medical Devices
- Export
- QC
- Pharmco.Vig
- Legal etc

ZONAL OFFICE (6)
- GMP Audits
- Enforcement
- Draw drug Samples

SUB ZONAL OFFICE (4)
- GMP Audits
- Coordination with States

PORT OFFICE (13)
- Import
- Export

LABORATORY (7)
- Testing of Drugs
- Validation of Test protocols

Drug Testing Laboratories

National Laboratories: 7

State Labs: 31

For Vaccines: CRI, Kasauli

For r-DNA and Diagnostic kits ï NIB, Noida

For Medical Devices(Mechanical Contraceptives)-
Central Drug Testing Laboratory(CDTL), Chennai

Import and Export of Drugs from notified ports only

- ***Medical Devices are notified as DRUGS under Drugs & Cosmetics Act.***

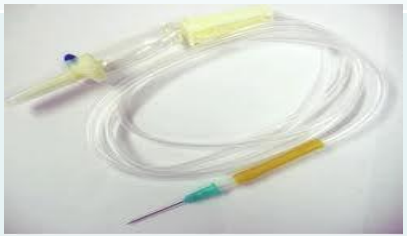
Section 3 (b) (iv) defines, Medical Devices as

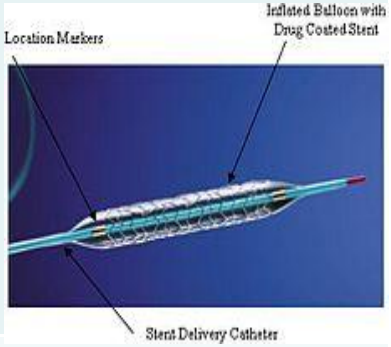
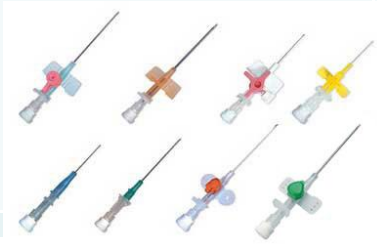
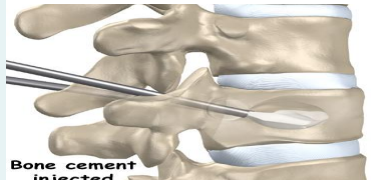
ñDevices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animalsò

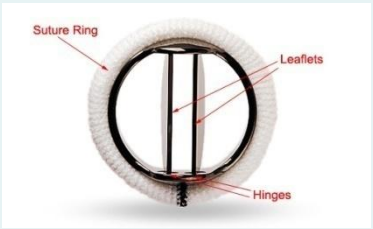
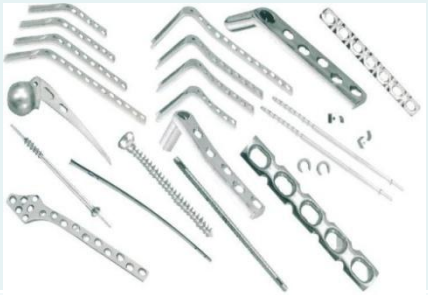
- GMP Requirements are specified under Schedule M III
- Rule 109-A Labeling of Medical Devices
- Rule 125-A Standards for Medical Devices

"Currently, 14 medical devices have been notified as Drugs"

S.No	Name of the device	Notification Number	Date of notification
1	Disposable Hypodermic Syringes	GSR 365 (E)	17-03-1989
2	Disposable Hypodermic Needles	GSR 365 (E)	17-03-1989
3	Disposable Perfusion Sets	GSR 365 (E)	17-03-1989
4	In vitro Diagnostic Devices for HIV, HbsAg and HCV	GSR 601(E)	27-08-2002
5	Cardiac Stents	S.O. 1468 (E)	06-10-2005
6	Drug Eluting Stents	S.O. 1468 (E)	06-10-2005
7	Catheters	S.O. 1468 (E)	06-10-2005
8	Intra Ocular Lenses	S.O. 1468 (E)	06-10-2005
9	I.V. Cannulae	S.O. 1468 (E)	06-10-2005
10	Bone Cements	S.O. 1468 (E)	06-10-2005
11	Heart Valves	S.O. 1468 (E)	06-10-2005
12	Scalp Vein Set	S.O. 1468 (E)	06-10-2005
13	Orthopedic Implants	S.O. 1468 (E)	06-10-2005
14	Internal Prosthetic Replacements	S.O. 1468 (E)	06-10-2005

