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MEDICAL DEVICEREGULATION - RECENT DEVELOPMENTS AND CHALLENGES IN INDIA

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ABSTRACT

The global medical device market is growing very fast from last decade and India had shown tremendous growth in this market and it is expected to grow in upcoming years. The new rules have been formulated to promote domestic manufacturing and to regulate import and manufacturing in the region. Currently, multinational companies occupy approximately 75 present of sales in the Indian medical device market. The new regulations follow the GHTF (Global Harmonisation Task Force) guidelines and are in consonance with these rules risk-based classification. In addition, inspections by notified bodies have been introduced in the new medical devices rules. This article explains medical device classification, rules, manufacturer registration procedures, dossier filing procedures and marketing application approval processes and some of the challenges faced by the manufacturer.

INTRODUCTION

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%. The major segments for growth are equipment and instruments, consumables and disposables, implants, and patient aids. 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. 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.[1-4] This market has witnessed continuous transformation over the past two decades. Before the *New Economic Policy* (1991), it was dominant in domestic manufacturing circles. Later, it transformed into an import-driven market. Prior to 2006, the medical device sector in India was unregulated; that era ended in 2006, when the Central Drugs Standard

Control Organization (CDSCO) notified 15 medical devices for which registration is required.[5] Previously Device Medical devices and IVDs are regulated by the Drug Controller General of India (DCGI) within the Central Drugs Standard Control Organization (CDSCO), part of the Ministry of Health and Family Welfare. The regulatory framework for medical devices is based on drug regulations under the Drugs and Cosmetics Act of 1940, and Drugs and Cosmetics Rules of 1945.In solidarity with the Make in India program, the CDSCO published the new *Medical Device Rules, 2017*, which came into force on Jan. 1, 2018.

Definition of Medical Devices

(A) 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)
(B) Substances including mechanical contraceptives (condoms, intrauterine devices, and tubal rings), disinfectants and insecticides notified in the Official Gazette under sub-clause (ii)
(C) Devices notified from time to time under sub-clause (iv), of clause (b) of section 3 of the Act.

Notified body

Medical devices, under the new rules, are classified into Class A, B, C and D based on associated risks. The notified bodies will be accredited by the National Accreditation Board for Certification Bodies (NABCB). The NABCB will, before accrediting them, assess their competence in terms of human resources and other requirements. These bodies will undertake verification and assessment of quality management system of medical device manufacturers. The regulations stipulate that chosen notified bodies can charge Rs 20,000 per man-day for audit of site and product assessment. The fee excludes travel expenses which shall not be more than Rs 12,000 per auditor or visit. The man-day calculation is based on number of products assessed, risk class and employee count.[7] (1) Any institute, organisation or body corporate may seek accreditation, after notification ofthese rules, as a Notified Body by applying to the National Accreditation Body referred to in rule 11 in such form and manner as may be determined by the National Accreditation Body from time to time.

(2) The Notified Body accredited under sub-rule (1) shall be competent to carry out audit of manufacturing sites of Class A and Class B medical devices to verify conformance with the Quality Management System and other applicable standards as specified under these rules in respect of such medical devices as and when so advised by the State Licensing Authority.
(3) Any Notified Body accredited under sub-rule (1) shall, if it intends to carry out audit of a manufacturing site of Class A or Class B of medical devices in accordance with sub-rule (2), register with the Central Licensing Authority.
(4) Any Notified Body under sub-rule (3), with an experience of at least two years, may apply to the Central Licensing Authority for registration as a Notified Body for carrying out audit of Class C and Class D medical devices, provided it has personnel with requisite qualification and experience.
(5) With effect from the 1st day of the July, 2017, the Notified Body accredited in accordance with sub-rule (3) may make an application to the Central Licensing Authority for registration in Form MD-1 through online portal accompanied with a fee specified in the Second Schedule along with documents as specified in Part I of the Third Schedule.

