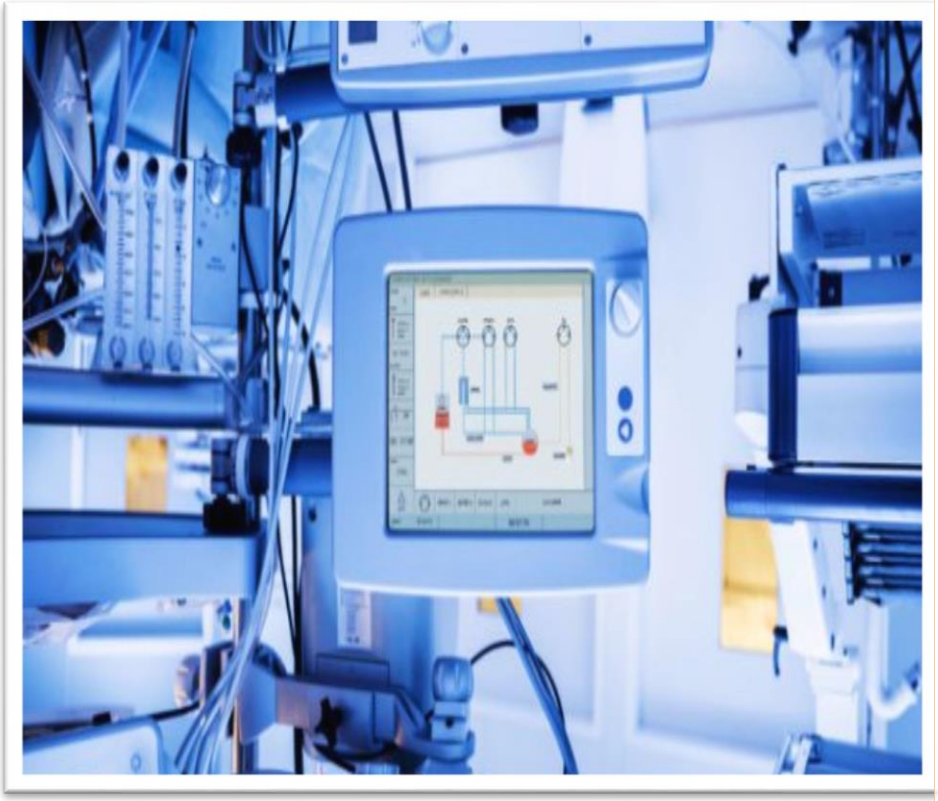
2022

MEDICAL DEVICE INDUSTRY ANALYSIS REPORT



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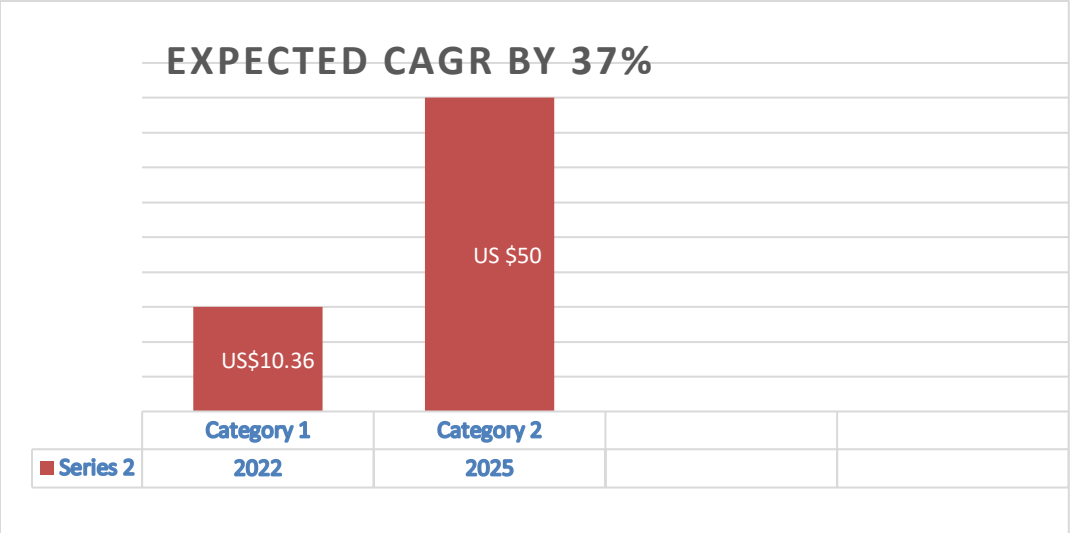
Introduction

