

# Regulatory Guidelines of Medical Devices in India - Associated Challenges and Opportunities

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**Abstract:** *Medical devices, according to the Central Drugs Standard Control Organization (CDSCO), are tools used to identify, minimize, treat, or prevent disease or abnormalities in people or animals. A medical device can be as basic as a blood pressure monitor or sphygmomanometer, or it can be as sophisticated as imaging diagnostics and other tools for managing physiological issues. The objective of the current study is to provide an overview of Indian regulatory standards for medical devices. Modern medical care now includes a vast array of medical devices. They frequently relate to the standard of treatment. The use of technology has undoubtedly increased quality in some situations. In other instances, several issues have been linked to devices. The approach to device quality has been heavily reliant on regulation. The law's revision and recently established guidelines will give producers and relevant authorities the necessary direction to handle instances effectively. While these rules and reforms aim to simplify, standardise, and speed up the process for manufacturing and importing medical devices into India, they also come with their own difficulties. For international companies wishing to enter or grow their business in Indian medical markets, understanding the impending regulatory reforms in India would be essential. It is expected that the regulations and implementation of the recommendations would result in successful outcomes. This article describes the rules that are now in effect for applications for clinical trials, manufacturing licences, and registration certificates for medical devices.*

**Keywords:** Medical devices, classification, regulatory guidelines, import, license, key challenges

## 1. Introduction

The national regulating organisation for cosmetics, drugs, and medical devices in India is the Central Drugs Standard Control Organization (CDSCO).

The Food and Drug Administration (FDA) of the United States, the European Medicines Agency of the European Union, the PMDA of Japan, the Medicines and Healthcare Products Regulatory Agency of the United Kingdom, and the National Medical Products Administration (NMPA) of China are additional organisations that regulate for other nations.

India's Central Drugs Standard Control Organization (CDSCO) regulates the control of pharmaceuticals, cosmetics, and medical equipment.

The Central Drugs and Standard Control Organization would assess all medical devices, including implants and contraception, according to a plan made public by the Indian government (CDSCO).

There are 8 divisions in the Central Drugs Standard Control Organization:

Clinical Trials, Biological Products, Medical Devices & Diagnostics, DCC - DTAB, Import & Registration, New Drugs, and BA/BE

The Central Licensing Authority (CLA) and State Licensing Authority (SLA) of India's Central Drug Standard Control Organization (CDSCO) are in charge of issuing licences to import, manufacture for sale or for distribution and sale, stock, exhibit, or offer for sale.

The different regulatory classification for medical devices are

Class A – Low Risk (example: thermometers, tongue depressors)

Class B – Low - moderate Risk (example: hypodermic needles, suction equipment)

Class C – Moderate - high risk (example: lung ventilator, bone fixation)

Class D – High Risk (example: heart valves, implantable devices)

All import device licencing as well as Class C and Class D medical device manufacturing, loan, and wholesale licences are handled by CLA.

SLA manages licences for Class A and Class B medical device manufacturing, loan, and wholesale.

## Steps for the Indian Registration Process for Medical Devices

- Designate a local agent in India to act as the applicant and licence holder
- Prepare the Device Master File (DMF)
- Prepare the Plant Master File (PMF)
- Prepare application Form with supporting documents
- Submit the aforementioned documents to DCGI with fees
- The applicant answers to the DCGI's questions and addresses them. The DCGI may ask for a technical presentation.
- Approval

## 2. Regulatory Environment

The scale of the Indian medical devices market presents prospects, and the regulatory environment is also favourable for the establishment of a manufacturing facility in this sector. In order to bring the regulatory framework for the medical device industry up to line with worldwide standards, the

government revised it in 2017 and put into effect "The Medical Device Rules, 2017" (MDR). The government provided regulatory licences to import, produce, or sell medical devices and introduced the idea of "risk - based" regulation.

Due to India's sizeable population and favourable regulatory environment, producers of medical devices are interested in setting up a production unit there. 2017 saw the implementation of medical device rules that incorporated updates that met international requirements.

All medical devices will fall under the regulatory jurisdiction of manufacturers, importers, and suppliers thanks to the 2017 Medical Device Rules (MDR). Low risk and medium risk are the two different types of risk.

MDR currently covers 16 medical items; eight more will be subject to drug control regulation by 2021, and 13 will be. The industry has long been troubled by the slow pace of medical device regulation.