(6) The Central Licensing Authority, on being satisfied, shall register the Notified Body and issue a registration certificate in Form MD-2.
(7) The Registration Certificate shall remain valid in perpetuity, unless, it is suspended or cancelled, provided the registration certificate holder deposits a registration retention fee as specified in the Second Schedule every five years from the date of its issue.
(8) If the registration certificate holder fails to pay the required registration certificate retention fee on or before due date as referred to in sub-rule (7), the registration certificate holder shall, in addition to the retention fee, be liable to pay a late fee calculated at the rate of two per cent. of the registration certificate retention fee for every month or part thereof within ninety days, and in the event of non-payment of such fee during that period, the registration certificate shall be deemed to have been cancelled.
(9) The Notified Body shall perform the functions as specified in Part II of the Third Schedule.
(10) The Central Licensing Authority, may, in cases where the requirement specified for registration of Notified Body have not been complied with, reject the application and shall inform the applicant of the reasons for such rejection.
(11) An applicant who is aggrieved by the decision of the Central Licensing Authority under sub-rule (10), may file an appeal within forty five days from the date of receipt of such rejection before the Central Government, which may after such enquiry and after giving an opportunity of being heard to the appellant, dispose of the appeal within a period of sixty days

Duties of Notified Body.— A registered Notified Body, referred to in rule 13, shall carry out its duties and functions, in respect of Class A or Class B medical devices as specified in Part II of the Third Schedule.

Central Medical Device testing laboratory

As per the Medical Devices Rule, 2017,
The Central Government may, by notification, establish Central medical devices testing laboratory for the purpose of,—
(a) Testing and evaluation of medical devices; or
(b) Functioning as an appellate laboratory; or
(c) To carry out any other function as may be specifically assigned to it.

Government of India have designated the laboratories specified in column of the Table below having facilities for carrying out test and evaluation of medical devices, as Central Medical Device Testing Laboratory

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.[9]

SUGAM Portal

An online licensing **portal** of Central Drugs Standard Control Organization (CDSCO) has been implemented on January 2016 and has been named "**SUGAM**" to file applications for various services like Application Submission, Processing and Grant of permission for quick delivery of services.

Table 1. Chapters of Medical Devices Rules, 2017[6]

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.Classification of Medical Device

Class	Risk	Examples
Class A	Low Risk	Examination gloves; Enema devices, Bandages, Cotton wool
Class B	Low Moderate Risk	Needles, Lancets, Suckers, Staplers
Class C	Moderate High Risk	Catheters, Radioisotopes, Insulin pens, Brachytherapy Devices
Class D	High Risk	Absorbable Sutures, Cortical Electrodes, Spinal Stents

Table 3.List of Application/Forms for Medical Device

Form No	Description
Form MD-1	Application for grant of Certificate of Registration of a Notified Body
Form MD-2	Certificate of Registration for a Notified Body under the Medical Devices Rules, 2017
Form MD-3	Application for Grant of Licence to Manufacture for Sale and Distribution of Class A or Class B medical device
Form MD-4	Application for Grant of Loan Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device
Form MD-5	Licence to Manufacture for Sale or for Distribution of Class A or Class B Medical Device.
Form MD-6	Loan Licence to Manufacture for Sale or for Distribution of Class A or Class B medical device
Form MD-7	Application for Grant of Licence to Manufacture for Sale or for Distribution ofClass C or Class D
Form MD-8	Application for Grant of Loan Licence to Manufacture for Sale or for Distribution of Class C or Class D
Form MD-9	Licence to Manufacture for Sale or for Distribution of Class C or Class D
Form MD-10	Loan Licence to Manufacture for Sale or for Distribution of Class C or Class D medical device
Form MD-11	Form in which the Audit or Inspection Book shall be maintained
Form MD-12	Application for licence to manufacture medical device for purpose of clinical investigations, test, evaluation, examination, demonstration or training
Form MD-13	Licence to Manufacture Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training