Indian Healthcare industry is growing rapidly; however, the provisions related to healthcare remain inadequate, and there are challenges pertaining to accessibility, reliability and affordability in the country.

With the increasing demand for medical facilities in India, the market for medical devices is growing rapidly. The medical devices Industry in India is one of the largest in Asia and is amongst the top 20 players in the world. It can be said that this industry is highly capital intensive, and there is immense scope as far as a skilled workforce and Research & Development are concerned. The Government has devised a few schemes to promote the market of medical devices in India. As per the Indian Brand Equity Foundation (IBEF) report, the market of medical devices in India is expected to grow at a Compound Annual growth rate (GAGR) of 37% to reach US$ 50 billion in 2025, from US$ 10.36 billion in Year 2020. This sector comprises large multinationals to small and mid-sized companies.



In 2020, the Government of India initiated The Production Linked Incentives Scheme (PLI) to boost the medical Devices industry. The primary aim of scheme is to provide financial benefits to boost domestic manufacturing and attract significant investments in the medical device sector. The scheme's tenure is from the financial year 2020-21 to the financial year 2027-28.

The reports of IBEF suggest that inflow from FDI in the medical devices and surgical appliances sector at US$ 2.35 billion between April 2000-December 2021. Between 2020 and 2025, diagnostic sector will likely expand at a CAGR of 13.5%. In the union budget 2022-2023, Rs. 86,200 crores (US$ 11.3 billion) was allocated as a budget for the pharmaceutical and healthcare sector.

In India, there is more import dependency in the medical device sector, i.e., around 80% of total sales. India is primarily involved in manufacturing low risks devices for domestic and international consumption. Apart from dependency on imports, there is also a complex regulatory environment.

Recent initiatives by the Government

- The Government of India took various initiatives recently to enhance the medical devices industry. The medical device industry not only offers excellent opportunities in terms of growth, but the Government is also coming up with new schemes and policies to encourage this industry.
- In the Union Budget of 2022-23, Rs 86,200 Crores was allocated to the pharmaceutical and healthcare sector. In November 2021, the Centre of Excellence (CoE) for Make-in –India Product development and commercialization in the medical devices and diagnostic space was established by The Indian Council of Medical Research (ICMR) and collaborated with the Indian Institute of Technology.
- To increase the acceptability of Indian Devices in the global market, the Government of India announced a plan to draft a new drug, cosmetics and medical devices bill in October 2021.

- The major announcement was made in October 2021 that under the PLI scheme, 13 companies have received approval for manufacturing medical devices in the country, which is expected to bring significant expansion in the medical devices sector in India[i].
- The Government of India recognized this sector as a sunrise sector under the 'Make in India 'campaign in 2014.
- The proposal of Rs 5000 crore was sanctioned in 2021 to build a medical device park in Nalagarh, solan, a Himachal Pradesh industrial township.
- In the same year, Government announced medical devices park in Oragadam (Tamil Nadu) and Uttar Pradesh, with an estimated investment of Rs. 3,500 crore and Rs. 500 crores, respectively. These investments in the medical device industry are also expected to offer direct and indirect employment to many.
- In June of 2021, to check the quality, safety and efficacy of medical devices, the Association of Indian Manufacturers of Medical Devices (AiMeD) and the Quality Council of India (QCI) launched the Indian certification of Medical Devices (ICEMD) 13485 plus scheme.
- There was a need to boost domestic manufacturing of medical devices and attract more investments in India; the department of pharmaceuticals launched a PLI scheme for manufacturing medical devices in the country, with a total outlay of funds of Rs 3420 crore for the period FY21-FY28.
- The PLI scheme was launched in 2021, aiming primarily to boost India's manufacturing capabilities by increasing investment and production in the medical devices sectors. The worth of the scheme is Rs 15000 crores. The scheme aims to contribute an affordable and broader range of medicine to consumers.
- The revised notice was related Department of Pharmaceuticals (DoP) released a revised notice on the Public Procurement Order (PPO), where 19 medical devices were incorporated in the revised guidelines of the PPO; this is done to push domestic medical devices manufacturing and reduce import bills by Rs 4000 crore (US$ 538.62 million)
- The import of critical medical devices such as nebulizers, oxygen concentrators, Oxygen canisters etc., has been made accessible by easing the clearance required under the Legal Metrology Act (Packaging Rules 2011) in April 2021. The easing of requirements under legal metrology has expedited the process. The Government has also approved nine eligible projects led by healthcare giants, e.g., Siemens Healthcare Private Limited, Allengers Medical Systems Limited (AMSL), Allengers OEM Private Limited (AOPL), Wipro G.E. Healthcare Private Limited, Nipro India Corporation Private Limited, Sahajanand Medical Technologies Private Limited, Involution