The industry supports the move to regulate all medical devices, although stakeholders have reservations regarding the registration procedure. Poor registration procedures can result in sales and revenue losses for medical equipment manufacturers as well as a lack of products on the market, endangering the health and safety of patients. In October 2019, the health ministry released a new edition of the MDR notifications available for public comment. However, none of the suggestions from the industry were included in the published version.

The Central Drugs Standard Control Organization (CDSCO) released a draft risk categorization list for medical devices through the new definition notification. The list of risk classifications divides medical equipment into 24 main categories using universal classification codes, with independent software being classed in a separate category.

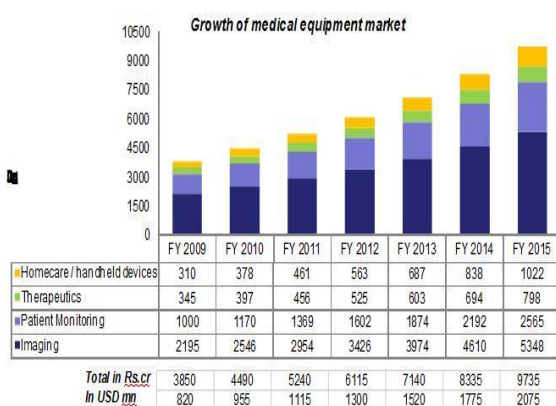


Figure 1: Growth of medical equipment market

As was already mentioned, once a medical device is subject to the MDR's control, companies involved in its manufacture, import, or sale must obtain a licence from the relevant drug regulatory organisations.

Additionally, for restricted medical devices, firms and importers are either prohibited from raising prices by more

than 10% in any 10 - month period or are compelled to price the equipment in accordance with a government - set ceiling price.

Although the government is streamlining medical device laws, the sector is concerned about the slow progress. Only 29 medical devices, out of the 1, 700 different varieties available on the global market, would fall under the MDR by 2021.

**Importance of Medical Devices**

The benefits that medical devices can provide are constantly expanding since they are essential for the safe and effective diagnosis, prevention, treatment, and rehabilitation of illnesses and disorders. Medical devices are regarded as a fundamental component of health systems.

The morbidity and mortality of life have decreased in the era of modern development and technology. Drug and gadget advancements in medicine have significantly altered people's quality of life (as offered by the cosmetic treatment, dentist, face and cardiology devices).

Medical innovations have greatly improved health and quality of life by enhancing doctors' capacity to identify and treat ailments. Complete regulatory programme implementation can be quite resource - intensive, especially for a developing country. To provide a clear direction for all people concerned, it is a good idea to create a comprehensive national medical device policy or guideline.

Medical devices imported into India, and its regulations must be followed. Manufacturers of imported equipment are required to disclose the name and address of the authorised agent or representative in India when requesting a compliance evaluation. All imported equipment sold in India must have the name and address of this authorised person or organisation on their label or packaging.

**Import and Registration**

In India, medical devices is imported. The buyer (whether it be a government hospital, a private hospital, or a doctor) assesses the product's quality. The FDA and Conformité Européenne (CE) approved items are typically favoured due to their higher quality and effectiveness. However, because India is a price - sensitive market, there is a large demand for inexpensive medical equipment. The Government of India (GOI) is working on drafting regulations for medical devices to ensure the quality of healthcare services. The CDSCO within the Ministry of Health is in charge of regulating medical devices in India. The regulatory process won't be obvious until the government announces the rules and the CDSCO offers import guidance. The normal procedure for importing medical devices into India is presented in this paper along with the registration requirement. It is a summary of the proposal for medical device regulation by the Indian government.