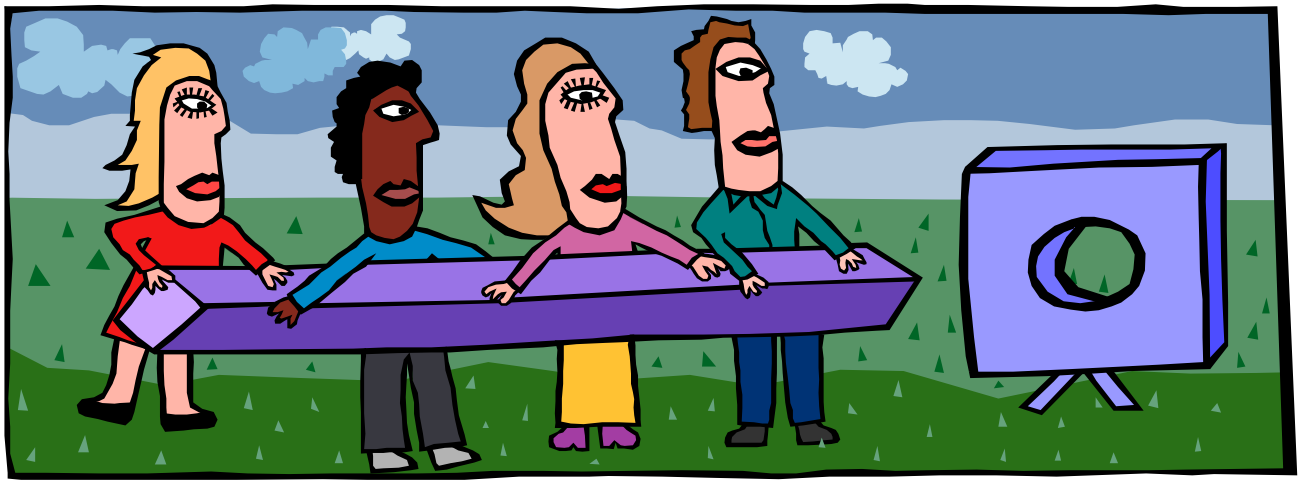
Sr. No.	Name of the device	Picture	Material of construction	Intended use
1	Disposable Hypodermic Syringes		Plastic	Syringes are often used to administer injections, insert intravenous drugs into the bloodstream.
2	Disposable Hypodermic Needles		Stainless steel	used with a syringe to inject substances into the body or extract fluids from it.
3	Disposable Perfusion set		Plastic	For transfusion of I.V. Fluid into the bloodstream.
4	Cardiac Stents		stainless steel and cobalt chromium, titanium	It helps to prevent arteries from re-narrowing after an angioplasty.

No	device		construction	
5	Drug Eluting Stents		Stainless steel , titanium and cobalt chromium (Drugs ï Paclitaxel, Everolimus, Rapamycin)	It keep the arteries open in the treatment of Coronary heart disease.
6	Catheter		Silicon rubber, latex	It allow drainage, administration of fluids or gases, or access by surgical instruments
7	Intra Ocular Lenses		(PMMA) Polymethylm ethacrylate	It is used for the treatment of cataracts.
8	I.V. Cannulae		Plastic	It can be inserted into the body, often for the delivery or removal of fluid
9	Bone Cements		(PMMA) Polymethylm ethacrylate	It fills the free space between the prosthesis and the bone

Sr. No.	Name of the device	Picture	Material of construction	Intended use
10	Heart Valves		Synthetic material, Animal origin (Bovine, Procine)	It allows blood flow in only one direction through the heart
11	Scalp Vein Set		Plastic	Its provide rapid venous access during infusion.
12	Orthopaedic Implants		Stainless steel, Nitinol, Titanium, cobalt chromium	Its used to replace or provide fixation of bone or to replace articulating surfaces of a joint
13	Internal Prosthetic Replacements		Hydroxyaptite	The globe-shaped portion of the eye surrounded by the socket and covered externally by the eyelids. The eye itself.
14	In vitro Diagnostic Devices for HIV, HBsAg and HCV		Nitrocellulose membrane	For quantitative detection of HIV, HBsAg and HCV in