Healthcare Private Limited, Integris Health Private Limited and to generate employment[ii].

Medical device Industry and market share

As stated above Medical devices market in India is expected to grow by 37% and touch 50 billion dollars by 2025. Multiple reasons are responsible for India's medical device industry growth. Most importantly, there has been a tremendous increase in spending of people in healthcare as they now have more disposable income, there has been improvement in healthcare infrastructure, there is a visible increase in affordability, and lifestyle changes are also leading to more ailments than before. There is significant growth in 'Medical Tourism' as well. Foreign direct investment (FDI) is also increasing every year in the medical device sector, which clearly shows the confidence of foreign players in the Indian Market. Export is also rising, as export stood at 2.51 billion U.S. $ in 2019 -20 and are expected to rise to US$ 10 billion by 2025.

Meaning of Medical Device

The Drug and Cosmetic Act 1940 & Rules of 1945 defines Medical Device as

a. Any instrument, material, apparatus, appliance, implant, or any other substance, which can be used alone or in combination, and it also includes the software intended by its manufacturer to be explicitly used either for human beings or animals for any of the purposed specified below -

i. Diagnosis, monitoring, prevention, treatment or finding out any of the disorder or disease;

ii. Monitoring, diagnosis, treatment, alleviation or assistance for any disability or injury;

iii. Investigation, modification or replacement or support of the physiological process or an anatomy process;

iv. Sustaining or supporting life;

V. used for Disinfection of IVD or medical devices;

vi. Controlling conception, and which does not achieve primary intended action either in human body or animals by any immunological or pharmacological or metabolic means, but which may be used for;

b. An accessory to such an apparatus, instrument, appliance, material or another article;

c. In-vitro diagnostic Device, which is a reagent, reagent product, calibrator, control material, instrument, kit, apparatus, system or equipment, which can be used alone or in combination for examination and providing information for medical or diagnostic examination of specimens derived from the human bodies or animals.

Meaning of In Vitro Diagnostic Device (IVD)

IVDs are Medical devices only; earlier, there were no provisions for the registration of IVD in India. However, in 2017 an official notification for the registration of medical devices and IVD was published by the Government of India. There are around 462 Products classified as 250 products, medical devices and IVD, respectively, under the New Medical Device Rules of the Government of India.

In vitro, diagnostic devices are reagents, kits, systems or instruments which intend to diagnose a disease or other health conditions and are also used to determine the state of health to cure, treat, or prevent disease or its sequelae. Such products are intended for collecting, preparing, and examining specimens taken from the human body.

Medical Device Classification and grouping

Under the Medical Device Rules 2017, medical devices are primarily classified by considering four important parameters.

I) *what is a meaning of* medical device*?*

As per the medical device rules 2017, "Medical Device" means:

- As per sub-clause (i) of section 3 of the Act, any 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

- As per sub-clause (ii) of section 3, any substance, including mechanical contraceptives (condoms. intrauterine devices, tubal rings), disinfectants and insecticides notified in the official gazette.
- Devices are notified from time to time under sub-clause (IV), clause (b) of section 3 of the Act.

