EVOLVING REGULATORY LANDSCAPE: A REVIEW OF THE INDIAN MEDICAL DEVICE RULES 2017 AND AMENDMENTS

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Abstract
The medical device market in India is in the top 20 worldwide and ranks as the fourth largest in Asia. Its 2020 valuation was Rs. 75,611 crore (US$10.36 billion), and at a 37% compound annual growth rate (CAGR) it is expected to reach US$ 50 billion by 2025. In the field of healthcare, medical devices are used for many different purposes, including but not limited to monitoring, treatment/care, screening and diagnosis, and restoration. Since 1940, medical devices have been governed under the Drug and Cosmetic Act 1940 and Rules 1945. Only a small number of medical devices—referred to as "notified devices"—have been subject to regulation by CDSCO (Central Drug Standards Control Organization) through gazette notifications. This system was basic in nature and did not adhere to international requirements for CDSCO. The Medical Device Rules of 2017 updated the medical device regulatory framework when it was realized that stricter and more targeted regulations were needed to distinguish medical devices from drugs. This rule, which primarily addresses the production, marketing, import, distribution, and clinical research of medical devices in India, went into force on January 1st, 2018. According to the Medical Device Regulations of 2017, there are now 37 medical devices registered with CDSCO. With the upcoming revisions to the guidelines, CDSCO intends to bring all medical devices under one roof and establish uniform standards and regulations for them all. These policies would facilitate ease of doing business in India and present numerous chances for medical device manufacturers to invest in the country.
Keywords: CDSCO, Medical Device Rules 2017, Notified Devices

1. INTRODUCTION

The medical devices and healthcare sector have witnessed significant growth in recent years. Medical devices play a crucial role in various healthcare aspects, including diagnosing illnesses, monitoring treatments, assisting people with disabilities, and intervening to treat both acute and chronic conditions.[1] The medical device market in India ranks as the fourth-largest in Asia and stands among the top 20 globally.[2] With a valuation of Rs. 75,611 crore (US$10.36 billion) in 2020, the Indian medical device market is anticipated to reach US$50 billion by 2025, reflecting a Compound Annual Growth Rate (CAGR) of 37%[3]. Medical device is defined as any instrument, apparatus, appliance, software, material used alone or in combination intended for use in diagnosis and treatment purpose to prevent and cure disease or disorder. In India, the regulation of Medical Devices is overseen by the Central Drug Standard Control Organization, led by the Drug Controller General of India. Initially, the Medical Device sector operated with minimal regulation, and in the absence of specific regulations, all medical devices were classified and regulated as "drugs" under the Drugs and Cosmetics Act of 1940. From 1989 to 2005 only 14 products were notified and regulated as Medical Device. CDSCO, after recognizing the requirement to establish more stringent and specific regulations for separating medical device from drug, refurbish the regulatory framework for medical device by passing the Medical Device rules 2017. The Medical Device Rules 2017 were issued through Gazette notifications GSR 78(E) dated 31.01.2017 and came into effect on 01.01.2018.[4]

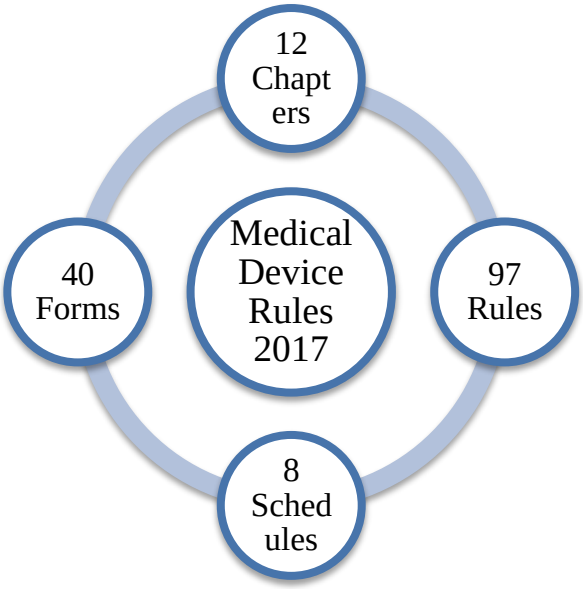


Figure 1: Content of Medical Devices Rules 2017

The definition of a medical device as suggested by the Global Harmonisation Task Force, formerly known as the International Medical Device Regulators Forum, has been adopted by India. The definition is as follows: 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

i. Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
ii. Diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability;
iii. Investigation, replacement or modification or support of the anatomy or of a physiological process;
iv. Supporting or sustaining life;
v. Disinfection of medical devices; and
vi. Control of conception[5].

2. SALIENT FEATURES OF MDR 2017

Before the implementation of the Medical Device Rules 2017 on January 1, 2018, the Indian medical device industry adhered to the Drug and Cosmetic Act 1940 and Rules 1945, which were obscure, complex and lacking in transparency. Following the framework of the Global Harmonization Task Force (GHTF), the Medical Device Regulations 2017 (MDR 2017) aim to distinguish medical devices from pharmaceuticals to enhance regulation and provide greater clarity.

These are some of the key highlights of the Rule which are as follows:

2.1 Classification of Medical Device: MDR 2017 has classified all the medical device on the bases of risk associated with them and its intended use.

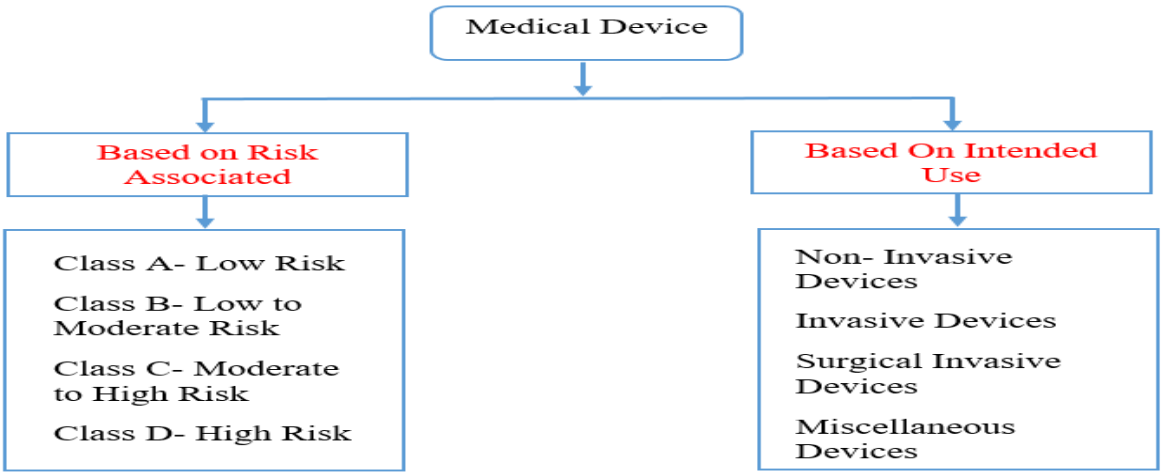


Figure 2: Classification of Medical Device

2.2 Single window clearance: A single central government web platform is used to submit all applications to the licencing authorities for import, manufacturing, sale, distribution, or clinical investigation. [4][6].

2.3 Perpetual licenses: Manufacturer and importer licences will be granted in perpetuity and require payment of a licence retention fee every five years, unless they are suspended or revoked [4] [6].

2.4 Clinical Investigation: In compliance with MDR 2017, clinical trials for investigational medical devices will now be conducted in two phases instead of the previous four phases. The first phase is 'Pilot Clinical Investigation' – Clinical investigation conducted for the first time in human participants. The second phase termed 'Pivotal Clinical Investigation' involves a confirmatory study conducted to collect evidence supporting the investigational MD. Furthermore, post-market surveillance has been made mandatory after the device has gained market approval [4] [6].

