An overview of regulations of Medical Device and IVDs in India (India Regulatory update)

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Drugs and Cosmetics Act 1940

The quality, safety and efficacy of notified medical devices manufactured, imported and sold in the country regulated under the Drugs and Cosmetics Act, 1940. Medical devices are regulated as drugs as defined in Section 3 (b) (iv) that:

"Such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification after consultation with the Board"

Notified Medical Devices are…..

- Disposable Hypodermic Syringes
- Disposable Hypodermic Needles
- Disposable Perfusion Sets
- In vitro Diagnostic Devices for HIV, HbsAg and HCV and blood grouping sera
- Cardiac Stents
- Drug Eluting Stents
- Catheters
- Intra Ocular Lenses
- I.V. Cannulae
- Bone Cements
- Heart Valves
- Scalp Vein Set
- Orthopedic Implants
- Internal Prosthetic Replacements
- Ablation Devices

MD Regulation in India

- Presently, Medical Devices and IVDs are regulated under D&C Rules, 1945.
- To simplify medical devices regulation, Medical Devices Rules, 2017 , published by GOI on 31.01.2017
- MDR, 2017 shall commence from 1st January, 2018 for the regulation of medical devices and IVDs in the country.
- The licences and RCs issued under D&C Rules shall continue to be valid till July, 2018 or their expiry, whichever is later.

Medical Device Rules, 2017

- Medical Device Rules, 2017 under the provisions of the Drugs and Cosmetics Act, 1940 has been published, vide GSR 78(E) dated 31.01.2017 proposed to be effected from 01.01.2018.
- New Rules will override all the previous notifications issued under the D&C Rules,1945 related to the regulations of medical devices.
- New rules have provisions for the regulation of devices for their import, manufacture, clinical investigation and sale.

Scope of the regulation

New Rules shall be 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 and insecticides 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);

Proposed Medical Device rule 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
Chapter -X	Regulation of Laboratories for carrying test or evaluation
Chapter - XI	Sale of Medical Devices
Chapter - XII	Miscellaneous – Rejection of application, Debarment of applicant, Exemptions

Proposed 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 IL
Fifth	Quality Management System
Sixth	Post Approval - Major and Minor Changes
Seventh	Requirements to conduct Clinical Investigation
Eight	Exemptions

MDR 2017 - Salient Features

New Definitions

- Medical Device
- Substantial Equivalence
- Predicate device
- Investigational Medical Device
- New in-vitro diagnostic
- Clinical Investigation
- Notified Body
- Clinical Performance Evaluation

Risk based Classification

- Devices notified under D&C Act will be classified by the CLA based on classification rules specified in First Schedule.
- Following are the risk Classes

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.**

Licensing Authorities…..contd.

- Application for Import, Clinical Performance evaluation of new IVD and manufacture of Class C and Class D IVDs, test licence, Free Sale Certificate, and personal use will be submitted to CLA through online portal. Inspection of manufacturing site will be carried out by Drugs Inspectors.

- Application for sale, manufacture of Class A and Class B devices will be submitted to SLA through online portal. Audit of manufacturing site will be carried out by Notified Bodies.

Scope of Notified Bodies

- Only Class A and Class B medical Devices
- To verify QMS conformance at manufacturing site where necessary by inspection
- Verification of Essential Requirements
- Verifying validation of manufacturing process through objective evidence
- conformity of material with defined specifications
- Responsibility for ensuring conformance to QMS and conditions of license/registration
- State Licensing Authority to audit at least 2% of the audits carried out and recommended for grant of license by of each Notified Body.

Registration & Regulation of Notified Bodies

- Registered with CDSCO.
- Accredited by National Accredited Body (such as NABCB).
- Procedures prescribed in schedules for registration of notified bodies.
- Schedule of fee to be charged by notified bodies.
- Duties, functions and obligations of notified bodies specified in the *Third Schedule* of the rules.

Standards of medical devices

- BIS or those set by Central Government.
- Failing (i) by International Organization for Standardization (ISO) or International Electro Technical Commission (IEC).
- Failing both, manufacturers validated standards.

Clinical investigation

- MDs do not have a predicate device undergo through CI for safety
- Pilot Clinical investigation (on 3 to 5 subjects)
- Pivotal clinical investigation (on 10 to 50 subjects)
- Supervision by Ethics Committee.
- Application to CLA Waiver in case of National Emergency.
- Maintenance of investigation records mandatory.

Exempted Medical Devices

- Class A devices exempted from clinical investigation.
- Custom made devices are exempted from provisions of import and manufacture.
- Medicated Dressings, Mechanical Contraceptives, bandages and disinfectants are exempted from provisions of Sale.
- Devices intended for charity – exempted from import licence

Asian Harmonization Working Party
WORKING TOWARDS MEDICAL DEVICE HARMONIZATION IN ASIA

Ministry of Health & Family Welfare
Government of India

Thank You