Updates on Medical Device and IVD Regulation in India

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Introduction

- Total market Size ~ USD 11 Billion
- Projected Growth Rate - 20%
- Imports - 75% of the total market size
- Notified Medical Devices and In Vitro Diagnostic Kits are regulated
- Approx. 1500 manufacturing sites are for medical devices and 200 manufacturing sites of IVDs in India.
- 100% FDI

Regulation of Medical Devices

- The Medical Device Rules, 2017 have been implemented w.e.f. 01.01.2018 vide G.S.R 78(E) dated 31.01.2017.

- The Medical Devices Rules, 2017 are harmonised with the international regulatory practices and provide comprehensive legislation for the regulation of Medical Devices like import, clinical investigation, manufacturing, sale and distribution.

Scope of the regulation

Medical Device Rules, 2017 are applicable to:

(i) substances used for in vitro diagnosis and surgical dressings, surgical bandages, surgical staples, surgical sutures, ligatures, blood and blood component collection bag with or without anticoagulant covered under sub-clause (i) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940);

(ii) substances including mechanical contraceptives (condoms, intrauterine devices, tubal rings), disinfectants are notified under sub-clause (ii) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940); and

(iii) devices notified from time to time under sub-clause (iv),

of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940);

The Govt of India has notified…

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

Cont....

The Products which were regulated as ‘drugs’ but now fall under the scope of Medical Devices Rules, 2017

16. Blood Grouping Sera and substances for In Vitro Diagnosis
17. Ligatures, Sutures and Staplers
18. Intra Uterine Devices (Cu-T)
19. Condoms
20. Tubal Rings
21. Surgical Dressings
22. Umbilical tapes
23. Blood/Blood Component Bags
24. Disinfectant

Cont...

Ministry of Health and Family Welfare has notified the following Medical Devices vide S.O. 5980 which are under regulation with effect from 01.01.2021

25. Nebulizer

26. Blood Pressure Monitoring Device

27. Digital Thermometer

28. Glucometer

Cont..

Ministry of Health and Family Welfare vide S.O. 775 (E) dated 08.02.2019 has notified following medical devices which are under regulation with effect from 01.04.2021,

29. All implantable medical devices
30. MRI equipment
31. CT Scan equipment
32. Dialysis machine
33. PET equipment
34. X-ray machine
35. Defibrillator
36 .Bone marrow cell separator.
37. Ultrasound equipment (w.e.f. 01.11.2021)

Definition vide S.O. 648(E) dated 11.02.2020

- All devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of —
  - diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
  - diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
  - investigation, replacement or modification or support of the anatomy or of a physiological process;
  - supporting or sustaining life;
  - disinfection of medical devices; and
  - control of conception.

Registration of non-notified Medical Devices (G.S.R 102(E) dated 11.02.2020)

- The Medical devices shall be registered with the Central Licensing Authority through an identified online portal established by the Central Drugs Standard Control Organization.

- Applicant's registration number will be generated by CDSCO. Manufacturer/ Importer shall mention the registration number on the label of the medical device.

Risk based Class	Voluntary Registration	Mandatory Registration	Licensing regime
Class A & B	01.04.2020 to 30.09.2021 (18 months)	01.10.2021 to 30.09.2022 (12 months)	w.e.f. 01.10.2022
Class C & D	01.04.2020 to 30.09.2021	01.10.2021 to 30.09.2023	w.e.f. 01.10.2023

Medical Device Rules,2017 Content

Chapter- I	Title, Application, Commencement, Definition
Chapter - II	Classification of MD, Grouping of MD, Essentials Principles
Chapter - III	Authorities, delegation of powers, Notified bodies, Medical Devices Testing Centres,
Chapter - IV	Manufacture of MD-Application, Inspection, grant of lic, conditions of lic, Suspension, Cancellation, Appeal, Test License
Chapter - V	Import of MD-Application, Overseas Inspection, grant of lic, Test lic, Hospital use, Personal use
Chapter - VI	Labelling requirement
Chapter - VII	Clinical Investigation- Permission, Medical management, Compensation, Inspection
Chapter - VIII	Permission to import or manufacture medical device which does not have predicate medical device
Chapter -IX	Duties and Powers of Medical Device Officer, Medical Device Testing Officer and Notified Body