**Import of Medical Devices**

The registration and import licence requirements outlined in the Drugs and Cosmetics Rules must be followed in order to import devices:

- 1) From the moment these rules were published, importers would have 60 days to submit applications for import and registration.
- 2) For devices that hadn't been brought into the nation before the notification date, no import would be allowed without the competent authority's clearance.
- 3) Devices that are currently in use may be sold for a temporary term of up to six months, or until an application is approved or rejected, whichever comes first. Importation of stents or drug - eluting stents is not permitted if the applicant sold less than 1, 000 stents with the same specifications before these recommendations were published. For their professional opinion on the evaluation of particular categories of devices, separate committees made up of topic specialists and a representative from the DCG (I) office would be established up. The expert panels would create their own evaluation criteria, processes, and norms that such devices should follow.
- 2) From the day these rules were published, applicants would have 60 days to submit an application for manufacture.
- 3) No production will be allowed moving forward without the approval of the relevant authority in accordance with the standards stipulated in the case of devices belonging to the aforementioned categories that have not been produced in the country before the date of notification.
- 4) The applicant must submit the following details with their application for the licencing body to take into account.
- 5) Expert Committees must be established for the evaluation of novel medical devices or those without any benchmark certification in order to thoroughly review the data submitted by the applicant.
- 6) The committees submit their recommendation to the competent authority for consideration in granting authorisation to commercialise the device after completing their evaluation.
- 7) Following a Joint Inspection and Verification, the State Licensing Authority would send the licence to CLAA for approval.
- 8) Following proper CLAA clearance, the licence will be given in accordance with Form 28 of the aforementioned Rules.

The following is included in the "Form 10" import licence guidance document:

- 1) A letter of cover
- 2) A letter of authorization
- 3) Form - 8 (Application for Drug Import License) (excluding those specified in Schedule X)
- 4) Form - 9 (Form of Undertaking to Support an Import License Application) (Form of undertaking to accompany an application for an import licence)
- 5) Requisition costs and TR6 Challan
- 6) Manufacturing or whole sale licence
- 7) Form 41 Registration Certificate (by CDSCO)
- 8) A FORM 10 copy of the import licence
- 9) Documents needed according to the CDSCO's Form 41 registration certificate.

#### Registration of Medical Devices for Import

- 1) The manufacturer, importer, or his agent in India must submit a form 40
- 2) To register the manufacturer of the devices that are intended for import, a charge of US\$ 1500 or its equivalent must be paid along with the application.
- 3) A fee of US\$ 1000 or its equivalent must be paid for the registration of a single medical device, which may change in size or shape without altering the material or technique of use. A separate US\$ 1000 fee must be paid for each additional device.
- 4) The fee must be paid using a challan at the Bank of Baroda in accordance with the aforementioned Rules.
- 5) In order to accommodate the demands of devices as opposed to conventional pharmaceutical items, the information and undertakings required under Schedules DI and DII may be modified.

#### Manufacture of Medical Devices in the Country

- 1) To get a licence to manufacture these notified sterile devices in the nation, an application in Form 27 must be submitted to the State Licensing Authority (SLA), along with the required fee in the form and manner specified in the aforementioned Rules and a copy to the office of the DCG (I).

#### Sale of Medical Devices in the Country

Importers and retail sellers of medical devices must get the required selling permits from the state licencing authorities for these medical devices within three months after the publication of these guidelines.

#### Clinical Trials

India follows the Global Harmonization Task Force (GHTF) Guidelines set out by the United States, Australia, Japan, Canada, and the European Union for clinical trials and clinical evaluation of medical devices. The GHTF Study Group 5's recommendations for clinical evaluation and research have been supported by industry. For further debate and potential implementation, it will also supply a copy of ISO 14155 on clinical studies and compare it to the ICH guidelines on good clinical practices for pharmaceuticals. The document's goal is to offer advisory council that is not legally enforceable for conducting clinical trials of medical devices in India.

Medical device trials should take into account all the broad guidelines for clinical trials that were previously discussed for drug trials. Before pre - market certification, medical devices should have their safety assessed and their pre - market efficacy for 1 - 3 years including data on adverse responses. The authorised authorities may decide on a case - by - case basis how long the trial will last and how much will be used. However, when assessing the associated research initiatives, the following crucial aspects specific to medical devices should be taken into account:

- 1) Safety data of the medical device in animal testing should be gathered, and any dangers should be taken into account.
- 2) Clinical trials for medical devices cannot be conducted on healthy participants, unlike clinical trials for drugs. As a result, Phase I trials are not required for testing of medical devices.

- 3) Medical devices that are inserted into the body may pose a higher danger than those that are inserted onto or outside the body, such as orthopaedic pins versus crutches.
- 4) Medical devices that are not regularly used carry less risk than those that are, for instance, contact lenses versus intraocular lenses.
- 5) Safe introduction methods should also be followed because the operation itself could be harmful to the patient.