The classification guidance document can easily find a list of products requiring registration.

II) ***What are different classes of medical Device?***

As Per the Medical Device rule 2017, risk-based classification for medical devices and IVDs was done. This classification was as per the rules established by IMDRF.

Risk Level	Medical Device /IVD Device
Low Risk	A
Low Moderate Risk	B
Moderate-High Risk	C
High Risk	D

III) ***What all categories of Medical devices are exempted?***

The 8th schedule of the Medical Devices Rules 2017 establishes conditions for exemptions which are as follows.

- Custom-made devices are exempt from all provisions
- Medicated dressings and first-aid bandages are exempt from being covered by a sales license if their manufacturers are licensed.
- Registered medical practitioners supply devices to Individual patients.
- Devices supplied by a hospital or dispensary are maintained or supported by the Government or local body.
- Mechanical contraceptives are exempt from being covered by a sales license if they are sold, supplied or dispensed within their labelled shelf –life and complaint with the product.

- Devices are imported in small quantities and donated to a charitable hospital for free patient treatment.

IV) *How can Device be grouped*

CDSCO provides guidance governing the grouping of medical devices. The devices are grouped as below.

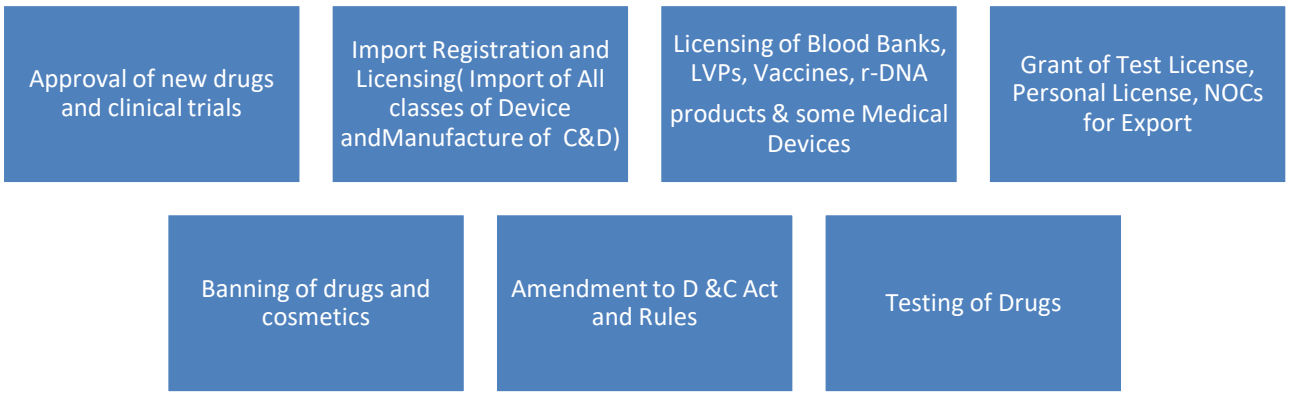
- Single
- Family
- IVD cluster
- Group
- IVD test

REGULATORY AUTHORITY GOVERNING MEDICAL DEVICES

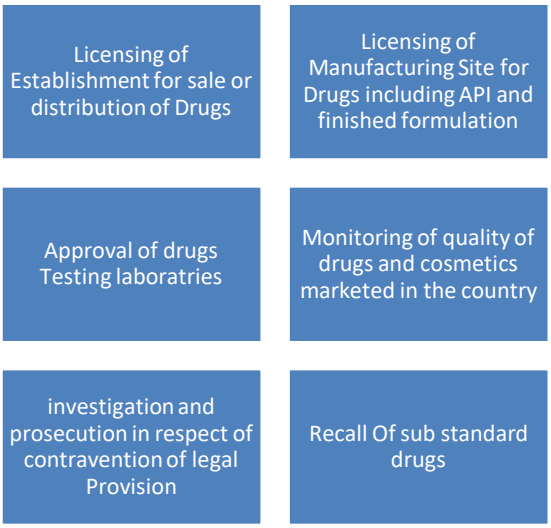
The Medical Device Rules issued under the Drugs and Cosmetic Act regulate the functioning of Medical Devices in India. The Drug comes under the concurrent list of the Indian Constitution. It is governed by Centre and State Governments under the Drugs & Cosmetics Act, 1940. Central and state governments are responsible for enforcing the Act and rules. The Drug Controller General (DCGI) heads The Central Drugs Standard Control Organization (CDSCO), which primarily focuses on coordinating activities of state licensing authorities, formulation policies and ensuring proper implementation of the Drug and Cosmetic Act and Medical Device Rules throughout India.