Medical Device Rules, 2017-Schedules

Schedule	Title
First	Classification of MD and IVD
Second	Fee
Third	Registration and functions of Notified Bodies
Fourth	Documents required for grant of mfg and Import licence
Fifth	Quality Management System
Sixth	Post Approval - Major and Minor Changes
Seventh	Requirements to conduct Clinical Investigation
Eight	Exemptions

Risk based classification……

- **Medical devices shall be notified by the Central Government and classified by the CLA based on the classification rules specified in the *First Schedule* of the drafted rules.**

- **Following are the risk Classes and the classification criteria based on the severity of risk associated with the medical device.**

Risk Criteria	Risk Class
Low	Class A
Low-Moderate	Class B
Moderate-High	Class C
High	Class D

Regulatory Authorities

Device Class / Activity	Class A	Class B	Class C	Class D
Import	CLA	CLA	CLA	CLA
Manufacture	SLA	SLA	CLA	CLA
Permission to conduct CI	Permission from CLA			
Sale	SLA			
QMS Verification by	*Notified Body	*Notified Body	CLA	CLA

***Note: Notified Bodies shall be registered with Central Licencing Authority. Prior inspection shall not be required before the grant of manufacturing of Class A devices.**

Salient features of Schedule V

Schedule V in line of Quality Management System (QMS) as per ISO 13485 applicable to Medical Device and In-vitro Diagnostics Kits

- Management Responsibility
- Control of Documents
- Control of records
- Competence, awareness and training
- Design and Development
- Purchasing information
- Control of Non-conforming product
- Analysis of data
- Corrective action and preventive action
- Consumer related processes
- Environmental requirements for notified device with type of operation and ISO Class

Standards of Medical Devices

The medical device shall conform to the standards laid down by BIS or may be notified by Central Government from time to time. If, such standards are not available then ISO, IEC or any other pharmacopeial standard. If these standards are not available, then device shall conform to the validated manufacturers standards.

Definitions from MDR-2017

"Clinical investigation" (CI) means the systematic study of an investigational medical device in or on human participants to assess its safety, performance or effectiveness;

New in vitro diagnostic medical device: means any medical device used for in vitro diagnosis that has not been approved for manufacture for sale or for import by the Central Licensing Authority and is being tested to establish its performance for relevant analyte or other parameter related thereto including details of technology and procedure required.

MDR 2017

Investigational medical device: (i) which does not have its predicate; or (ii) which is licensed under manufacturing license or import license and claims for new intended use or new population or new material or major design change; and is being assessed for safety or performance or effectiveness in a clinical investigation.

"Clinical performance evaluation" (CPE) means the systematic performance study of a new in vitro diagnostic medical device on a specimen collected from human participants to assess its performance;

Clinical Investigation of Medical Devices

Pilot clinical Investigation

means to be carried out for the first time in human participants.

Pivotal Clinical Investigation

based on the data emerging from pilot clinical investigation.

No permission for conduct of academic clinical study on licensed medical device is required.

Medical devices claiming substantial equivalence to a predicate device shall not be marketed unless CLA approved.

CLA has to grant permission to conduct clinical investigation within a period of 90 days from the date of application if all requirements fulfilled.

Where an injury/death is caused related to clinical investigation, the sponsor shall provide the compensation and medical management.

Materio-vigilance Programme

Materiovigilance programme of India was launched **on 6th July 2015 at Indian Pharmacopoeia Commission, Ghaziabad**.

Indian Pharmacopoeia Commission functions as National Coordination Centre (NCC).

Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram act as National Collaborating Centre,

National Health System Resource Centre (NHSRC), New Delhi, act as Technical support partner

Central Drugs Standards Control Organisation (CDSCO), New Delhi, support MvPI with experience of functioning as National regulator.

Under MvPI, 250 Medical Devices Adverse Events Monitoring Centres have been identified in the country to report the events on voluntary basis (spontaneous).

PERFORMANCE EVALUATION/ VALIDATION

- List of Laboratories identified for validation of IVD kits available in CDSCO website.
- Prior to issue of Import/ manufacturing permission, PE/ Validation require for In-vitro Diagnostics Reagents/ Kits used for the detection of :

1. HIV
2. HBV
3. HCV
4. Blood Grouping reagent
5. Cancer
6. Tuberculosis
7. Malaria
8. Dengue
9. Chikungunya
10. Syphilis
11. Typhoid
12. Influenza
13. Toxoplasma Gondii
14. Cytomegalovirus
15. Pneumonia
16. Methicilline-Resistant Staphylococcus Aureus
17. Entero Virus (A/B)
18. Markers for Congenital disorders
19. Neisseria Gonorrhoeae
20. Human Papilloma Virus infection
21. Autoimmune Disorders
22. Human Genetic testing
23. Other life threatening infections/agents (eg. COVID-19, Nipah Virus, Zika Virus etc.)

Specification/Criteria for IVDs

Product	Type	Specification/Criteria
HIV HBsAg	ELISA / RAPID	Sensitivity 100% Specificity ≥ 98%
HCV	ELISA	Sensitivity 100% Specificity ≥ 98%
HCV	RAPID	Sensitivity ≥99% Specificity ≥ 98%
Rapid Plasma Reagin (RPR) Test And TPHA (Hemagglutination) Test for Syphilis	ELISA / RAPID	Sensitivity ≥ 85% Specificity ≥ 93%
Malaria Antigen Detection of Pf / Pv (Plasmodium falciparum / Plasmodium vivax)	RAPID	1. For the detection of Pf / Pv in all transmission settings the panel detection score (PDS) should be at least 75% at 200 parasite/µL. 2. False positive rate should be less than 10% 3. The invalid rate should be less than 5%

Acceptance Criteria for SARS-CoV-2 IVD Kits

Type of Kit	Acceptance Criteria
RT-PCR Kit	Sensitivity: 95% and above Specificity: 99% and above
RNA Extraction Kit	At least 95% concordance among positive At least 90% concordance among negative samples > 95 % samples showing amplification in internal control
VTM	100% concordance among spiked samples 100% samples showing amplification in internal control
Antibody Rapid Kit	Sensitivity: 90% and above Specificity: 99% and above
ELISA / CLIA Kit	IgM: Sensitivity- 90% and above Specificity- 99% and above IgG: Sensitivity- 90% and above Specificity- 95% and above
Rapid Ag Test Kits	• Validated as a Point of Care Test (POCT) without transport to a laboratory setup: Sensitivity: 50% and above; Specificity: 95% and above • Validated in a laboratory setup with samples collected in Viral Transport Medium (VTM): Sensitivity: 70% and above; Specificity: 99% and above

Fast track Approval for COVID-19 IVD Kits/Reagents

- Fast track clearances of COVID-19 IVD kit applications from March 2020 to till date.
- Latest list of approved COVID-19 kits are being uploaded in CDSCO website. The following kits for the detection of COVID-19 infection have been approved by this office.
- Total: 542

Rapid / ELISA / CLIA (Serology based)	RT-PCR (Molecular based)	Antigen Test	Antigen Home Test / Self Test
158	270	98	16
Importer - 97	Importer - 162	Importer - 37	Importer–02
Indigenous - 61	Indigenous - 108	Indigenous – 61	Indigenous - 14

