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Regulatory Insight

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Medical Device Rules 2017 –PART 1 – Overview

GEOGRAPHY
India

SECTOR
Medicine

SUB SECTOR
Medical Devices and In vitro Diagnostic Medical Devices

CATEGORY
Medical device classification, Notified bodies, Standards, Manufacturing, Clinical investigation, Labelling, Import, Distribution,

REGULATOR
Central Drugs Standard Control Organisation (CDSCO)

STATUS : IMPLEMENTED
Published in January 2017. Implemented from 1st January 2018.

BACKGROUND

India, of late, has moved on from being the largest medical devices market in Asia to being a market which is showing an impressive appetite for conventional and new technology enabled medical devices. Although around, 80% of the current demand for medical devices is catered through imports, there are a few India based manufacturers with an impressive product portfolio and market share in specific segments.

Even though Schedule R and R1 of the Drugs & Cosmetics Act 1940 & Rules 1945 regulated a very limited number of products (primarily condoms, mechanical contraceptives, perfusion sets, Hypodermic syringes and needles), Medical device specific regulations are quite young in India. The year 2005 was when a limited number of products(Notified Medical Devices) were brought under regulatory control. These products were being regulated as Drugs rather than as Medical Devices under the Drugs & Cosmetics Act & Rules till 1st January 2018.

A comprehensive set of rules called the "Medical Device Rules 2017" were specifically framed for Medical Devices under the Drugs & Cosmetics Act & Rules and were implemented from 1st January 2018 to regulate the medical devices industry with relevant and applicable regulations.

PART 1 of this series deals with an overview of the regulation and classification of Medical Devices and In vitro diagnostic medical devices.

IMPACT SUMMARY :

Sl.	Categories	Area / Activities
1.	Medical Devices & In-vitro diagnostic medical devices	Definition, Classification, Product Grouping, Essential principles for manufacturing medical devices, Applicable Product Standards
2.	Notified Bodies	Definition, Accreditation, Registration, Responsibilities, Function, Audit Process
3.	Manufacturing	Application process, Approval process, Quality Standards, Notified body audits
4.	Import	Application process, Approval process, Authorized agent role & Responsibilities
5.	Clinical Investigation	Application process, Approval process, Conduct
6.	Product Labelling	Content (for Testing & Commercial sale), Format, Exemption, Unique device identifier

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INTRODUCTION

The Medical Device Rules 2017, published in January 2017 and being implemented from 1st January 2018, can be termed to be the first formal Indian regulation which has been specifically drafted after considering "Medical Devices" and "In vitro diagnostic medical devices" to be different from a drug.

Although these rules have been implemented under the Drugs & Cosmetics Act & Rules, they have completely overhauled the way Medical Devices and In vitro diagnostic medical devices are regulated in India. These regulations are compatible with globally accepted and practiced regulations but also take into consideration the existing and anticipated health needs, industry sector growth, market situation for these products in India.

Overall, as with all regulations in this domain, the objective of this regulation is to make available medical devices and in vitro diagnostic medical devices which are safe and effective to the Indian population.

OVERVIEW

The Medical Devices Rules 2017 comprises of 12 Chapters, 8 Schedules and 40 Forms. It has been drafted to ensure its as comprehensive as possible within present day limitations and is designed to be flexible enough to add or delete the list of categorized products which are to be published from time to time by Central Drugs Standard Control Organisation (CDSCO).

The changes through this regulation encompasses all areas of import, export, manufacturing, and supply of medical devices and In vitro diagnostics medical devices. Critical changes to existing procedures are presented below, in brief, to help the reader have an overview of the changes and help them understand how these changes can affect their areas of interest.

- *Definitions (Chapter I) :*
  - A few definitions such as Medical device, active medical device, invasive device, active therapeutic medical device, active diagnostic medical device, clinical evidence, clinical investigation, clinical performance evaluation, intended use, notified body, predicate device, medical device grouping, etc., have been defined or modified to enhance its scope of applicability.
    - A medical device, amongst other things is also defined to include mechanical contraceptives. The definition also includes disinfectants & insecticides and other devices which are to be notified as required.
    - Substances used for in vitro diagnosis will be referred to as "in vitro diagnostic medical device".