Functions of CDSCO

Central Licensing authority



State licensing authority



Organizational structure of CDSCO

The CDSCO is headed by Director Controller General and has its headquarters in New Delhi. There are zonal and sub-zonal offices of CDSCO.

The list of CDSCO Zonal offices is as follows

- North Zone – Ghaziabad
- South Zone – Chennai
- West Zone – Mumbai
- East Zone – Kolkata
- Hyderabad zone
- Ahmedabad Zone

The list of Sub Zonal Offices is as follows

- Bangalore
- Varanasi
- Goa
- Jammu
- Indore
- Guwahati
- Baddi

Port /Airport Offices

- Ahmedabad

- Chennai port
- Chennai Airport
- Bangalore
- Hyderabad
- Goa
- Kochi
- Delhi
- Kolkata port
- Kolkata Air Cargo
- Mumbai, Nhava
- Sheva
- Mumbai Custom house

Licenses Required for Import, Sale, Manufacture and Loan of Medical Devices under the MDR

License for or Registration Certificate	Form (template) of the License	Application form	Relevant Rule	Licensing Authority	Licensing Authority
Import of Notified Medical Devices	Form MD - 15	Form MD-14	Rule 36(1)	Central Licensing authority	Nine months
Import of Notified Medical Devices for clinical investigation	Form MD-17	Form MD -16	Rule 41(1)	Central Licensing authority	30 days
Permission to import new Notified	Form MD 29	FORM MD 28	Rule 64(2)	Central Licensing authority	90 days

Medical Device for clinical trial or marketing					
Permission to conduct a clinical investigation	Form MD-25 Form MD 23	Form MD-24 Form MD-22	Rule 59(5) Rule 52(1)	Central licensing authority	90 days
Permission to import or manufacture a medical device that does not have a predicate device	Form – MD27	Form MD-26	Rule 63(2)	Central Licensing authority	120 days
Retail sale of Notified Medical Devices	Form -21	Form -19	Rule 61(2)	State Drug Licensing Authority	No period is prescribed (usually between three to six months)
Wholesale of Notified Medical Devices	Form -21B	Form 19	Rule 61(2)	State Drug Licensing Authority	No period is prescribed (usually between three to six months)
License to manufacture Notified Medical Devices	Form MD-5 for Class A or Class B. Form MD-9 for Class C or Class D	Form MD-3 for Class A or Class B. Form MD-7 for Class C or Class D	Rule 20 sub-clause (4) and 20 sub-clause (6) for Class A or Class B Rule 25(1) for Class	The State Drug Licensing Authority for classes A and B devices, Central Licensing Authority	45 days from the date of Application

			C or Class D	for Classes C and D devices	
License to manufacture a Notified Medical Device for Clinical Investigation	Form MD-13	Form MD-12	Rule 31(3)	Central Licensing Authority	30 days
Loan License (manufacturing unit owned by the third party)	Form MD-6 for Class A or Class B. Form MD-10 for Class C or Class D	Form MD-4 for Class A or Class B. Form MD-8 for Class C or Class D	Rule 20(4) and Rule 20 (6) for Class A or Class B, Rule 25(1) for Class C or Class D	The State Drug Licensing Authority for classes A and B devices, Central Licensing Authority for Classes C and D devices	45 days

Manufacturing of Notified Medical Devices in India

The manufacturing of notified medical devices of category A&B is regulated by state Licensing authority, whereas a License to manufacture C&D is issued by Central Licensing authoring. It is to be noted the License is required for each manufacturing location and each Notified Medical Device at the manufacturing location.

