REGULATORY FOCUS

A New Regulatory Paradigm for Medical Devices in India

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This article explains medical device classification rules, manufacturer registration procedures, dossier filing procedures, and pre-clinical and marketing application approval processes.

Introduction

Medical devices are a multi-billion-dollar global industry with continuous growth opportunities due to advancements in technology and new innovations. However, innovations and new advancements do not always reach patients due to a lack of clarity related to the approval process of such innovations and stringent regulations by national health authorities. These regulations can pose challenges for innovators, manufacturers, and exporters to obtain approval for market distribution in India. This article provides an overview of the new *Medical Devices Rules, 2017* released by India's Ministry of Health and Family Welfare to be implemented 1 January 2018, as well as recommendations for addressing identified gaps in the rules, less obvious features of the regulation, and a listing of changes to the regulations.{1}

India is one of the top 20 markets for medical devices in the world, valued at EUR 4.6 billion (approximately $5.4 billion) and the fourth largest medical device market in Asia. The medical device industry in India alone is expected to reach EUR 8.6 billion (approximately $10.1 billion) in 2020, having a reported Compound Annual Growth Rate (CAGR) of 11% between 2008 and 2015 with an estimated 10-year CAGR of 15%. {2-4} The major segments for growth are equipment and instruments, consumables and disposables, implants, and patient aids.{5} India's medical device market is currently 70% import dependent with the instrument and diagnostic imaging equipment segments accounting for 66% of the overall market. Only 38% of devices manufactured in India are exported from India; therefore, there is a very low level of export competency.{6}

To curb these challenges and to overcome the import market, the Ministry of Health and Family Welfare of India drafted *Medical Devices Rules, 2017*. The new rules are well defined and provide a 360 degree focus to boost manufacturing capabilities, reduce import product dependence, and increase market size.{7}

It is expected that the changes effected by *Medical Devices Rules, 2017* will encourage more Multinational Companies (MNC) to set up medical device manufacturing facilities in India, which in turn will allow innovative products to reach patients in India faster. These rules, based on Global Harmonization Task Force (GHTF) guidelines, will significantly improve the domestic market friendliness to the medical device industry.{8}

Mandatory certifications by the Bureau of Indian Standard (BIS) and International Standards Organization (ISO) will ensure quality standards are practiced, promote domestic manufacturing, and require product testing and certifications, as recognized by the government of India. Most of the rules focus on the classification of devices, clinical investigations, and registration and post-marketing license requirements and procedures.

Medical Devices Rules Chapters and Differences from Prior Rules

The *Medical Devices Rules, 2017* consist of the 12 chapters described in **Table 1** and contain a total of 97 rules. Some differences in the new and old rules are provided in **Table 2**.

Table 1. Chapters of *Medical Devices Rules, 2017*{9}

Chapter	Chapter Title
I	Preliminary
II	Regulation of Medical Device
III	Authorities, Officers, and Bodies
IV	Manufacture of Medical Devices for Sale and Distribution
V	Import of Medical Devices
VI	Labelling of Medical Devices
VII	Clinical Investigation of Medical Device and Clinical Performance Evaluation of new *In Vitro* Diagnostic Medical Device
VIII	Import or Manufacture Medical Device Which Does not Have Predicate Device
IX	Duties of Medical Device Officer, Medical Device Testing Officer and Notified Bodies
X	Registration of Laboratory for Carrying out Test or Evaluation
XI	Sale of Medical Devices
XII	Miscellaneous

Table 2. Before and After Enactment Comparison of the *Medical Devices Rules, 2017*