- *Regulations of Medical Device (Chapters II & III):*
  - Chapter II talks about the risk based approach used to classify medical devices and in vitro diagnostic medical devices, Medical device grouping that manufacturers and marketers are expected to follow, Essential principles for manufacturing and product standards that are expected of medical devices that are manufactured and or marketed in India.
  - Chapter III, amongst other things talks about Notified body, National accreditation body, Roles, responsibilities, Duties, Procedures, Fees etc., as applicable to notified bodies.

- *Manufacturing of Medical Device (Chapters IV):*
  - This chapter is about regulations applicable to manufacturing of Class A, B, C, D medical devices, types of manufacturing licenses, procedures to apply for and obtain appropriate licenses, timelines for review & approval or rejection of applications etc.,

- *Import of Medical Device (Chapters V):*
  - One of the critical changes under this section, compared to the previous procedure is that, every importer has to be an authorized agent.
  - The concept of a single registration certificate (issued to a manufacturer or his authorized agent) and multiple import licenses (issued to various individual distributors) based on the registration certificate has been revamped. In the present regulation, every importer has to apply for the

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import license, which is possible only if he is an authorized agent of the manufacturer.

- *Labelling of Medical Device (Chapters VI):*
  - Labelling requirements including exemptions, unique device identification, labelling of medical devices and in vitro diagnostic medical devices for test, evaluation, clinical investigation have been outlined.

- *Clinical investigation / Evaluation(Chapters VII):*
  - This chapter outlines regulations governing clinical investigations with reference to medical devices and clinical performance evaluation with regards to in vitro diagnostic medical devices. The procedure to garner approvals to conduct appropriate studies and the timeline by when CDSCO should respond is also outlined.
  - The studies should comply with Good Clinical Practice (GCP) standards where applicable and have to be conducted only after appropriate ethics committee approvals are in place. Medical management and compensation in case of any adverse reaction/s are also outlined.

- *Schedules:*
  - Out of the eight schedules, the first schedule contains the basic principles and various parameters based on which medical devices and in vitro diagnostic medical devices and software are classified. The second schedule outlines the fee structure for various activities that are required to be conducted by CDSCO.
  - The third schedule talks about Notified bodies, the fourth schedule talks about documents required for approval for manufacturing and the fifth schedule outlines the quality management system for medical devices and in vitro diagnostic medical devices.

CLASSIFICATION OF MEDICAL DEVICES :

Classification of medical devices and in vitro diagnostic medical devices follow the internationally accepted risk based approach.

Based on the level of anticipated risk for the intended use, both, medical devices and in vitro diagnostic medical devices are classified either as :

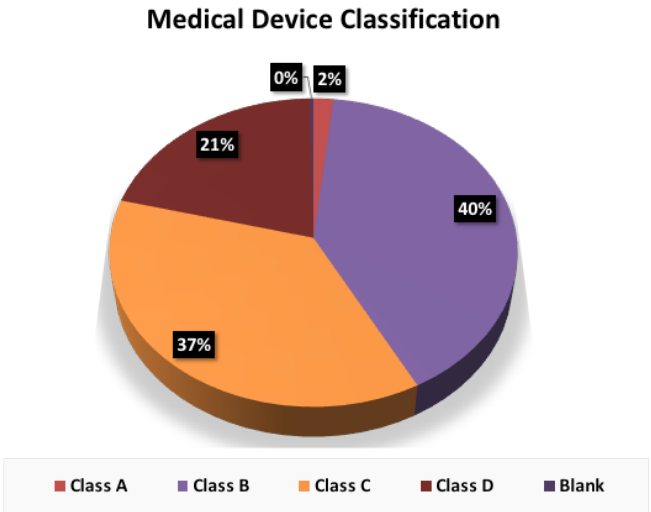
- Low risk – Class A;
- Low Moderate risk – Class B;
- Moderate High risk – Class C and
- High risk – Class D.

Parameters to be considered when assessing risk level and hence Class of a particular device is detailed under the First Schedule on this regulation. Medical devices grouping should follow the guidelines issued by CDSCO as and when available.