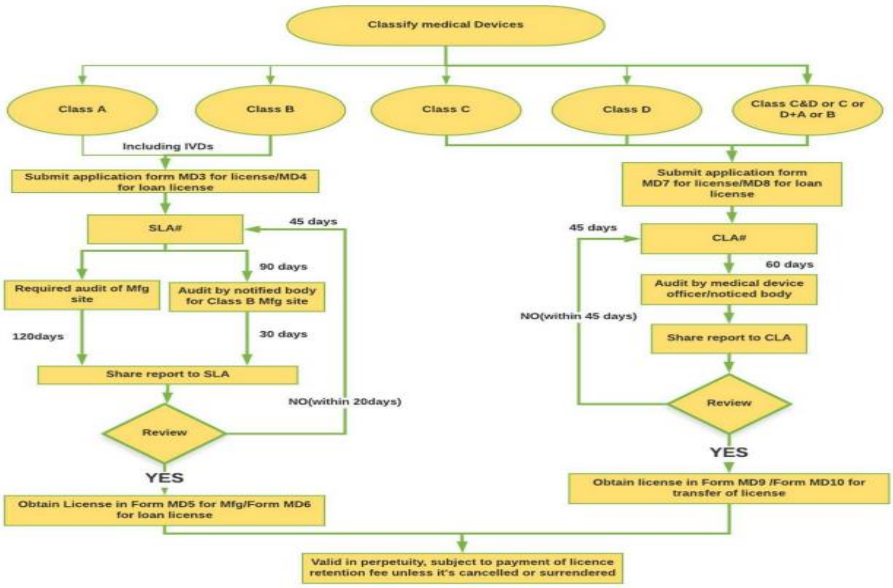
Form MD-14	Application for issue of import licence to import medical device
Form MD-15	Licence to Import Medical Device
Form MD-16	Application for Licence to Import Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training
Form MD-17	Licence to Import Medical Devices for the Purposes of Clinical Investigations or Test or Evaluation or Demonstration or Training
Form MD-18	Application for licence to import investigational medical devices for the purposes by a government hospital or statutory medical institution for the treatment of patients
Form MD-19	Licence to import investigational medical device by a government hospital or statutory medical institution for the treatment of patients
Form MD-20	Application for permission to import small quantity of medical devices for personal use
Form MD-21	Permission to import of small quantity of medical devices for personal use
Form MD-22	Application for Grant of permission to conduct clinical investigation of an investigational medical device
Form MD-23	Permission to conduct Clinical Investigation
Form MD-24	Application for grant of permission to conduct clinical performance evaluation of new *in vitro* diagnostic medical device
Form MD-25	Permission to conduct clinical performance evaluation of new *in vitro* diagnostic medical device
Form MD-26	Application for grant of permission to import / manufacture for sale or for distribution of medical device which does not have predicate medical device
Form MD-27	Permission to import or manufacture for sale or for distribution of medical device which does not have predicate medical device
Form MD-28	Application for grant of permission to Import or Manufacture for sale or for distribution of new *in vitro* diagnostic medical device
Form MD-29	Permission to Import or Manufacture New *In Vitro* Diagnostic Medical Device
Form MD-30	Memorandum to the Central Medical Device Testing Laboratory
Form MD-31	Certificate of test or evaluation by the Central Medical Device Testing Laboratory
Form MD-32	Report of Test or Evaluation of Medical Devices by Medical Device Testing Officer
Form MD-33	Application from a purchaser for test or evaluation of a Medical Device under section 26 of the Drugs and Cosmetics Act, 1940 (23 of 1940)
Form MD-34	Order under clause (c) of sub-section (1) of section of the Drugs and Cosmetics Act,1940, (23 of 1940) requiring a person not to dispose of stock in his possession
Form MD-35	Receipt for stock of medical devices for record, register, document or material objectseized under clause (c) or clause (cc) of sub-section (1) of Section 22 of the Drugs andCosmetics Act (23 of 1940)
Form MD-36	Intimation of Person from Whom Sample is taken
Form MD-37	Receipt for Sample of medical device(s) taken where fair price tendered thereof undersub-section (1) of Section 23 of the Drugs and Cosmetics Act, 1940 is refused
Form MD-38	Memorandum to Medical Device Testing Officer
Form MD-39	Application for grant of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of manufacturer
Form MD-40	Certificate of registration to Medical Device Testing Laboratory for carry out Test or Evaluation of a medical device on behalf of manufacturer