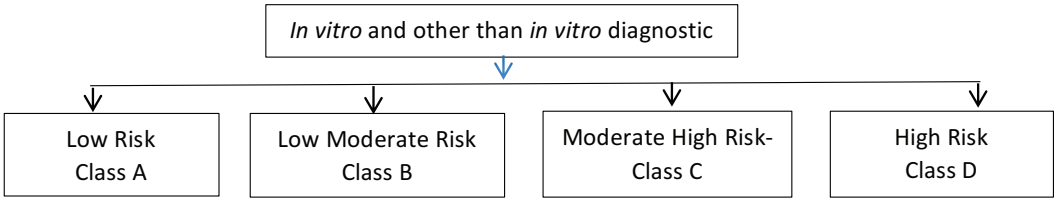
Parameters	Before Medical Devices Rules, 2017{10-14}	After Medical Devices Rules, 2017{15,16}
Market Overview	Archaic regulatory standard	Streamlined regulatory standards
	Largely unregulated. Tough challenges faced to place devices on market.	Possibility of strong, sustainable and technically sound domestic industry with high-quality standards and affordable pricing.
	Lack of MNC/investor interest	International practice. *Medical Devices Rules, 2017* will help to significantly increase the market value. Many MNC focused to set up facilities in India.
	Only CE* mark and US Food and Drug Administration (FDA) approved products allowed to enter the India market. *Conformité Européene (CE)	India has its own regulatory approval procedures. Manufacturers do not need foreign regulatory/marketing approval. Should limit the cost required for approvals to market in India.
Regulatory	Medical devices regulated as "drug" under *Drug and Cosmetic Act, 1940 and Rules 1945.* No device-only rules or regulations.	Separate *Medical Devices Rules, 2017* in force.
	Nascent regulatory framework	Robust regulatory framework
	Classified as notified medical device, list of only 15 Notified Medical Device categories	Well defined categorized classifications based on risk as A, B, C, and D, where, A and B are low-risk devices
	No online procedure for application filing	Entire process from submission to grant of permission/license processed through online electronic platform
	No defined approval procedure, no list of required documents, no audits, and no renewal requirements	Defined approval procedure, list of documents per product classification, and audits of the manufacturing facility and renewal requirements
Quality-Audit, Registration, and Renewal	No audits of facility required	Audits required to ensure a standard quality of product reaches consumers Facilities required to be in line with the new rules
	No assessment required from the third party	Third Party Conformity Assessment and Certification through government-appointed notified bodies
	High import dependency	Medical devices can obtain marketing approval from Indian medical device regulating authority.
	Unfavorable duty structure	All duties of the manufacturer, importer and exporter, auditor clearly explained.
	Inadequate quality standards and most Indian made products found not in compliance with standards.	Quality documents are required to be maintained at the manufacturing site and list of required documents defined to obtain approval.
	Registration certificate and approval valid for three years	Fee payable every five years; no renewal required
	Application applied in Form 40 and registration issued in Form 41	Selection of application form depends on the type of medical device
Manufacture, Distribution and Sale, Import and Export	Not well defined	Well defined Special forms are available to apply.
	Quality Management System (QMS) not included.	Need to comply with ISO-13485 and have documented QMS.
	Central Device Standard Control Organization (CDSCO) was handling all activities.	Import and clinical trials will be handled by CDSCO. Manufacturing will be handled Central Licensing Authority.
	Regulations applicable to drugs are applicable, unmet clinical regulations.	Separate provisions for regulation of Clinical Investigation (clinical trials) of investigational medical devices (i.e., new devices)
	Periodic renewal is required.	License is valid unless suspended, cancelled or surrendered.
Labelling and Shelf Life	No evidence required.	Not to exceed five years from the date it was manufactured unless the Central Licencing Authority extends it upon receiving satisfactory evidence. New labelling provisions are provided.

The rules include definitions to overcome the confusion between various terminologies, such as active medical device, active diagnostic device, invasive device, investigational device, and predicate device.

Medical Device Classification Rules

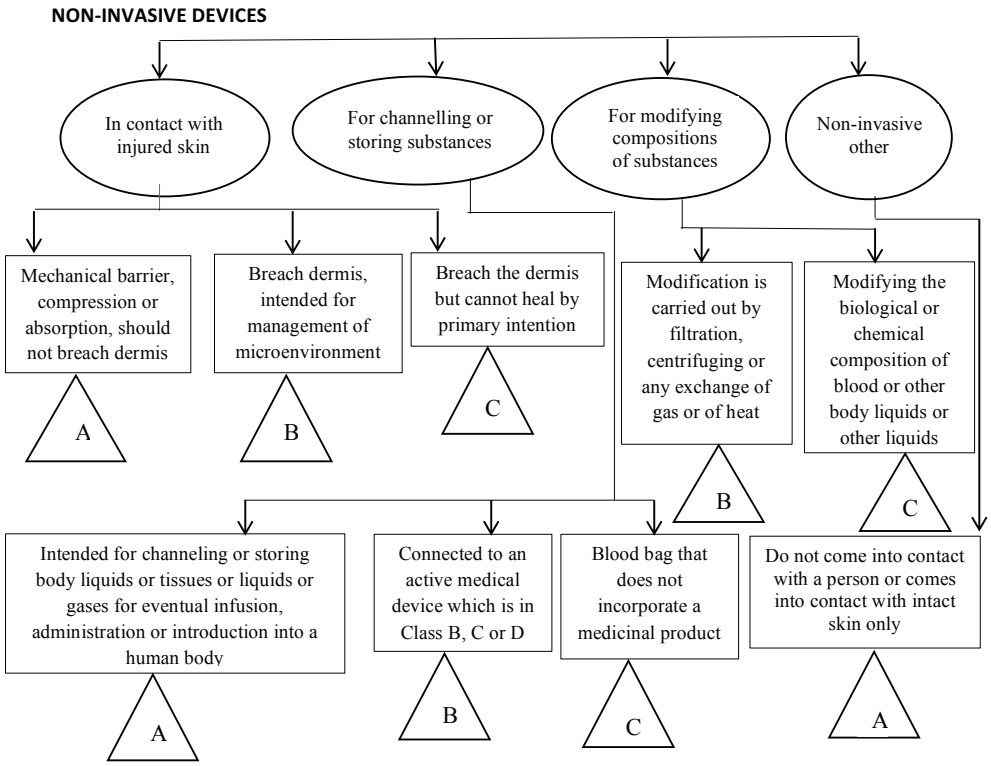
The well-defined classification system, based on the GHTF, is intended to help manufacturers determine a device category and regulatory requirements for gaining marketing authorization. The system includes "medical devices other than *in vitro* and *in vitro* diagnostic device categories classified into categories as A, B, C, and D based on their low, moderate and high risks associated with them as described in **Figure 1**. Device classifications are further defined in **Figures 2-6**.