Import of Notified Medical Device

The import of Medical devices in country is widespread. There are a few more legal requirements in notified medical device import compared to medical device manufacturing. The central licensing authority wholly regulates the import of medical devices. Like all other export-import, the import of medical devices is also governed under the Export-Import policy ("EXIM policy). Before importing

Notified Medical Device in India, the Importer must obtain the Importer and exporter code (IEC) from the director general's office. The IEC number is an important number required when getting clearance from customs for imported goods. The IEC number can be obtained by submitting an application form in the prescribed format wherein details of Bank Account Number and PAN have to be mentioned. The form is to be submitted to the office of the Jurisdictional Joint Director of Foreign Trade. As per the Act, an import license from CDSCO is required to import notified medical devices in India.

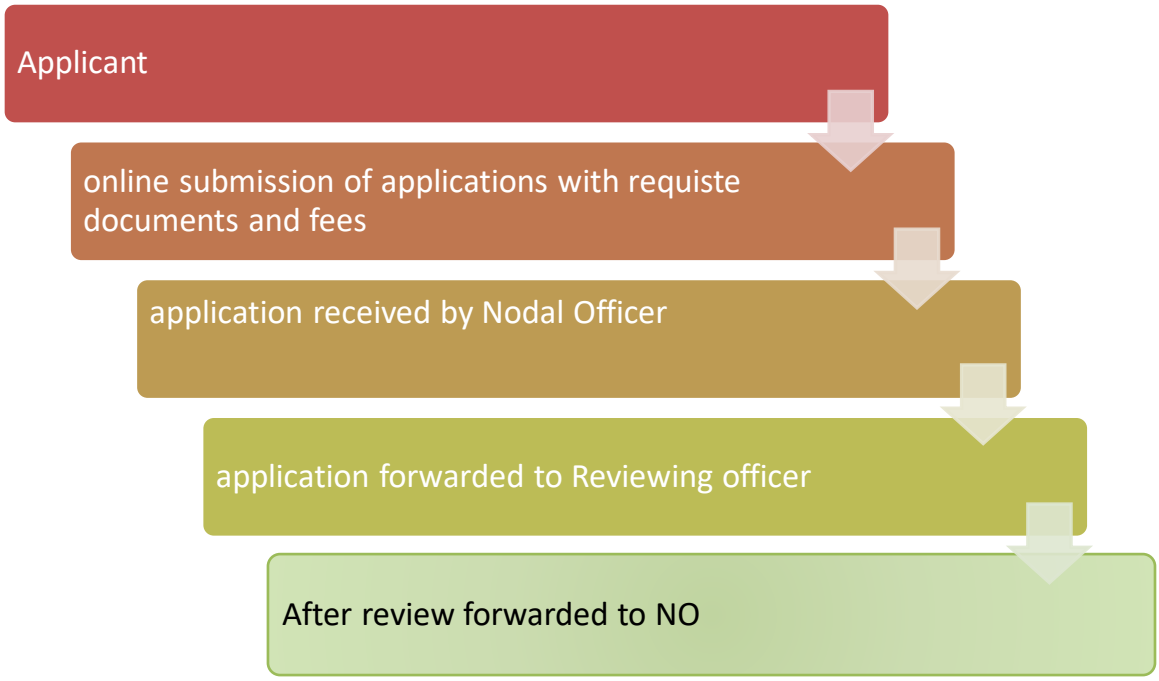
There is an online process for getting an import licence for notified medical Devices from CDSCO. The foreign manufacturer has a valid manufacturing license as per MDR to manufacture or can appoint an authorized agent in India on his behalf. The authorized agent appointed must also have a manufacturing or wholesale License for the sale and distribution of Notified Medical devices in India. The foreign manufacturers often do not have an office in India with good manufacturing or wholesale License for selling and distributing medical devices. So, in that case, when foreign manufacturers do not have an office in India, they appoint an authorized Indian agent to grant an import License. The Foreign manufacturers authorize agents by power of attorney. Apart from a power of attorney, other documents are also required for an import license, such as a free sale Certificate in the country of origin issued by the National Regulatory Authority or other competent authority. Also, the concerned authority issued a notarized copy of the Quality Management System Certificate regarding the manufacturing site.