Table 4.Notified Bodies that have been registered with CDSCO[8]

1	M/s Intertek India Pvt. Ltd. E-20, Block B1, Mohan Cooperative, Industrial Area New Delhi (India) - 110044 Telephone No.: 011-41595475, 9310412823 Fax: 011-41595460 E-Mail: kamal.gupta@intertek.com
2	M/s TUV Rheinland India Pvt. Ltd. 82/A West Wing, 3rd Main Road 82/A West Wing, 3rd Main Road Electronic City (India) - 560100 Telephone No.: 080- 46498030 Fax: 08046498042 E-Mail: guruprasad.hc@ind.tuv.com
3	M/s TUV Sud South Asia Pvt. Ltd. TUV SUD House, Off Saki Vihar Road, Saki Naka Andheri (East), Mumbai-400072. Telephone No.: 022-49035508 Fax: 022-49035508 E-mail: info@tuv-sud.in
4	M/S, Dnv GI Business Assurance India Private Ltd., Equinox Business Park, Tower 3, 6th Floor, BKC, LBS Road, Kurla West, Mumbai- 400070 (India), Telephone No.:022-61768909 Fax- 022-61768950 E-Mail- JOHER.JERWALLA@DNVGL.COM

Table 5.Central Medical Device Testing Laboratory

Sl.No	Name of Laboratory	Category of Medical Device
	The National Institute of Biologicals, Noida	In-Vitro Diagnostics for human Immunodeficiency virus, Hepatitis B Surface Antigen and Hepatitis C Virus, Blood Grouping sera, Glucose Test Strip, Fully Automated Analyser Based Glucose Reagent
	The Central Drugs Testing laboratory, Chennai	Condoms
	The Central Drugs Laboratory, Kolkata	Surgical Dressings, Surgical Cotton, Surgical Bandages, Disinfectant
	The Regional Drugs Testing Laboratory (RDTL), Guwahati	Disposable Hypodermic Syringes, Disposable Hypodermic Needle, Disposable Perfusion Sets, I.V. Cannulae
	The Central Drugs Testing Laboratory, Mumbai	Intra Uterine Devices (IUD) and Falope Rings