Figure 1. Risk-based Classification of Medical Devices Rules 2017



Medical devices other than *in vitro* diagnostic devices are classified in **Figures 2-5**{17-20} as non-invasive medical devices, invasive medical devices, surgically invasive devices and miscellaneous. **Figure 6** details about the *in vitro* diagnostic medical devices for detecting transmissible agents, blood grouping, devices for self-testing and devices used as *in vitro* diagnostics.{21}

Figure 2: Non-invasive Medical Device Classifications 21, 22 was [5, 12]



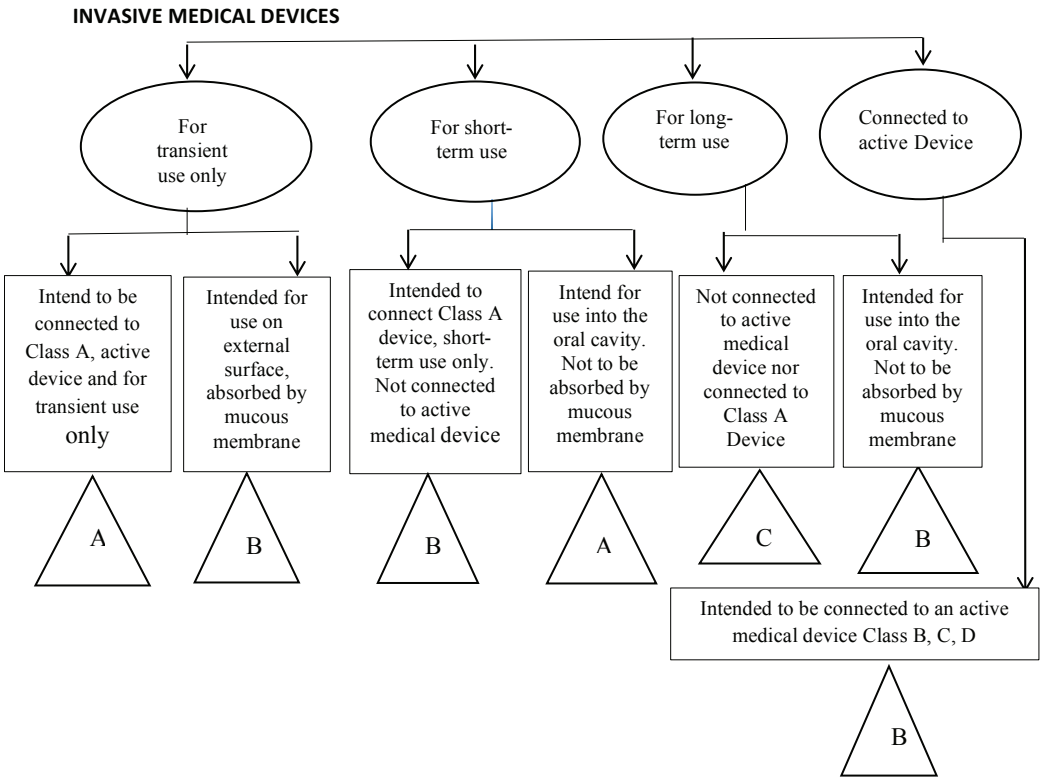
Examples of devices within each risk class are presented below:

Class A: wound dressings, absorbent pads, island dressings, cotton wool, wound strips, adhesive bandages, gauze dressing, anti-static tubing for anesthesia, anesthesia breathing circuits, pressure indicator, pressure limiting device, syringes for infusion pumps, syringes without needles, cups and spoons intended for administering medicines, urine collection bottles, ostomy pouches, incontinence pads, wound drainage devices, corrective glasses and frames, stethoscopes, eye occlusions, incision drapes, conductive gels, non-invasive electrodes.

Class B: polymer film dressings, hydrogel dressings, non-medicated impregnated gauze dressings, adhesive for topical use, refrigerators specially intended for storing blood, medical devices used for filtration of blood or the removal of carbon dioxide.

Class C: dressings for severe decubitus wounds, dressings for chronic extensive ulcerated wounds, dressings for severe burns, dressings incorporating to provide a temporary skin substitute, blood bag, hemodialyzers, sperm separators.

Figure 3: Invasive Medical Device Classifications 23,24 was[5, 12]