2.5 Product Standards for Medical Devices: The following requirements, listed in the same order of importance, must be met by all medical devices: Bureau of Indian Standards (BIS), Any other pharmacopoeial standards, the International Electro-Technical Commission, or the International Organisation for Standardisation (ISO) & Manufacturer's standard validated [4][6].

2.6 Notified Body: According to the MDR 2017, Notified Bodies are now responsible for third-party conformity assessment and certification of Indian medical devices. As per Rule 13 of the MDR 2017, a notified body is a registered legal entity authorized to perform audits of manufacturing site, as well as assess and verify a specified category of medical devices for compliance with a standard. A National Accreditation Body and a Central Licensing Authority registration certificate are required for notified bodies to conduct audits of Class A and Class B MD manufacturing sites. A Notified Body with a minimum of two years of experience can audit the manufacturing site of Class C and Class D MD, given that human resources possessing the necessary qualifications and experience. [4][6].

2.7 Timelines: In accordance with the 2017 Rules, applicants can have assurance about the timeframe for the decision on their application. They can also plan for the expected time of an audit or inspection, as timelines have been designated for each regulatory function. For a license to manufacture Class C or Class D MD, after application date, the application scrutiny must be submitted within forty-five (45) days. Within sixty (60) days of the application date, the manufacturing site inspection must be completed. The applicant then receives the inspection report, and within forty-five (45) days after receiving the inspection report, they are informed of the application's outcome. The approvals will be automatically considered granted if the licensing authority, either the DCGI or the State licensing body, is unable to communicate its decision on the aforesaid application within the allotted time frame, which is 45 days for production and 60 days for import. [7].

3. COMPARISON OF DRUGS AND COSMETICS ACT 1940 AND RULES 1945 VS

MEDICAL DEVICE RULES 2017[6][4]

This table provides a comparison of the regulation of medical devices under the D&C Act and highlights the changes since the introduction of MDR 2017.

Table 1: Comparison of drugs and cosmetics act 1940 and rules 1945 vs medical device rules 2017

Parameter	Drug and Cosmetic Act 1940 rules 1945	Medical Device rules 2017
Classification of All types of Medical Devices	Medical gadgets classified as Notified Medical gadgets	Classification of Medical Devices (Class A, B, C & D) based on the risk & Also, on the basis of intended use (Invasive, Non-invasive, Surgical invasive, Miscellaneous)
Regulatory framework	Early-stage regulatory framework	A Strict regulatory framework
	Only paper submission	Every step of the application process, from submission to approval, is done online.
	Absence of a defined approval procedure, Lack of a list of necessary documents, No Defined audit procedure, No criteria for renewal	A defined approval process, A specific framework of papers determined based on the product classification, Inspections of manufacturing facilities, Defined Renewal Process
Quality audit, registration and renewal.	Audits of facility required only for notified devices.	Quality audit of facility is required for all devices
	No need for third-party assessment.	Conformity assessment and certification conducted by third-party entities appointed by the government, known as Notified Bodies.
	Registration certificate and approval valid for 3 years.	The stipulated fee for perpetual validity is paid every 5 years, and the license cannot be suspended or cancelled.
	The application process involves submitting Form 40, and upon approval, the registration is granted through Form 41 for all types of medical devices.	Different types of Forms based on class of medical devices.
Quality Management System	The Quality Management System was not part of the inclusion.	Compulsory implementation of the Quality Management System, specifically ISO 13485.
Test License	Import regulated by the Central Licensing Authority, and manufacturing seen by State Licensing Authority.	Handled by Central Licensing Authority
License Validity	3 Years	Renewal fee at every 5 year
Medical Device Testing	National Institute of Biologicals, Noida	Central Medical Device Testing Laboratory
Conformity Assessment	Absence of third-party assessment.	Conformity assessment and certification by a third-party, known as a Notified Body.
Labelling and Shelf-life	No evidence required	It is required to adhere to the new labeling provisions, and the expiration period should not exceed 5 years from the manufacturing date unless approved by the CLA after receiving adequate evidence.