Devices are not Drugs

One size does not fit all



Drug	Device
Based on Chemistry & Pharmacology	Based on Engineering
Safety and Efficacy	Safety and Performance/Accuracy
Clinical Trials(4 Phases)	Clinical Evaluation(Feasibility/Pivotal)
GMP	QMS
Local and Systemic Toxicity	Biocompatibility
Long Product Life Cycle	Short Product life Cycle
Drug Interactions	Device Malfunction

Drug	Device
Clearly specified, For Eg. Paracetomol	Based on design, effectiveness and Intended use Design changes quiet frequently like Mobile models.
Regulated by licensing system	Regulated by notified bodies(in most of the countries)
Clearly specified labeling requirements	As per ISO Symbol are used
Bulk or Formulation	Components or Accessories or Assembled or Finished product
Around 65 years experience	Only Seven years experience

Drugs

Drug interactions

Wrong drug/wrong dose

Devices

Malfunction

User error

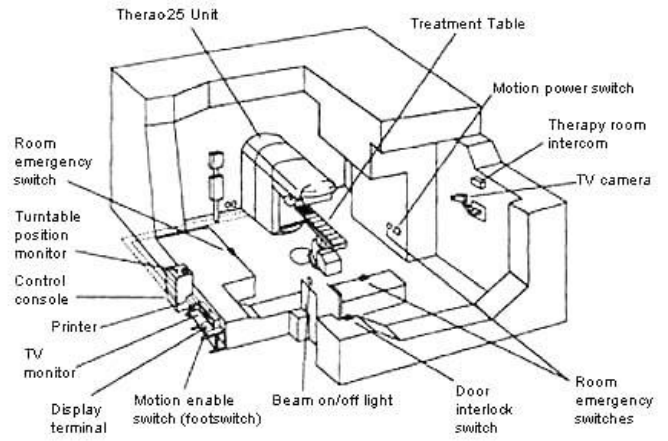
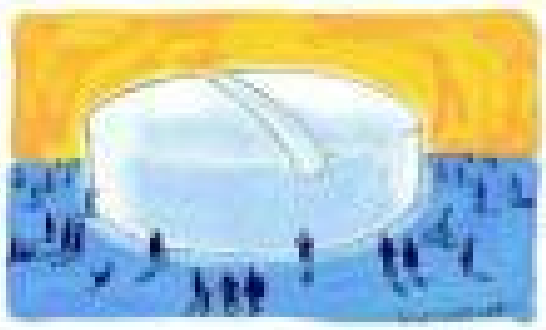