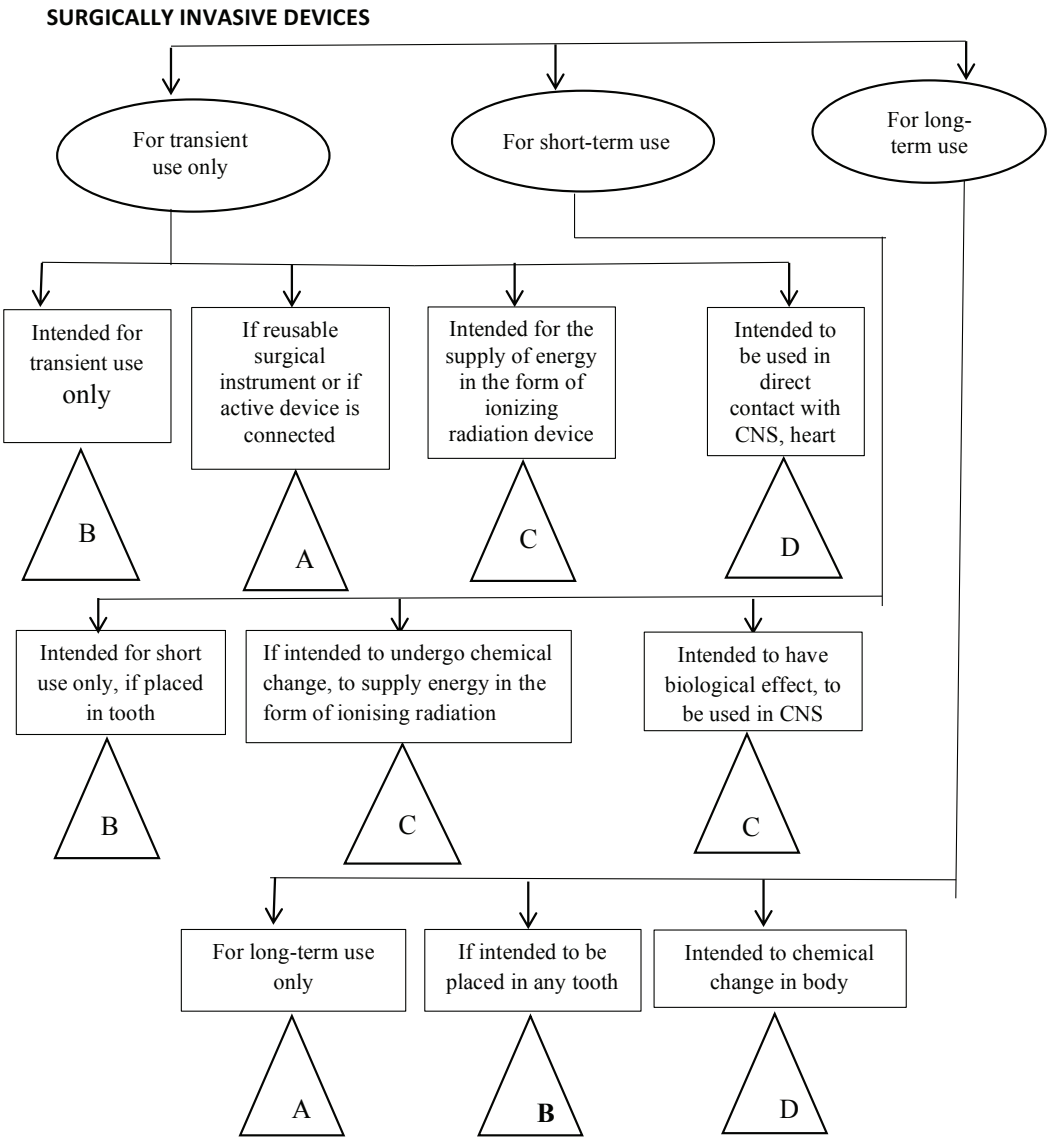
Class A: handheld mirrors used in dentistry to aid in dental diagnosis and surgery, dental impression materials, tubes used for pumping the stomach, impression trays, enema devices, examination gloves, urinary catheters intended for transient use, dressings for nose bleeds, materials for manufacturing dentures.

Class B: urinary catheters, tracheal tubes, orthodontic materials, removable dental prosthesis.

Class C: urethral stents, long-term corrective contact lenses, tracheal cannula, urinary catheters intended for long term use, short term corrective contact lenses, tracheal tubes, stents, vaginal pessaries, indwelling urinary catheters intended for short term

use, orthodontic wires, fixed dental prostheses, fissures sealants, tracheostomy or tracheal tubes connected to a ventilator, blood oxygen analysers placed under the eye-lid, powered nasal irrigators, nasopharyngeal airways, some enteral feeding tubes, fibre optics in endoscopes connected to surgical lasers, suction catheters or tubes for stomach drainage, dental aspirator tips.

Figure 4. Surgical Invasive Device Classifications 25,26 was [5, 12]



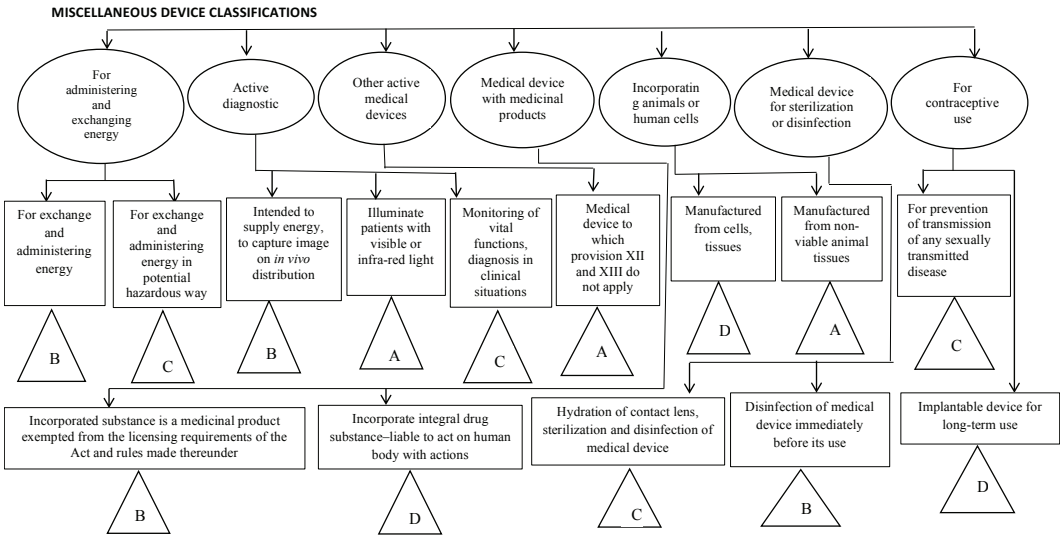
Class A: scalpels, retractors forceps and sternum retractors.