**Documents Required for Clinical Trial Application of Notified Medical Devices in India**

- 1) Cover letter, first
- 2) A properly completed Form 44, Request for Permission to Import or Produce a New Drug or to Conduct a Clinical Trial
- 3) Requisite fee
  - a) Feasibility study, which is equal to Phase I drug trials in terms of safety and efficacy: Rest 50, 000/ -
  - b) Pivotal Study, or "confirmatory trials, " which are comparable to Phase II/III drug trials: Rest 25, 000/ -
- 4) Responsibility - sharing
- 5) Protocol: Contains the following items
- 6) Global regulatory status
- 7) Investigational undertaking
- 8) Certifications from the ethics committee
- 9) Form of informed consent
- 10) Case file format
- 11) Patient information form
- 12) Relative published articles
- 13) A researcher's brochure
- 14) Summaries of any reported issues and suspected unexpected serious adverse reactions (SUSAR) from other participating countries.
- 15) The Investigator's Brochure, which contains the condensed information, and the affidavit from the sponsor stating that the study has not been discontinued in any country and, in the event that it has, the reasons why, and that the applicant would further communicate with DCG (I) about the future discontinuation are based on the facts. (On plain paper with proper notarization).
- 16) Any other detailed information related to the device.
- 17) The format, contents, and structure of a clinical study report.

**Licensing**

Guidance document requirements for granting a Form - 28 licence to an Indian manufacturer of medical devices. Form 27 must be used to submit an application for the issuance of a licence to manufacture medical devices in India.

- a) The authorized state licencing body for pharmaceuticals,
- b) The relevant CDSCO Zonal/Sub - Zonal office, and (HQ)
- c) The Drugs Controller General of India CDSCO,

**Status of Indian Medical Device Market**

India is currently transitioning from communicable to non - communicable diseases in terms of disease burden. According to the World Health Organization, noncommunicable diseases like cancer, chronic respiratory disease, diabetes, and cardiovascular disease cause 60% of deaths in India.

This mortality data suggests a need to emphasise research in the areas of the cardiovascular, anti - diabetic, gastrointestinal, neurological CNS, and respiratory systems, leading to a prominence seen in our medical device sector in recent years.

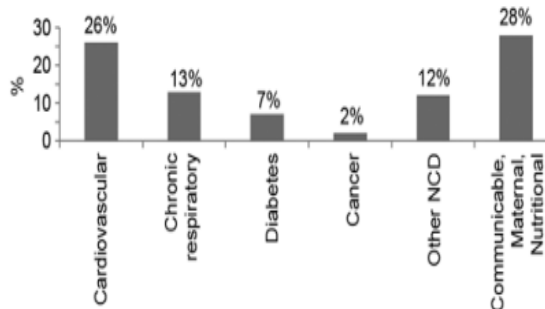


Figure 2: Current factors of deaths in india

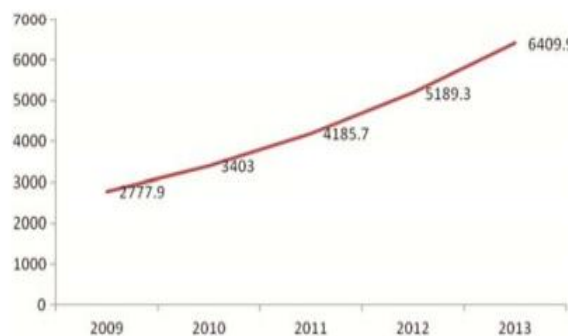


Figure 3: Indian medical device market size in US\$ millions

The distribution of the Indian medical technology market is shown in a report by Deloitte (2010). Medical instruments and appliances account for 25% of the market, followed by orthopaedic and prosthetic products (20.0%), syringes/ needles/ catheters (12.4%), electro - medical (12.4%), x - ray equipment (9.5%), and bandages (7.6%). The total IVD market in India was predicted to be worth US\$ 900.2 million in 2016 (with a CAGR of 18.1% over the previous 7 years of study). The increase is primarily motivated by the prevalence of chronic disorders and the progress of treatment facilities like corporate hospitals.

The multinational companies (MNCs) have been taking advantage of the Indian medical device market by adapting their product portfolio.