Medical Device Innovation in India

Medical device innovation in India

- "Innovation in India" can help drive :
  - Make in India
  - Enhance Quality
  - Reduction in Cost for Domestic and developed market.
  - Increase of Export.
  - The medical device sector in India needs to be empowered through private-public partnerships among the Indian Government, Indian researchers, Indian clinicians and MNCs

Recent Notifications

- MOHFW has published a notification G.S.R. 777(E) dated 14.10.2022 regarding the registration of Class A (Non-sterile and Non-measuring) Medical Devices, eg: Cotton Crepe Bandages, Cutting and Dissecting Surgical Instruments, Grasping and holding surgical instruments like tissue forceps, needle holders (exemption of Chapter IV, V, VII, VIII and XI).

  Registration of such devices on the portal established by CDSCO.

- MOHFW has published a notification G.S.R. 754(E) dated 30.09.2022 regarding the provision for registration for sale of Medical Devices.

Achievements

- New Online System for Medical Devices is functional for uploading the applications for Import License and Manufacturing License of Medical devices and IVDs, for post approval changes, registration of medical devices testing laboratories, clinical investigation, notified bodies etc.

- Classification of more than 26 categories of Medical Devices including IVDs has been finalized in consultation with the stakeholders and uploaded in the CDSCO website.

- Grouping of Medical Devices and IVDs along with essential principle checklist has been finalized in consultation with the stakeholders and uploaded in the CDSCO website.

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- 236 Medical Device Officers are notified by Central Government.
- CDSCO has registered twelve notified bodies for the audit of Class A and Class B Medical Devices.
- Six Central Medical Device testing laboratories have been notified by the MoHFW.
- CDSCO has registered Twenty eight laboratories for the testing of Medical Devices on the behalf of manufacturers.

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- CDSCO organize workshops to impart trainings for State Licensing Authorities for the effective implementation of Medical Devices Rules, 2017.

- Regular interactions with all the stakeholders to resolve the issues pertaining to regulatory pathway.

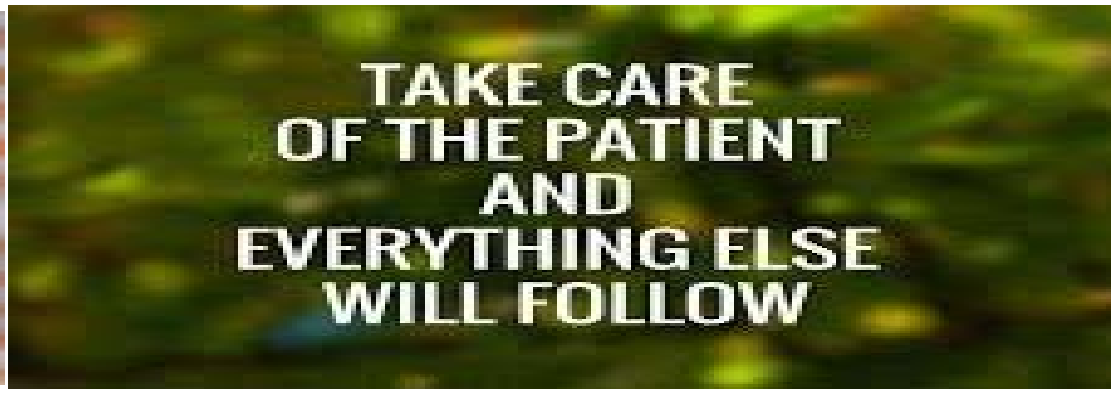
- For addressing various questions on regulatory practices in medical devices, Frequently Asked Questions (FAQ) on medical devices and In vitro diagnostics kits is available on CDSCO website.