Class B: needles, lancets, suckers, scalpels, staplers, surgical swabs, drill bits, surgical gloves, etchants, heart valve, swabs, single use aortic punches, adhesives, clamps, dental filling materials, dental alloys.

Class C: catheters, radioisotopes, insulin pens, brachytherapy devices, nails and plates, shunts, intraocular lens, internal closures, penile implants.

Class D: neuro endoscopes, brain spatula, spinal needles, catheters, distal protection device, absorbable sutures, cortical electrodes, spinal stents, Cochlear Nerve Deficiency (CND) electrodes.

Figure 5: Miscellaneous Medical Device Classifications 27,28 was [5, 12]



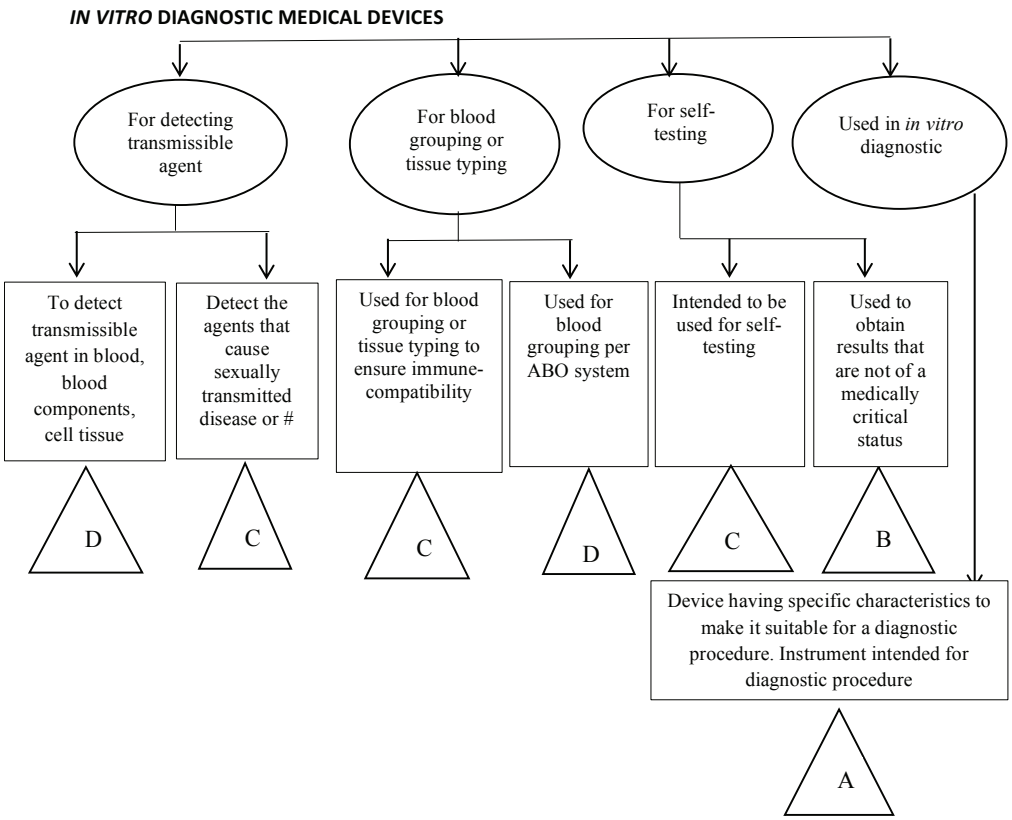
Class A: reusable surgical instruments.

Class B: eye electromagnets, electrical acupuncture, powered dermatomes, cryosurgery equipment, pulp testers.

Class C: blood warmers, electrosurgical generators, electroconvulsive therapy, kinetic energy.

Class D: instruments to be used for Central Nervous System (CNS) and heart defects.

Figure 6: In Vitro Diagnostic Device Classifications 29, 30-31 was [5, 12-13]



#The presence of infectious agents in cerebrospinal fluid that cause significant risk and that an erroneous result will cause death or severe disability to the individual or fetus being tested, pre-natal screening of women, determining infective disease status or immune status, diagnosis of cancer, human genetic testing, AIDS, Down syndrome.

Class A: clinical chemistry analyser, prepared selective culture media.

Class B: vitamin B12, Pregnancy self-testing, anti-nuclear antibody, urine test strips.

Class C: blood glucose self-testing, Human Leukocyte Antigens (HLA) typing, Prostate-Specific Antigen (PSA) screening, rubella.

Class D: Human Immunodeficiency Virus (HIV) blood donor screening, HIV blood.{33,34}

Application forms and documents required for import, sale, manufacturing, and loan licensing before the enactment of *Medical Devices Rules 2017*, devices were regulated by the Central Device Standard Control Organization (CDSCO) and followed the regulations laid down in the *Drug and Cosmetic Rule (1940)* with much ambiguity. The sector was largely unregulated with only a list of notified medical devices regulated under the *Drugs and Cosmetics Act 1940 and Rules 1945* thereunder. Previously, the import and manufacturing registration application required few documents to be submitted with application Form 8 and Form 9 with the registration issued in Form 41 and Form 10 for import.

The application number and list of documents have been revised in *Medical Devices Rules, 2017.* **Table 3** and **Table 4** list the required application documents and corresponding application form.