List of Notified Medical devices

1. Disposable Hypodermic Syringes
2. Disposable Hypodermic Needles
3. Disposable Perfusion Sets
4. IVD Devices for HIV, HBsAg, HCV
5. Cardiac Stents
6. Drug Eluting Stents
7. Catheters
8. Intra Ocular Lenses
9. V. Cannulae
10. Bone Cements

11. Heart Valves
12. Scalp Vein Set
13. Orthopaedic Implants
14. Internal Prosthetic Replacements
15. Blood Grouping Sera
16. Ligatures, Sutures and Staplers
17. Intra Uterine Devices (CuT)
18. Condoms
19. Tubal Rings
20. Surgical Dressings
21. Umbilical tapes
22. Blood/Blood Component Bags
23. Ablation Devices
24. Organ Preservation Solution
25. Blood Pressure Monitors (Effective January 1st, 2021)
26. Digital Thermometers (Effective January 1st, 2021)
27. Glucometers (Effective January 1st, 2021)
28. Nebulizers (Effective January 1st, 2021)
29. X-Ray Machines (April 1st, 2021)
30. CT Scan Equipment (April 1st, 2021)
31. MRI Equipment (April 1st, 2021)
32. PET Equipment (April 1st, 2021)
33. Defibrillators (April 1st, 2021)
34. Dialysis Machines (April 1st, 2021)
35. Bone Marrow Cell Separators (April 1st, 2021)
36. All Implantable Medical Devices (April 1st, 2021)
37. Ultrasound Devices (November 1st, 2021)
38. Disinfectants and insecticides specified in *Medical Device Rules, 2017*

The approval process for the Application received Online Sugam Portal with respect to Medical Devices.



After review from Nodal Officer, it is forwarded to DDA /DA, and in case of any deficiency in the document, the query is raised at this stage.

Notification to regulate all Medical devices

On February 11 2020, Health Ministry published a notification regarding two major changes: the definition of medical devices **("New Definition Notification")**, which made it an expansive definition; secondly, it made the registration of such

newly notified medical devices on a portal mandatory. The notification stated that it's effective from April 1, 2020.

Interestingly, there has been no change in the New Definition of medical devices under section 3(b)(iv) of the DCA. The New Definition Notification notifies a catch-all definition of medical devices, effectively bringing all medical devices under the regulation of the MDR as follows: “All devices including an instrument, appliance, apparatus, material, implant or any article; which is to be used in combination or alone, also includes software or an accessory, required by its manufacturer to be used especially for either 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 -

- diagnosis, prevention, monitoring, treatment
- or alleviation of any disease or disorder;
- diagnosis, monitoring, treatment, alleviation
- or assistance for any injury or disability;
- the investigation, replacement or modification or
- support of the anatomy or of a physiological
- process;
- supporting or sustaining life;
- disinfection of medical devices; and
- control of conception.”

Therefore, once the New Definition Notification comes into effect, manufacturers and importers of New Devices would be required to obtain manufacturing and import licenses under the MDR to manufacture and import medical devices.