4. LIST OF NOTIFIED MEDICAL DEVICES AS PER IMDR 2017[8]

Prior to the implementation of MDR 2017, all medical devices were regulated as drugs under Section 3, Clause (b), Sub clause (iv) of the D & C Act. According to Indian Medical Device Rules (IMDR) 2017 "Notified" refers to a Central Government notification published in the Official Gazette.
Notified devices are:

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

5. REGULATORY FILING FEES FOR REGISTRATION, LICENSING, IMPORT AND CONDUCT OF CLINICAL INVESTIGATION

The information on regulatory filing fees for the registration, licensing, importation, and clinical investigation of medical devices is presented in the following table.[9]

Table 2: Regulatory filing fees as per IMDR 2017

Notified Body		
Registration	INR 25,000	
Manufacturing license or loan license		
Class A or B	Per site: INR 5,000 and for each distinct MD: INR 500	
Class C or D	Per site: INR 50,000 and for each distinct MD: INR 1000	
Clinical		
Permission to conduct pilot or pivotal clinical investigation	INR 1,00,000	
Permission to conduct clinical performance evaluation	INR 25,000	
Import license		
	For MD	**For IVD devices**
Class A	Per site: $1,000 each distinct MD: $50	Per site: $1,000 each distinct IVD device: $10
Class B	Per site: $2,000 each distinct MD: $100	
Class C or D	Per site: $3,000 each distinct MD: $1,500	Per site: $3,000 each distinct IVD device: $500

6. IMPORT OF MEDICAL DEVICES [10]

An authorized agent who has been granted an authorization to manufacture for sale or distribution, or a wholesale license for sale or distribution, must use the Ministry of Health and Family Welfare's designated online portal in order to obtain an import license for medical devices from the Central Licensing Authority. The import of MD into India must be approved by the CLA, who will also demand "Form MD 14" along with the necessary fees and documentation. If the import license is not revoked or surrendered, it is valid for a very long period. The license retention fee must be submitted by the authorised agent to the CLA only when five years have passed since the date of issuance. For medical devices from other nations, an import license can be

granted if a free sale certificate from the country of origin is offered and the safety and performance have been shown by clinical research or published data in the country of origin. For class C/D devices, this requires a clinical investigation to be conducted in India to establish their safety and effectiveness. Figure 3 briefs the major process steps required in the import of medical devices according to medical device rules 2017.