Procedure to Apply for Import of Medical Device

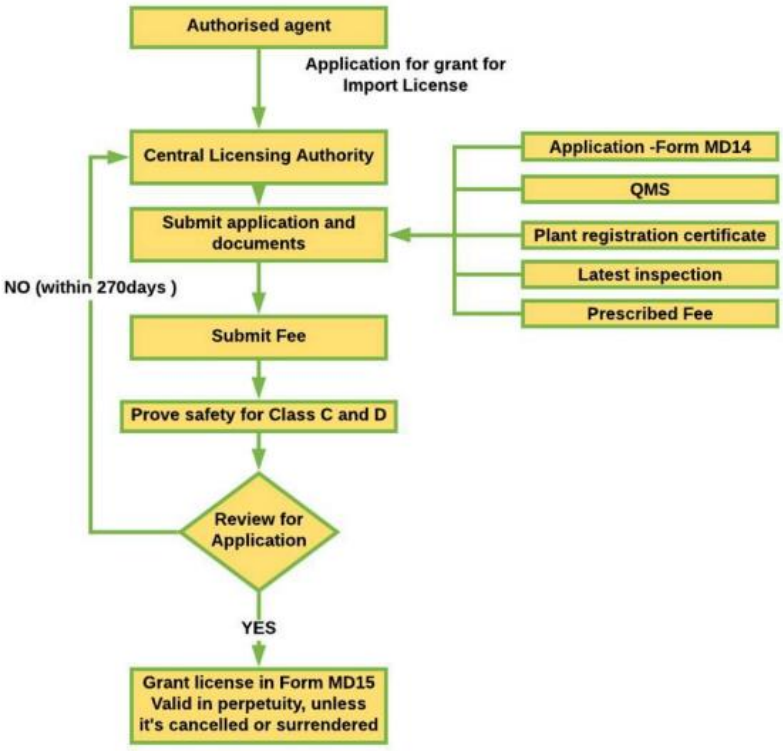


Table 6.Timeline to obtain Manufacturing/ Import Licence for Medical Device

Class/Timelines	Class A	Class B	Class C	Class D
Manufacturing Licence	45 Days	140 Days	150 Days	150 Days
Import Licence	Within 9 months			

Table 7.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 importation
For Manufacturing			
Device description Intended use Specifications including variants & accessories Material of construction Working principle and use of novel technology if any Labels, package inserts, user manual, wherever applicable Summary of serious ADR in India/other countries Site/plant master file	• 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 • Test licence for testing and generation quality control data	• Data analysis • Design input/output documents •Mechanical and electrical test results •Reliability test results •Validation of software • Performance test results • Biocompatibility test results	Notarized copy of overseas manufacturing site and Free Sale Certificate (FSC) Notarized copy of QMS or full Quality Assurance certificate Self-attested copy of whole sale license or manufacturing licence Copy of latest inspection/audit report carried out by Notified Bodies/NRA

Firm details Signed undertaking agreement Essential principles checklist Analytical performance Summary for in vitro device	• Signed undertaking agreement stating manufacturing site is compliant with fifth schedule • In-vitro performance evaluation report for in vitro device	• Risk management data • Animal performance data •Pilot and pivotal clinical investigation data •Regulatory status and restrictions in use •Proposed instructions for use	

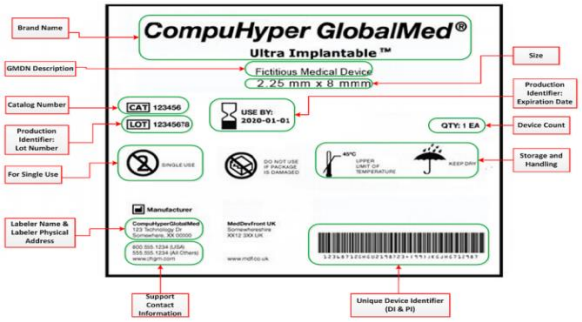


Table 8. Labelling of medical devices.

Name of the Medical Device
Details necessary for the user to identify the device and its use
Name of manufacturer and address of manufacturing premises
Correct statement about the net quantity in terms of weight, measure, volume, number of units
Month and year of manufacture and expiry
Label shall bear the shelf life of the product
To provide, wherever required, an indication that the device contains medicinal or biological substance
To provide, a distinctive batch number or lot number preceded by the word “Lot No.” or “Lot” or “Batch No.” or “B. No.”;
To indicate, wherever required, any special storage or handling conditions applicable to the device
To indicate, if the device is supplied as a sterile product, its sterile state and the sterilisation method.
To give, if considered relevant, warnings or precautions to draw the attention of the user of medical device.
To label the device appropriately, if the device is intended for single use
To overprint on the label of the device, the words “Physician’s Sample—Not to be sold”, if a medical device is intended for distribution to the medical professional as a free sample.
To provide, except for imported devices, the manufacturing licence number by preceding the words “Manufacturing Licence Number” or “Mfg. Lic. No.” or “M. L”;
To provide on the label, in case of imported devices, by way of stickering, where such details are not already printed, the import licence number, name and address of the importer, address of the actual manufacturing premises and the date of manufacture
Provided that the label may bear symbols recognised by the Bureau of Indian Standards or International Organisation for Standardisation (ISO)
In case of small sized medical devices on which information cannot be printed legibly, shall include the information necessary for product identification and safety such as information covered by clauses (a), (b), (c), (d),(e), (g), (k), and (m) shall be included.