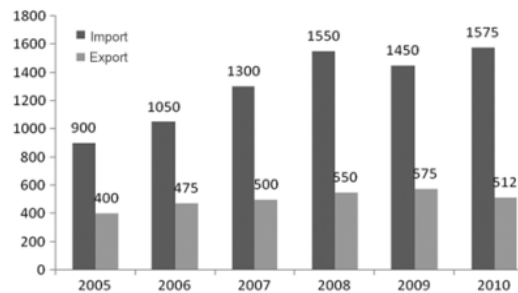


Figure 5: Import and export of medical devices in India

**Medical Devices Scenario in India**

Medical devices are important for patient screening, diagnosis, and treatment, as well as for returning patients to normal lives and for routinely tracking health indicators to

prevent disease. With the development of technology, the function of medical devices is currently being expanded to enhance the standard of care throughout the entire healthcare continuum. The healthcare industry as a whole has experienced numerous innovative changes, including increased usage of technology.

The COVID - 19 pandemic has unavoidably shaken the foundations of India's healthcare system, just as it has examined even the most cutting - edge healthcare systems worldwide, according to Dr. Kirti Chadha,

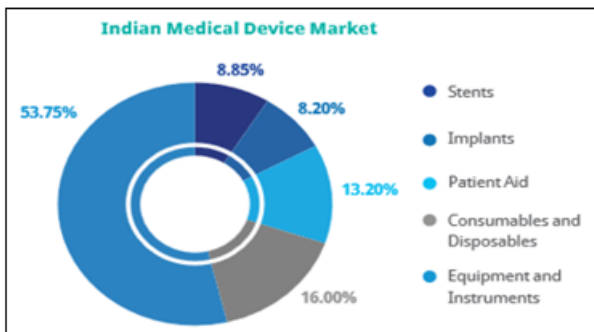


Figure 6: Indian medical device market

**Industry Scenerio**

By FY 2030, the Indian market for medical devices might grow by about four times its current size, driven by rising healthcare costs and the government's commitment to encouraging expansion.

There are five main categories into which medical gadgets fall:

- Among the consumables and disposables are needles and syringes.
- X - rays, ultrasounds, MRIs, and other diagnostic imaging procedures are available.
- There are braces, dentures, and other dental supplies accessible.
- Orthopaedics includes artificial joints and knee implants.
- Pacemakers and hearing aids are two examples of patient aids.

Approximately 65% of Indian manufacturers are domestic firms that primarily serve domestic demand while exporting only a small amount of their products. Large multinational firms control India's high technology medical device market thanks to their extensive service networks.

In India, there are 750–800 local makers of medical devices, with average investments of \$2.3 - 2.7 million and average revenues of \$6.2–6.9 million.

There are six medical device manufacturing "clusters" in the nation, indicating that the industry is expanding both in terms of scale and area.

**Market Scenerio**

Under the "Make in India" campaign, which promotes domestic manufacturing and aims to lessen reliance on imports, the Indian government has identified the medical device industry as a sunrise sector. Government initiatives emphasising and balancing self - reliance and ease of doing

business will be essential to the country's continued development.

According to IBEF, India is one of the top 20 markets in the world and the fourth - largest market for medical devices in Asia. The market's overall size was predicted to be US\$5.2 billion in 2020 and US\$50 billion in 2025. However, imports, which make up around 80% of overall sales, currently supply the majority of the nation's need for medical devices. This significant reliance on imports presents a compelling opportunity for domestic producers. The majority of Indian businesses currently produce low - end goods for both domestic and foreign markets.

Top 10 Medical Device Companies	Global Market Share
Medtronic PLC	7.5%
Johnson & Johnson Services Inc.	6.6%
Abbot	4.0%
Siemens Healthineers	3.8%
Koninklijke Philips N.V.	3.3%
Stryker Corporation	3.1%
F. Hoffmann-La Roche Ltd	3.0%
Becton Dickinson and Co	2.7%
GE Healthcare	2.5%
Boston Scientific Corporation	2.2%

Figure 7: Top 10 medical device company and their global market share

**Impact of COVID - 19**

The ongoing COVID - 19 pandemic has presented both opportunities and challenges for the medical device industry. The sector is also adjusting to the outbreak's effects on business disruptions. Supply chain interruption, negative effects on financial expectations, operations, and crisis response strategies are a few difficulties. Manufacturers have been tested by the demand for a sufficient quantity of products; as COVID - 19 cases increased and capacity became limited, the sector was compelled to move quickly forward to address the issue. These interruptions have highlighted the dangers of this sector's excessive reliance on imports.