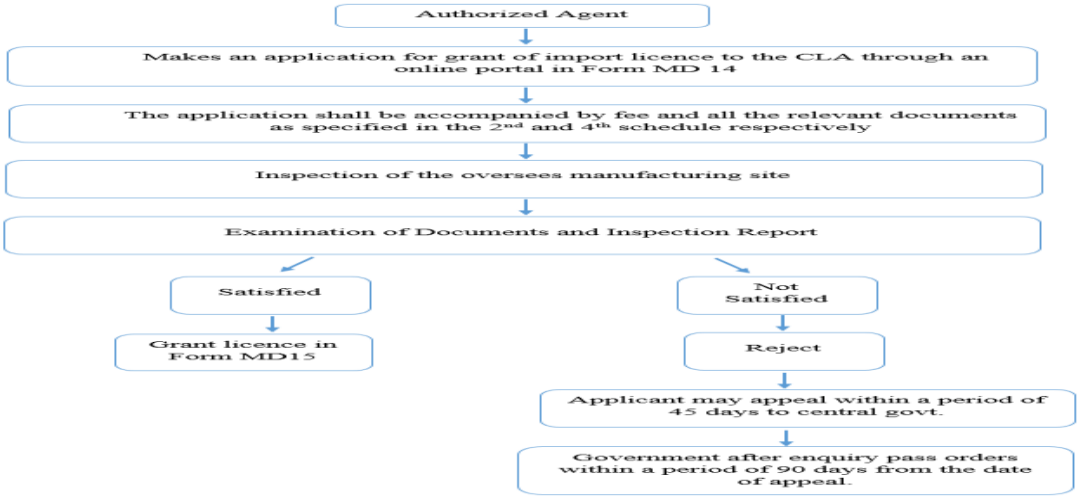
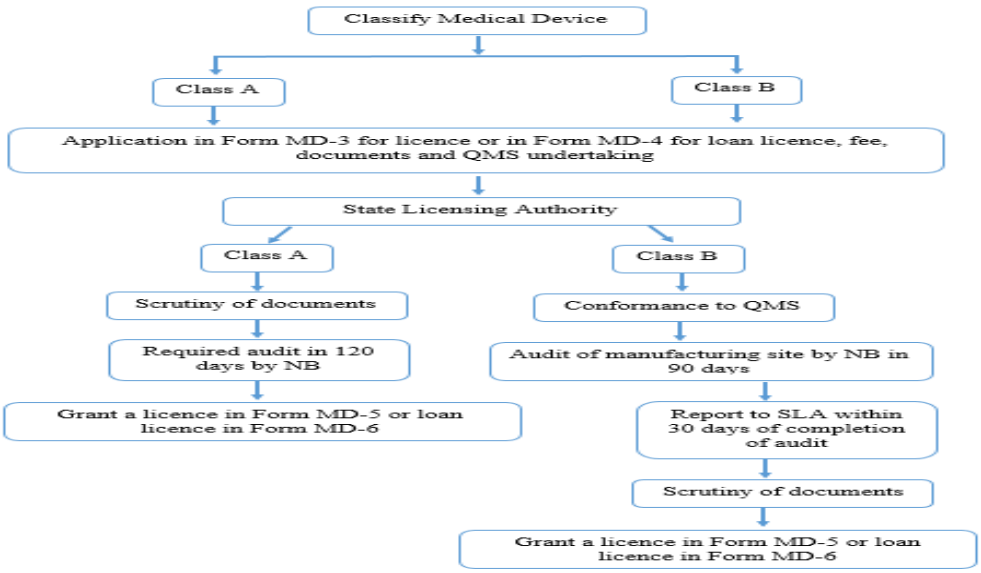


Figure 3: Import of Medical Device as per IMDR 2017

7. MANUFACTURE OF MEDICAL DEVICES

7.1 Application for manufacture for sale or for distribution of Class A or Class B medical device[10]:The State Licensing Authority is required to issue a license or loan license to a manufacturer planning to produce medical devices in Class A or Class B, including IVD medical devices. If someone wants to manufacture Class A/Class B MD for distribution or sale, they must submit an application in Form MD 3/Form MD 4 (Loan License) to the "State Licensing Authority" (SLA) via the Ministry of Health and Family Welfare's (MHFW) web portal along with the necessary fees and documentation. Figure 4 briefs the detailed application procedure of it.



7.2 Application for manufacture for sale or for distribution of Class C or Class D medical device[10]:The license or loan license for the production of class C or D devices is granted by the Central Licencing Authority. To manufacture for sale or distribute Class C & D MD, a procedure must be submitted to the CLA through a portal specified. Figure 5 briefs the application procedure for sale or distribution of Class C & D MD. There are various Documents Required for the Application of Permit of the Licence to Import

or Manufacture Class B, C and D MD: Details of agent Plant Master File, Device Master File, Essential Principle Checklist, Submission of test licence, Undertaking regarding plant site, Free Sale Certificate, Quality Management System (QMS) certificate, Self-attested copy of wholesale licencing, Latest Audit Inspection report.