Table 9: List of List of Notified devices and devices proposed to be notified[11]

Sl.No	Name of Devices
1	Disposable Hypodermic Syringes
2	Disposable Hypodermic Needles
3	Disposable perfusion Sets
4	In vitro Diagnostic Devices for HIV, HBsAg and HCV
5	Cardiac Stents
6	Drug Eluting Stents
7	Catheters
8	Intra Ocular Lenses
9	I.V. Cannulae
10	Bone Cements
11	Heart Valves
12	Scalp Vein Set
13	Orthopaedic Implants
14	Internal Prosthetic Replacements
15	Nebulizer
16	Blood Pressure monitoring Devices
17	Digital Thermometer
18	Glucometer

Table 10.Fee payable for licence, permission and registration certificate

Sl. No	Rule	Subject	In rupees (INR) except where specified in dollars ($)
(1)	(2)	(3)	(4)
	13(5)	Registration of Notified Body	25000
	13(7)	Registration retention fee of Notified Body.	25000
	20(2)	Manufacturing licence or loan licence to manufacture Class A or Class B medical device for,-	
		(a) one site; and	5000
		(b) Each distinct medical device.	500
	21(2)	Manufacturing licence or loan licence to manufacture Class C or Class D medical device for,-	
		(a) one site; and	50000
		(b) each distinct medical device.	1000
	29(1)	Manufacturing licence or loan licence retention fee for,-	
		(a) one site manufacturing Class A or Class B medical device; or	5000
		(b) one site of manufacturing Class C or Class D medical device; or	50000
		(c) each distinct medical device of Class A or Class B; or	500
		(d) each distinct medical device of Class C or Class D	1000
	31(1)	Test licence to manufacture for clinical investigations, test, evaluation, examination, demonstration or training for each distinct medical device.	500

	34(2)	Import licence for Class A medical device other than in vitro diagnostic medical device for,-	
		(a) one site; and	$1000
		(b) each distinct medical device.	$50
	34(2)	Import licence for Class B medical device other than in vitro diagnostic medical device for,-	
		(a) one site; and	$2000
		(b) each distinct medical device	$1000
	34(2)	Import licence for Class A or Class B in vitro diagnostic medical device for,-	
		(a) one site; and	$1000
		(b) each distinct in vitro diagnostic medical device	$10
	34(2)	Import licence for Class C or Class D medical device other than in vitro diagnostic medical device for,-	
		(a) one site; and	$3000
		(b) each distinct medical device	$1500
	34(2)	Import licence for Class C or Class D in vitro diagnostic medical device for,-	
		(a) one site; and	$3000
		(b) each distinct in vitro diagnostic medical device.	$500
	35(2)	Inspection of the overseas manufacturing site.	$6000
	37	Import licence retention fee for,-	
		(a) one overseas site manufacturing Class A medical device other than in vitro diagnostic medical device; or	$1000
		(b) one overseas site manufacturing Class B medical device other than in vitro diagnostic medical device; or	$2000
		(c) one overseas site manufacturing Class C or Class D medical device other than in vitro diagnostic medical device; or	$3000
		(d) each distinct medical device of Class A other than in vitro diagnostic medical device; or	$50
		(e) each distinct medical device of Class B other than in vitro diagnostic medical device; or	$1000
		(f) each distinct medical device of Class C or Class D other than in vitro diagnostic medical device	$1500
		(g) one overseas site manufacturing Class A or Class B in vitro diagnostic medical device;	$1000
		(h) one overseas site manufacturing Class C or Class D medical device other than in vitro diagnostic medical device;	$3000
		(i) each distinct in vitro diagnostic medical device of Class A or Class B in vitro diagnostic medical device;	$10
		(j) each distinct in vitro diagnostic medical device of Class C or Class D in vitro diagnostic medical device;	$500
	40(2)	Fee for Import licence for test, evaluation or demonstration or training for each distinct medical device	$100