Table 3. List of Application Forms Required to Apply for Medical Device Approval

Description	Form No
Application for grant of certificate of registration of a notified body	Form MD1
Application for license to manufacture for sale and distribution for Class A or Class B medical device For Class C or Class D or (ii) Class A or Class B, and Class C or Class D	Form MD3 Form MD4
Application for grant of loan license to manufacture for sale or for distribution of Class A or Class B medical device For Class C or Class D or (ii) Class A or Class B, and Class C or Class D	Form MD5 Form MD6
Application for license to manufacture for sale and distribution of (i) Class C or Class D or (ii) Class A or Class B, and Class C or Class D medical devices For Class A or Class B or Class C or Class D medical device	Form MD7 Form MD8
Form in which the audit or inspection book shall be maintained	Form MD9
Application for license to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration, or training	Form MD10
Application for issue of import license to import medical device	Form MD12
Application for license to import medical devices for the purposes of clinical investigations or test or evaluation or demonstration or training	Form MD14
Application for license to import medical devices for the purposes by a government hospital or statutory medical institution for the treatment of patients	Form MD16
Application for license to import small quantity of medical devices for personal use	Form MD18
Application to obtain permission to import small quantities of medical devices for personal use	Form MD19
Application for permission to conduct clinical performance evaluation	Form MD22
Application for permission to import or manufacture medical device that does not have a predicate medical device	Form MD24
Application for permission to import or manufacture a new *in vitro* diagnostic medical device	Form MD26
Report of test or evaluation of medical devices by medical device testing officer	Form MD28
Application from a purchaser for test or evaluation of a medical device under section 26 of the *Drugs and Cosmetics Act, 1940*	Form MD29
Order under section 22(1)(c) of the *Drugs and Cosmetics Act, 1940* requiring a person not to dispose of stock in his possession	Form MD30
Receipt for stock of medical devices for record, register, document, or material object seized under Section 22(1) (c) or (cc) of the *Drugs and Cosmetics Act, 1940*	Form MD31
Intimation of person from whom sample is taken	Form MD32
Receipt for sample of medical device(s) taken where fair price tendered thereof under sub-section (1) of Section 23 of the *Drugs and Cosmetics Act, 1940* is refused	Form MD33
Memorandum to medical device testing officer	Form MD34

Table 4. List of Documents Required for Manufacturer Registration and for Importation of Medical Devices

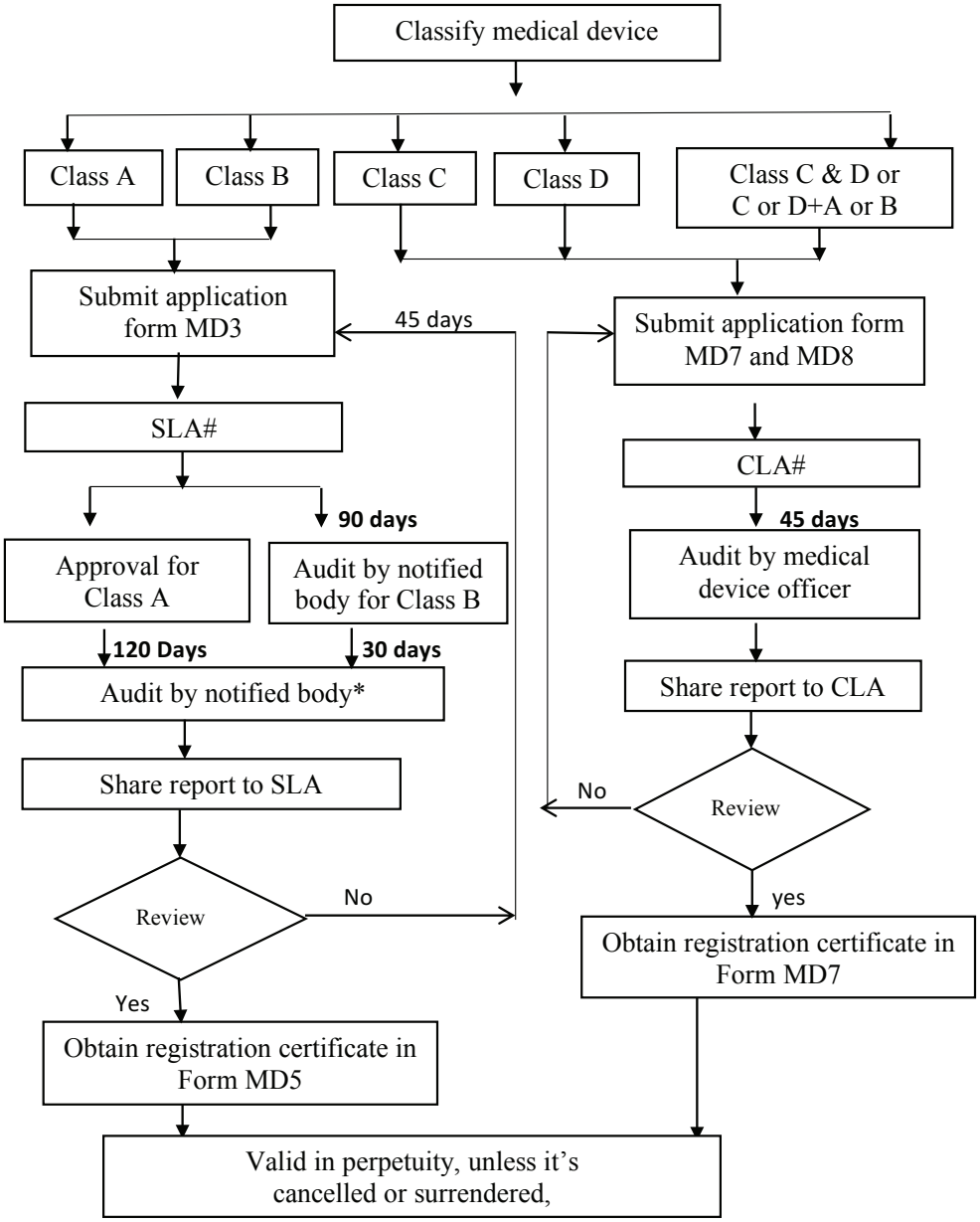
Class A *In Vitro* and Other Than *In Vitro*	Class B, Class C, and Class D *In Vitro* and Other Than *In Vitro*	Device Other Than Predicate
For Manufacturing		
• Device description • Intended use • Specification • Working principle and use of novel technology if any • Label package inserts • User manual • Summary of ADR • Site master file • Firm details • Signed undertaking agreement • Analytical performance Summary for *in vitro* device	• Constitution details of domestic manufacturer or authorized agent • Site or plant master file • Device master file • Essential principle checklist for demonstrating conformity for safety and performance • Quality control data • Signed undertaking agreement stating manufacturing site is compliant with schedule • *In vitro* performance evaluation report for *in vitro* device	• Data analysis • Design input/output documents • Mechanical and electrical test results • Reliability test results • Validation of software • Performance test results • Biocompatibility test results • Risk management data • Animal performance data • Pilot and pivotal clinical investigation data • Regulatory status and restrictions in use • Proposed instructions for use
For importation		
• Notarized copy of overseas manufacturing site or Free Sale Certificate (FSC) • Notarized copy of QMS • Self-attested whole sale license • Copy of latest inspection report		