Although the process of medical device and in vitro diagnostic medical device classification is outlined in detail, at present, the classification of devices as notified by CDSCO (based on the parameters listed in the regulation) and published in the official website(www.cdsco.nic.in) has to be considered. The latest classification update(as on 06 June 2018) lists 348 Medical Devices(although serial numbered from 1 to 350) and 243 In vitro diagnostic medical devices (although serial numbered from 1 to 247).

The 348 medical devices notified are grouped under the following 17 categories : Ablation devices, Bone cements, Cardiac stents, Drug eluting stents, Catheters, Contraceptives, Disinfectants, Hypodermic needles, Hypodermic syringes, Perfusion sets, Heart valves, Internal prosthetic replacements, Intra ocular lenses, IV Cannulas, Orthopedic implants, Scalp vein sets and Surgical dressings. One medical device has not been assigned any class. Medical devices categorized as Class A, B, C, D are represented in Figure 1 below.

FIGURE 1 : Medical Device Classification



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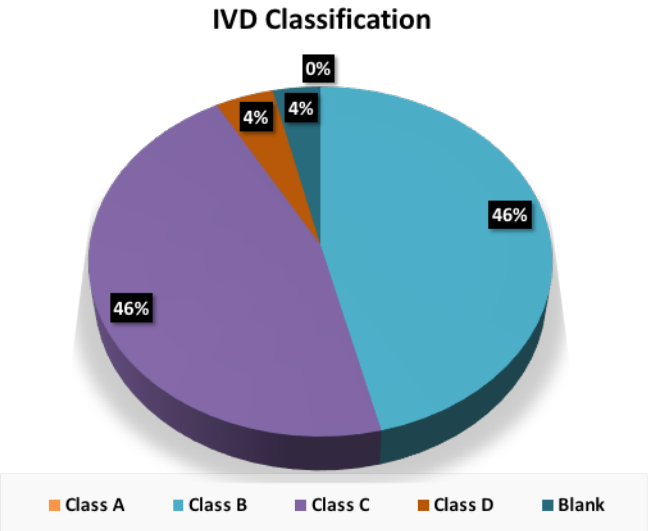
Notified In vitro diagnostic medical devices are grouped under 21 categories and include Clinical Chemistry Reagents/Kits; Hematology Reagents/Kits; Reagents/Kits for estimation of parameters in the urine; In - vitro Diagnostic Medical Devices for Self - Testing; In - vitro Diagnostic Medical Device for near patient testing; Reagents/Kits for estimation of parameters of ToRCH & other infectious agents; Reagents/Kits for detection of Cancer Markers; Reagents/Kits for estimation of Coagulation parameters; Reagents/Kits for monitoring of drug levels; Reagents/Kits for detection of autoimmune disorders; Reagents/Kits for detection of markers for Congenital disorders; Reagents/Kits for detection of Cardiac Markers; Reagents/Kits for human Genetic testing; Reagents/Kits for the management of life threatening infections; Reagents/Kits for the detection of sexually transmitted agent; Reagents/Kits for the Antigen detection of infectious agents with a risk of limited propagation; Reagents/Kits for the detection of Antibodies to infectious agents with a risk of limited propagation; In vitro Diagnostic Medical Devices for Blood Grouping or Tissue Typing; Reagents/Kits for the detection of transmissible agents; Other in vitro Medical Devices. Five in vitro diagnostic medical devices have not been assigned any class.

The total number of In vitro diagnostic medical devices categorized as Class A, B, C, D are represented in Figure 2.

FIGURE 2 : IVD Classification



- **REFERENCE :**
  - *G.S.R.78(E).— NOTIFICATION – Medical Devices Rules, 2017; Ministry of Health and Family Welfare (Department of Health and Family Welfare); New Delhi, the 31st January, 2017.*
  - *Notice File No. 29/Misc./3/2017-DC(292) : Annexure 1 (Amended as on 06.06.2018) - List of medical devices and in vitro diagnostics along with their risk class as per the provisions of rule 4 of the medical devices rules 2017.*

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