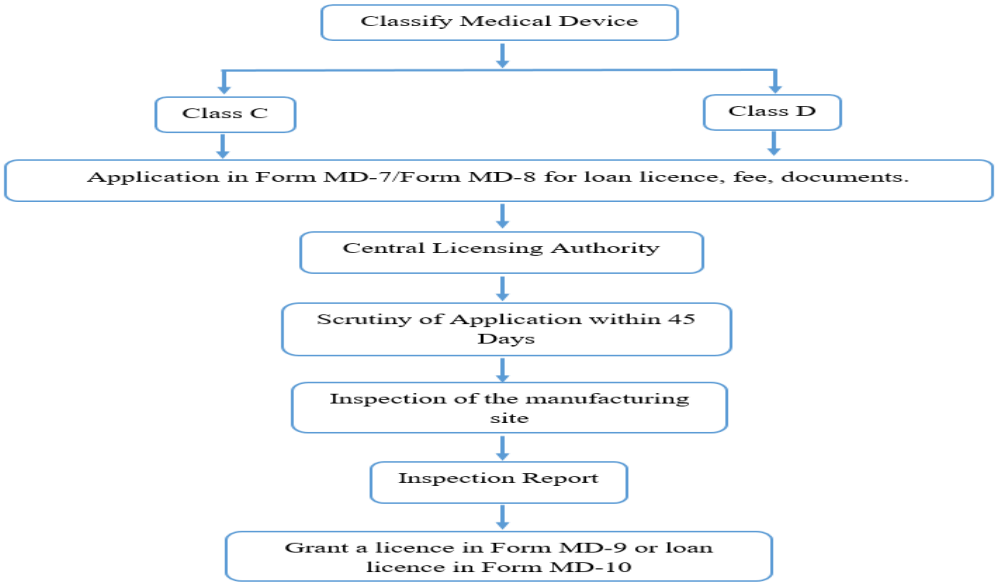


Figure 5: Detailed Flowchart for the manufacturing of Class C & D MD

8. AMENDMENTS OF MEDICAL DEVICE RULES 2017[11]

The Central Drug Standard Control Organization (CDSCO) Medical Devices and Diagnostics Division has created structured regulations for medical devices, known as the IMDR, which were published in January 2017 and went into effect in January 2018. The "Medical Devices (Amendment) Rules, 2020," which altered the IMDR, went into effect in April 2020 after being revised in February 2020. With the issuance of the 2020 amendment, "registration of certain medical devices" was also included. Future amendments of IMDR can focus on fulfilling the gaps that would have equated these regulations with that of EU and USFDA, which are the most recent international regulations for medical devices for device safety and performance. Following is a table describing the amendments to the Medical Device Rules 2017. [12]

Table 3: List of Amendments to IMDR 2017

TITLE	RELEASE DATE	SUMMARY
G.S.R. 102(E)_Registration of certain medical devices	11-02-2022	• In Medical Device Rules 2017 after chapter III, CHAPTER IIIA REGISTRATION OF CERTAIN MEDICAL DEVICES shall be inserted. • It is mandatory for MDs to register with Central Licensing Authority through online portal after 18 months of voluntary registration. • On the "Online System for Medical Devices" the manufacturer and importer are required to upload information about the medical device for registration[10].
GSR 918(E)_Amendment of rule 46 of MDR for Unique Device Identification	31-12-2021	Every approved medical device for manufacturing, sale, distribution, or import must carry a unique device identification as specified.[11].
GSR 356(E)_Insert rule 43A for	18-05-2022	• In Medical Device Rules 2017 after rule 43, rules 43A Suspension and cancellation of license shall be inserted.