Role of State Government and the Central Government

The State Drugs Controller serves as the State Licensing Authority (SLA) and shall be the competent authority for enforcement of the rules relating to the manufacture of Class A or Class B medical devices and the sale, stocking and exhibition of medical devices and other related functions.

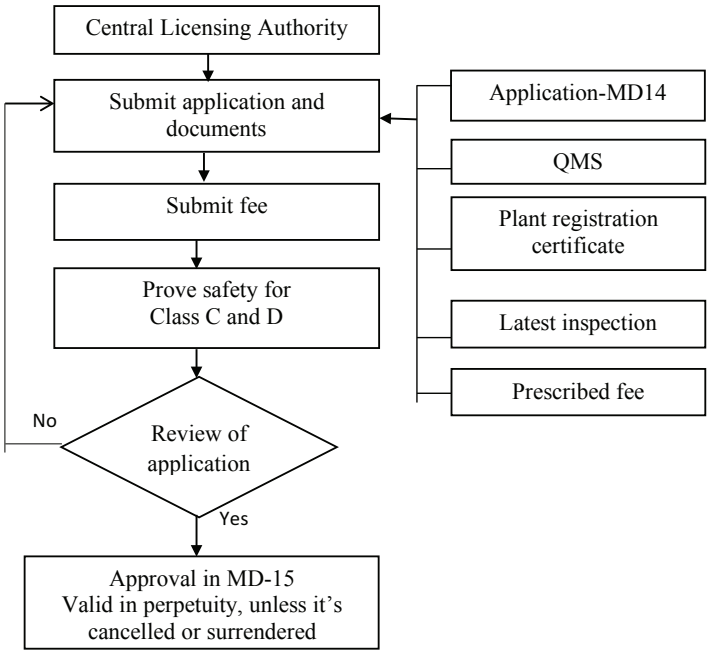
Class C and D high-risk devices are regulated by the Central Licensing Authority (CLA), which oversees the clinical investigation and clinical performance evaluation of medical devices and has other related functions. If the manufacturer intends to manufacture a predicate medical device, the manufacturer must receive approval from the CLA before applying to the SLA. **Figure 7** and **Figure 8** detail the requirements for receiving marketing and import approval.

Figure 7: Regulatory Approval process for Manufacturing for Sale or Distribution 34 was [5]



#State Licensing Authority (SLA), Central Licensing Authority (CLA)
*Audit of facility by notified body is conducted after approval of Class A medical device.

Figure 8: Procedure to Apply for Import of Medical Device 35 was [5]



Clinical Investigation and Evaluation of New Medical Devices and Performance Evaluation of New *In Vitro* Diagnostic Medical Devices

The *Medical Devices Rules, 2017* is more focused on clinical investigation, evaluation and clinical performance evaluation of medical devices. The rules provide a better understanding of the requirements to manufacture, import and conduct clinical investigation and evaluation of medical devices and clinical performance evaluations of *in vitro* diagnostic devices.

Clinical investigation is a systematic study of an investigational medical device in or on human subjects to assess its safety, performance and effectiveness. As per the rules, an application for the conduct of a clinical investigation of an investigational medical device only can be made to CLA in Form MD22 with the list of documents provided in **Table 5**.