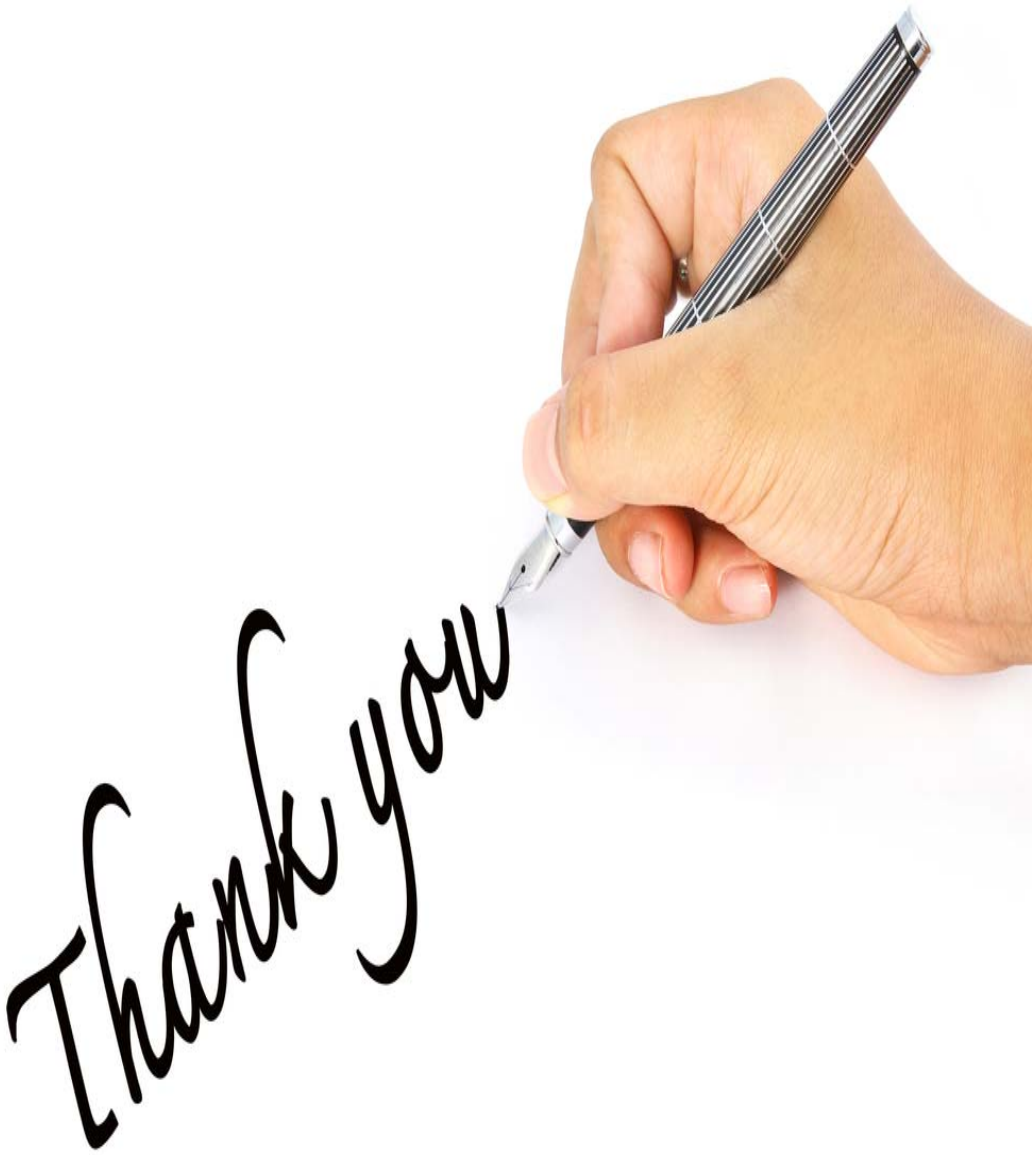
- CDSCO has also started Public relations office (PRO) to assist any start-up/ innovator/ industry person in facilitating regulatory clearances. Function from 10:00 am to 5.30 pm in all working days.

“ Changes calls for innovation.....

Innovation leads to progress.....

And Innovation is only the way to win”




Thank you