Figure 1. Typical Therac-25 facility

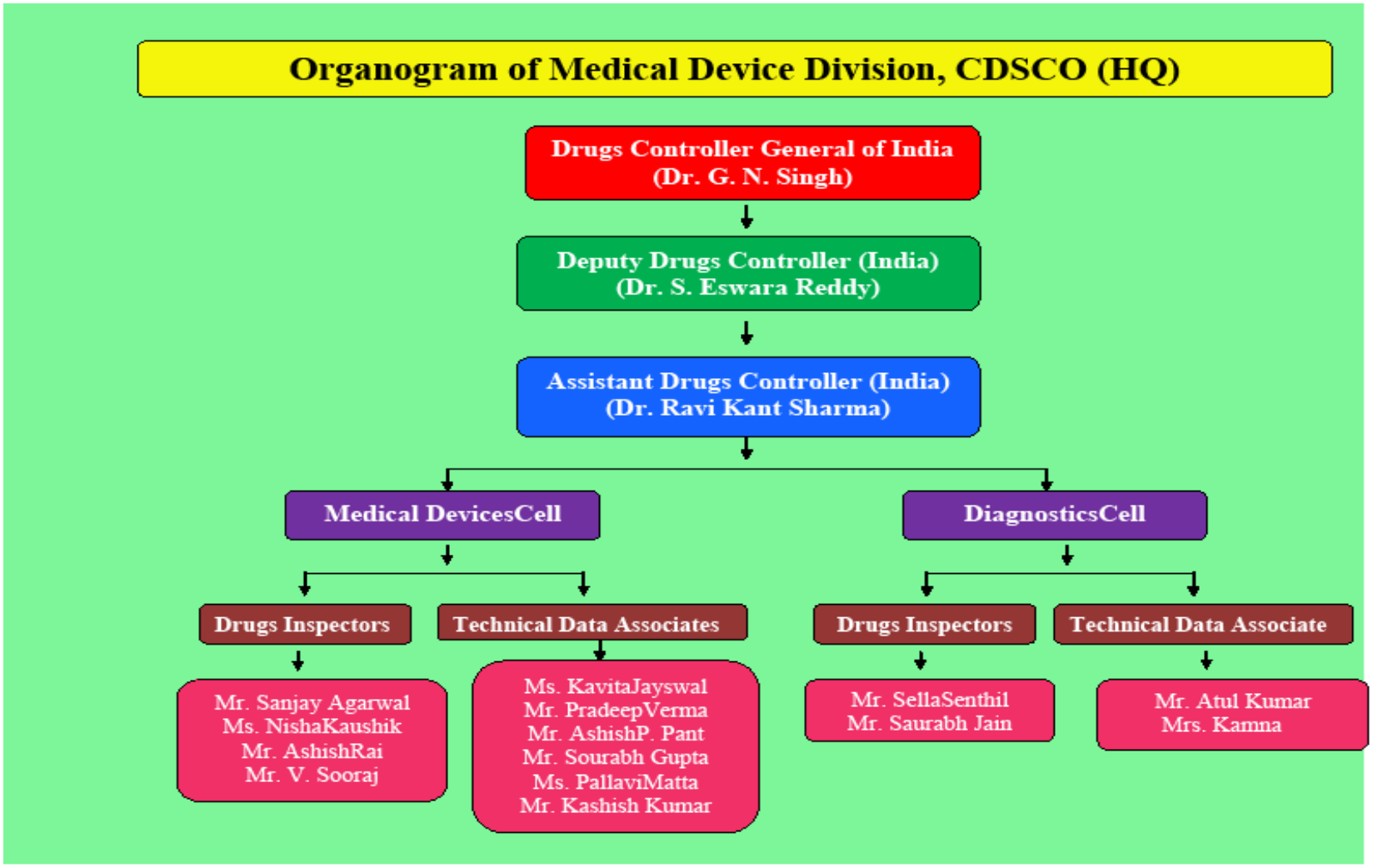
Drugs

- Clinical trial
- Clinical endpoints



Devices

- Risk-based
- Surrogate endpoints


Organogram of Medical Device Division, CDSCO (HQ)
Drugs Controller General of India
(Dr. G. N. Singh)
Deputy Drugs Controller (India)
(Dr. S. Eswara Reddy)
Assistant Drugs Controller (India)
(Dr. Ravi Kant Sharma)
Medical DevicesCell
DiagnosticsCell
Drugs Inspectors
Technical Data Associates
Drugs Inspectors
Technical Data Associate
Mr. Sanjay Agarwal
Ms. NishaKaushik
Mr. AshishRai
Mr. V. Sooraj
Ms. KavitaJayswal
Mr. PradeepVerma
Mr. AshishP. Pant
Mr. Sourabh Gupta
Ms. PallaviMatta
Mr. Kashish Kumar
Mr. SellaSenthil
Mr. Saurabh Jain
Mr. Atul Kumar
Mrs. Kamna

Functions of Medical Device Divison

- Import Registration and Licensing of Medical Devices
- Approval of New Medical Devices
- Manufacturing License to Indigenous Manufacturer under CLAA Scheme
- Grant of Test License
- NOCs for Import/Clarifications
- Neutral Code For Export
- Clinical Trials

Import. Registration & Licensing

Mfg sites and Products are required to be Registered

Issue of Registration Certificate in Form 41

Issue of Import License in Form 10 / 10A

Rules 21 to 30 ⇨ Rules related to grant of Registration Certificate and Import License

Schedule DI & DII ⇨ Information required for registration of Mfg site and Product