	42(1)	Fee for Import of investigational medical device by Government hospital or statutory medical institution for treatment of patient of each distinct medical device	500
	51(2)(a)	Permission to conduct pilot clinical investigation.	100000
	51(2)(b)	Permission to conduct pivotal clinical investigation.	100000
	59(2)	Permission to conduct clinical performance evaluation.	25000
	63(1)	Permission to import or manufacture a medical device which does not have its predicate device	50000
	64(1)	Permission to import or manufacture new in vitro diagnostic medical device.	25000
	81(1)	Registration of medical device testing laboratory to carry out testing or evaluation of a medical device on behalf of manufacturer.	20000
	84	Registration retention fee for medical device testing laboratory	20000
	91	Certificate to export of each distinct medical device.	1000

SUGAM portal used for application and grant of licence or permission for the following:

1) Blood Bank License.
2) NOC to manufacture unapproved drugs for the purpose of export.
3) Conduct BA/BE studies.
4) NOC to obtain test license for unapproved or new drugs.
5) Registration for import of cosmetics.
6) Indigenous manufacture and Import of Medical device and In-Vitro Diagnostics.
7) Registration for global clinical trial.
8) Pay Online any fee as required for all above applications in a Secure and convenient manner and Save time.
9) Import of drugs for the purpose of test or analysis.
10) Import of drugs for personnel use,
11) Registration for import of drugs.
12) Indigenous manufacture and Import of Biologicals including rDNA.
13) Registration of Ethics committee.

Benefits of the System:

SUGAM portal provides the single window for all its stakeholders to access the services provided by the portal by implementing role based access control and actions. It has consolidated the entire Drug Regulatory framework at centre and provides a centralized dashboard for the monitoring the various regulatory clearances all over the country.

- ✓ SUGAM portal provides high level of transparency to its stakeholders as status of the submitted applications can be tracked from applicant dashboard.
- ✓ SUGAM enables ease of business by providing the integrated workflow right from making an application for grant of permission/ license, online payment, online review process, query management and grant of permission/license online.
- ✓ SUGAM provides a framework for viewing and replying to the deficiencies raised during processing.[10]

Medical device Regulatory Review Process in India

Medical Device review process is presented in Figure. The review process map illustrates the main steps in the review process and identifies the key milestone dates for monitoring and analysing timelines for review.

Importor Manufacture of Medical Device which does not have Predicate Device

An application for grant of permission for such medical device after completion of its clinical investigation under Chapter VII shall be made to the Central Licensing Authority in Form MD-26 either by an authorised agent in case of import or a manufacturer, as the case may be, which shall be accompanied with fee as specified in the Second Schedule along with information specified in Part IV of the Fourth Schedule. The Central Licensing Authority, after being satisfied with the information furnished along with application under sub-rule (1), may grant permission to import or manufacture medical device which does not have predicate medical device in Form MD-27, or may reject the application for reasons to be recorded in writing, within a period of one hundred and twenty days or such extended period, not exceeding a further period of thirty days, from the date of application.

Challenges

- 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.
- Starting on January 1st, 2022, medical devices that are approved for import, sale, or distribution in India must bear two different types of unique identifiers: the device identifier and the production identifier. The device identifier is a global trade item number and the production identifier is the device's serial number, lot/batch number, software version, and/or manufacturing and/or expiration date. Much more information should be provided in the rule in order to comply.
- Time taken for the approval of medical device is 150 days in case of Class B, C and D devices. The timelines can be reduced with faster approval processes it is submitted electronically.

CONCLUSION

The Medical Device Rules, 2017 have many attractive features that encourage the medical device sector in India. By introducing a single online portal, the registration process has been streamlined. The government audit facility included in the new rules will enforce and ensure higher quality products enter the medical device market in India. An audit by the notified bodies will further increase the manufacturing quality of devices. The role of state licensing authority and central licensing authority is visibly outlined in the rule which in turn will help the manufacturer while filing the application. There are few areas which can be overlooked by the authorities like Medical devices incorporating software and standalone medical device software, and the timelines required for the approval of Class B, C and D can be reduced.

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