Suspension and cancellation of license in MDR 2017		● The Central Licensing Authority may suspend or terminate a license granted under these regulations if the licensee violates any of the Act's provisions. The licensee will be given the chance to explain why such an order should not be granted..[12].
GSR 450(E)_To amend Fourth Schedule wrt TSE or BSE certificate under MDR	15-06-2022	●If the source comes from an animal species in a nation where there is a documented little risk of bovine spoggly encephalopathy, then no TSE or BSE certificate is required. [13].
GSR 754 (E) sale of medical device retail and wholesale	30-09-2022	●Following Rule 87, the subsequent rules shall be inserted: **87A.**-Registration certificate to sell, stock, exhibit or offer for sale or distribute a medical device including in vitro diagnostic medical device. **87B.**-Conditions of registration certificate to sell, stock, exhibit or offer for sale or distribute a medical device including in vitro diagnostic medical device **87C.**-Validity of registration certificate **87D.**-Suspension and cancellation of Registration Certificate ●Following Form MD-40, the subsequent forms shall be inserted: **Form MD-41** APPLICATION FOR GRANT OF REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE A MEDICAL DEVICE INCLUDING IN VITRO DIAGNOSTIC MEDICAL DEVICE **Form MD-42** REGISTRATION CERTIFICATE TO SELL, STOCK, EXHIBIT OR OFFER FOR SALE OR DISTRIBUTE A MEDICAL DEVICE INCLUDING IN VITRO DIAGNOSTIC MEDICAL DEVICE **Form MD-43** Form in which the Inspection Book shall be maintained[14].
G.S.R. 777(E) Final notification for exemption of non-sterile and non-measuring Class A medical devices from licensing regime	14-10-2022	● After rule 19F, the following additions shall be made, namely: — "CHAPTER IIIB REGISTRATION OF CLASS A (NON-STERILE AND NON-MEASURING) MEDICAL DEVICES ● This Chapter applies to all non-sterile and non-measuring devices classified as Class A medical devices. [15].

9. DISCUSSION

The Indian Medical Device Rules, 2017, have had a significant impact on the medical device industry in India. The Indian Medical Device Rules, 2017, were introduced to regulate medical devices in India under the D & C Act of 1940. New regulations cover various aspects of device-related regulations, including the classification of medical devices into four classes based on associated risks, procedures for registration and regulatory approval, details regarding manufacturing, quality audit, import/export, and labelling requirements.[13]

The Indian Medical Device Rules, 2017, have improved the regulatory framework for medical devices in India in several ways. Firstly, the rules provide a well-defined regulatory framework for the manufacturing, import, export, and sale of medical devices in India. Secondly, the rules classify medical devices into four classes based on associated risks, which helps in better monitoring and regulation of medical devices in the country. Thirdly, the rules simplify the regulatory procedures for registration and regulatory approval of medical devices, making it easier for manufacturers to comply with the regulations. Fourthly, the rules promote domestic manufacturing of medical devices by establishing a regulatory environment that is at par with global standards, thus reducing the reliance on imports.

Finally, the rules aim to enhance patient safety by ensuring that medical devices meet global quality standards and are subject to stringent regulatory requirements. Overall, the Indian Medical Device Rules, 2017, have

significantly improved the regulatory framework for medical devices in India, addressing the need for a well-defined regulatory framework for medical devices in the country.

The new medical device regulations in India permit the introduction of new devices also; nevertheless, even after being published in a gazette notification, the regulations remain deficient in numerous areas, and numerous orders, notices, and amendments have been released to enhance the regulations like "Online application for registration of NB through SUGAM portal" (dated: 30 May'2017)". [14]

10. CONCLUSION

In the last several years, India has made significant strides in the fields of medical equipment and healthcare. With the implementation of IMDR in 2018, India has created new opportunities in the medical device industry. Regulatory procedures are now more open, and governments encourage manufacturers to shift to producing more domestically rather than importing. Still when we compare IMDR with European Union MD regulation or USFDA Regulations we can see a lot of scope for India to evolve under the area of governance, transparency and business accessibility due to regulatory requirements.

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