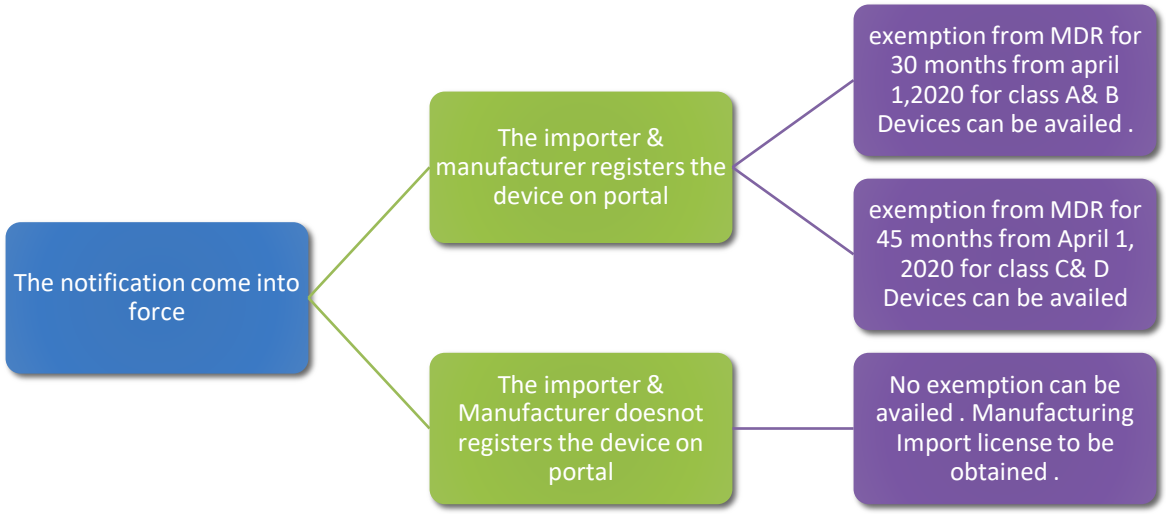
Once the new medical devices have been registered as per the portal, they will be exempted from MDR and consequently from getting manufacturing and import license for 30 months starting from April 1, 2020, in case of A & B new Medical devices and 42 months starting from April 1, 2020, in case of C& D new medical devices. These have been termed exemption provisions.

However, registering new medical devices on the portal is optional for 18 months and mandatory.

Alongside, the manufacturers and Importers of medical devices have to apply for a licensing process to comply with the larger ambit of the Medical Device Rule as and when the exemption provisions expire. The licensing process usually takes quite a few months which is nine months or so.

However, CDSCO is receiving many applications; it takes quite a long time to process, and CDSCO is also inadequately staffed to handle an increasing number of Applications.

Overview of the Registration process



Documents Required

S.no	Documents	Manufacturer	Importer
1.	Details of applicant	Deals of entity manufacturing the Medical Device and the name and address of the manufacturing site.	Name of the entity importing the Medical Device and specification and standards of that medical Device
2.	Details of Medical Device	Generic Name Model Number Intended Use category of Medical Device Material of Construction Dimension (if any) Shelf Life Sterile or Non-Sterile Brand Name (Registered under the Trademarks Act, 1999)	Generic Name Model Number Intended Use of Medical Device Category of Medical Device Construction material Dimension (if any) Shelf Life Sterile or Non-Sterile Brand Name (Registered under the Trademarks Act, 1999)
3	Compliance	certificate ISO 13485 standard accredited by either NABC, i.e. National Accreditation Board for Certification Bodies or International Accreditation Forum in respect of such medical	Device or IVD compliance certificate, i.e. ISO 13485 standard accredited by NABC, i.e. National Accreditation Board for Certification Bodies or International Accreditation Forum in respect of such medical Device
4.	Undertaking	There is a requirement of Undertaking duly signed by the manufacturer stating that the information furnished by the applicant is genuine and authentic. (As per the format)	Duly signed Undertaking by the Importer stating that the information furnished by the applicant is genuine and authentic. (As per the format)

Conclusion

There is significant and positive changes in the regulatory system for medical device in India. As discussed in the blog, there are certain challenges to do business of medical device in India, but growing market of this sector seems ready to overcome these hurdles. The major concern in the industry in 2022 appears to be the proper implementation of the Notifications and the way the large number of medical devices coming up in the market need to be brought under regulation. While the industry's concern with respect to the Notifications is justified, the CDSCO over the past year has demonstrated willingness to consider the industry's concerns and cooperate with the industry to arrive at solutions for the same. In spite loopholes in regulatory framework, it cannot be denied that the medical device market in India is giving a lot of opportunities to existing players, new investors and prospective investors.

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[i] https://www.ibef.org/industry/medical-devices

[ii] https://www.ibef.org/industry/medical-devices