The conduct of the investigation and evaluation can be started only after approval from the ethics committee and CLA of Form MD23. A clinical investigation approved by FDA is exempted from the clinical trial application requirement. The rules also set out medical management and compensation requirements related to any clinical investigation under rule 122DAB of the *Drugs and Cosmetics Rule 1945*.

Table 5. List of Documents Required for Permission to Conduct Clinical Investigation of a Medical Device

Document Description
Design analysis data
Biocompatibility data
Investigator brochure
Clinical investigation plan
Case report forms
Informed consent form
Investigator undertaking
Ethics committee approval letter
Regulatory status in other countries
Proposed instruction for use

Document Description
Investigational device developed in India: All clinical investigations must be conducted in India beginning with the pilot or First in Human (FIH) study to pivotal study and results submitted to the CLA.
Investigational device developed in a country other than India: pilot/FIH clinical investigation or relevant clinical study data should be submitted along with the application. The pivotal clinical investigation is required to be conducted in India before permission to market the medical device in India is granted.

As per the new rules, the clinical performance evaluation means the systematic performance study of a new *in vitro* diagnostic medical device on specimens collected from human participants to assess its performance. To conduct clinical performance evaluation of new *in vitro* diagnostics, an application must be filed with the CLA using form MD24 along with the following documents.

Table 6. List of Documents Required for Permission to Conduct Performance Evaluation of an *In Vitro* Diagnostic Medical Device

Document Description
Approval from Ethics Committee
Source and quantity of samples
Device description, raw material specification, proposed use, labels and regulatory status in other countries
In-house performance evaluation data: specificity, sensitivity, repeatability and reproducibility
Performance evaluation report from laboratory
Clinical performance evaluation plan
Case report form
Undertaking by investigators
List of laboratories
Duration of evaluation

The performance evaluation only can be initiated after Ethics Committee approval of the clinical investigation plan. It is necessary to evaluate performance in accordance with the approved Clinical Performance Evaluation (CPE) plan per Good Clinical Practices (GCP) guidelines. The CPE should be registered with the CTR. The annual status and any changes to the CPE plan should be submitted to CLA.{37}

Discussion

Following review of the *Medical Devices Rules, 2017*, it is evident there are significant differences between the old and new regulations for medical devices. The *Medical Devices Rules, 2017* have many more requirements than the previous version, such as a risk-based classification system, application of regulatory standards, proper manufacture licensing requirements, shelf life restrictions, quality management system and more focused clinical regulations.

The *Medical Devices Rules, 2017* appear to provide an environment conducive to fostering innovation while at the same time improving product quality and the availability of medical devices not only in India, but across the globe as well. As with the medical device and *in vitro* diagnostic regulations approved for the EU, the *Medical Devices Rules, 2017* call for the focused involvement by government notified bodies to audit device manufacturers in India, while at the same time improving the ease of doing business in India and ensuring the safety of high-risk devices. The rules also seek to nurture a culture of self-compliance by medical device manufacturers and the creation of a robust eco system for all stakeholders including innovators, manufacturers, providers, consumers, buyers, and regulators.

Furthermore, the improved rule includes specific guidelines for the compensation of subjects who participate in a clinical investigation or clinical performance evaluation. The regulations given in the rules for investigational medical devices also are less

cumbersome and restrictive than the regulations imposed under the drug rules that were applicable to medical devices.

Overall, the effect of the new *Medical Devices Rules, 2017* appears to be extremely positive for what was previously a highly unregulated market and will support entrepreneurship, market entry of new medical devices and sector growth. Any additional gaps can still be addressed during the rule revision process.

Recommendations

Medical devices incorporating software and standalone medical device software are not covered in the new rule. Manufacturers of medical devices containing software should be required to ensure software and any software-driven functions are reliable and perform per the intended use. For each identified risk for failure in the software there should be a proper means to eliminate the consequent risk. There needs to be well-defined software validation guidelines in place for post-authorization market surveillance, continued risk management and software performance verification.

Proper quality (permissible lower and upper limits) and safety guidelines are also missing from the new rules. Proper limits for parameters like validation, calibration, etc., should be defined for devices used to introduce energy, a medicinal product or other material into the body or for devices that expose the patient to radiation.

Finally, the rule needs to better define the procedure(s) for identifying and correcting a deficiency in the device during a performance or clinical evaluation, in its measuring or delivery accuracy, sterility or handling, or risk to the environment because of device use or disposal. Measures for determining the analytical performance and clinical performance and dossier evaluation parameters also should be provided in the new rules.

Conclusion

The *Medical Devices Rules, 2017* have many unique features to support the growth of the medical device sector in India. The rules when entered into force in January 2018 are expected to fill the current legislative void for medical devices due to the absence of medical device-specific legislation in India. The government audit facility included in the new rules will enforce and ensure higher quality products enter the medical device market in India. Furthermore, the entire process, starting from the submission by a manufacturer of a pre-market clinical trial application or marketing authorization, through the issuance of the marketing license will be processed through an online electronic procedure. The provision of clinical trial rules and allowance for clinical trial subject compensation should encourage the innovation of new medical device products and subject participation in clinical investigations in India. One more additive effect of the rule is the shortened timeline for new innovative products to gain marketing authorization. Therefore, it is expected that many new innovative products and MNCs will enter the Indian market. The streamlined regulations are expected to attract investors from around the world and because of the streamlined rules and improved government oversight, the quality and range of products and services will improve to better serve the citizens of India.

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