Timeline as per D & C Rules

For RC: Rules, 9 Months

For Import License: 3 Months

Registration Certificate(RC) and Import License - Valid for 3 years

Import Procedure

Application For Registration
(Form- 40/ Schedule D(I)/ Schedule D(II), Power of Attorney)

⇩

Registration Certificate issued by CDSCO
(Form-41)

⇩

Application For Import License
(Form-8, Form 9)

Drug License
Sell, Stock & Exhibit
by SLA

⇩

Import License issued by CDSCO
(Form- 10)

Application Fees:

Mfg. Site Registration
1500 USD per Site

Product Registration
1000 USD per product

Application Fees:

INR1000(22 USD)

Approval of New Medical Devices

Appl. in Form44 as per Schedule Y
TR6 Challan of Rs.50000/

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Review of Clinical Trial Protocol, Published reports, literature, Package Insert etc by CDSCO

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Evaluation By Medical Device Advisory Committee

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On Basis of Recommendations of MDAC

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Permission Under Rule-122A granted → Registration and Form-10

Six Medical Device Advisory Committees Constituted

- MDAC - Cardiovascular
- MDAC -Dental
- MDAC - Reproductive and Urology
- MDAC - Orthopedics
- MDAC - Ophthalmic
- MDAC - Miscellaneous

Clinical Trial Regulation

Requirements and Guidelines - Schedule Y

Rule 122 A	Permission to import new drug
Rule 122 B	Permission to manufacture new drug
Rule 122 DA	Definition of Clinical trials
Rule 122 E	Definition of New Drugs*

Regulation of Clinical Trials:

- Clinical Trials are regulated under the provisions of Drugs and Cosmetics Rules

- No clinical trials of New Drugs can be conducted without permission

Initiatives taken

- IND Committee for evaluation of Investigational New Drugs

- 12 New Drug Advisory Committees (NDACs) for Evaluation of clinical trials and new drug approvals

- 6 Medical Devices Advisory Committees

- Mandatory registration of Clinical Trials (Clinical Trial Registry of India)

Concerns in Clinical Trials

- Review of Clinical Trial applications
- Obtaining Informed Consent of subjects
- Examination of reports of Serious Adverse Events (SAEs)
- Compensation for clinical trial related injury or death
- Monitoring of Clinical Trials
- Functioning of Ethics Committees

CLAA Approval for Indigenous Manufacturer

- The "Guidance Document on Application for Grant of Licence in Form-28 for Manufacture of Medical Devices in India under CLAA Scheme" indicates the application requirements for a medical device manufacturing license.
- The manufacturing site is jointly inspected by the CDSCO Officials and State Drugs Control Officers.

Application in Form-27 along with fees, DMF & PMF

DCGI
Review & Examination
Directs Zonal office for
Joint Inspection

State Licensing Authority

Zonal Office

Joint Inspection Report

The State Licensing Authority after Joint Inspection and verification forward the license in triplicate to CLAA for approval.

The license shall be issued in Form 28 after due approval of CLAA.

Diversity of medical devices

Source: US FDA CDRH 2005 Strategic Plan (modified)

Definition of term "Medical Device"

Intended primary mode of action

Drug eluting stent

- Primary intended mode of action
  - stent opens artery
- Secondary action
  - drug reduces inflammation and restenosis of artery

➢ **Regulated as a device**

Definition of term "Medical Device"

Intended primary mode of action

Drug eluting stent

- Primary intended mode of action
  - stent opens artery
- Secondary action
  - drug reduces inflammation and restenosis of artery

➢ Regulated as a device

Drug eluting disc

- Primary intended mode of action
  - chemotherapy for brain tumour
- Secondary action
  - local delivery of drug by device

➢ **Regulated as a drug**

Pre-filled -Insulin

Definition of term "Medical Device"

Definition

Is a syringe a medical device?

Source: Google Images

Inert Material

Definition of term "Medical Device"

Definition

Is a syringe a medical device?

Source: Google Images

Definition of term "Medical Device"

Definition

Is a contact lens a medical device?

Definition of term "Medical Device"

Definition

Is a contact lens a medical device?

Medical device?

Latex Examination Gloves Textured Lightly Powdered

Ministry of Health & Family Welfare
(Government of India)

Thank you for your kind attention