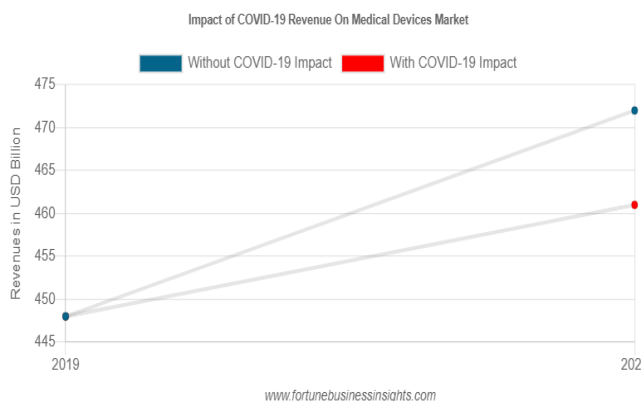


Figure 8: Impact of COVID - 19 revenue on medical device market

Similar to this, there are now 108 masking producer companies instead of just 30. There were just three N95 mask manufacturers producing fewer than one million per day as of March 2020. Presently, there are more than 3, 000 N95

producers and suppliers, some of which have BIS certification, and daily production capacity has risen to more than 8,000 masks. These are also widely exported from India.

Priority medical devices for COVID-19 prevention and treatment

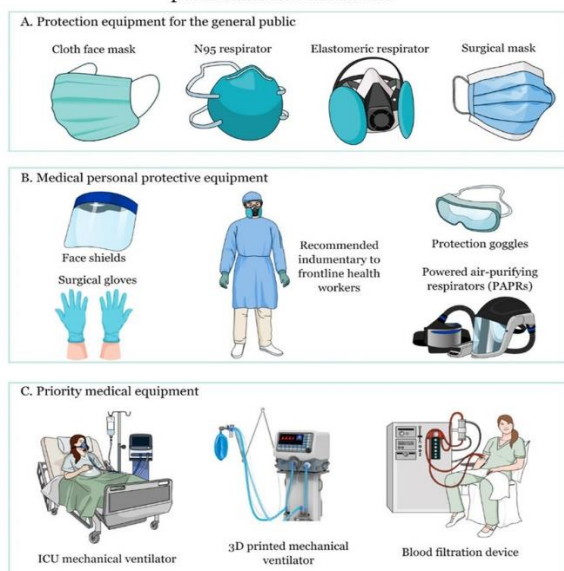


Figure 9: Medical devices used for COVID - 19 prevention and treatment

Nearly 40 million people have now received the free N95 respirator supply. While the price has lowered from 40 rupees to 12 rupees, the buffer quantity of N95 masks given to the governments has increased from 900,000 in March to 1.46 million.

A number of new firms began producing in the nation as a result of the outbreak. For instance, before COVID, there were only 20 companies producing 62 lakh PPE kits annually, but within a few of months, the number of producers jumped to 140, with a capacity of 25.55 crores. In a similar vein, the number of manufacturing companies in India increased, including those producing ventilators, which increased from 8 to 17, masks, which increased from 30 to 108, swabs, which increased from 0 to 5, sanitizers, which increased from 35 to 49, and RT PCR kits, which increased from 0 to 8.

**Key Challenges**

Medical device production in India faces several major obstacles, including inadequate infrastructure and logistics, congested supply chains, and exorbitant financing costs.

Even while the government is working to streamline rules and paperwork, the environment is still complicated and is characterised by the existence of numerous powerful institutions at both the state and federal levels. Additionally, India has some of the lowest per - capita health spending in the world.

**The Way Forward**

There are many opportunities in the medical device industry, but for India to be well - positioned in the post - pandemic world, it must keep working to establish a supportive climate for domestic medical device manufacture. It will be crucial for India to re - plan a long - term strategy to advance this industry. The primary objective should be to increase the

capability of the Indian medical device industry through skill development, upskilling, and reskilling in line with scientific and technological improvements. The second goal should be to increase opportunities and access by collaborating on policy support for the supply and demand sides of the medical device business.

Although the government has implemented various initiatives and policy changes to support the medical device industry, there is still room for growth. For the efficient use of resources and scalability, it is essential to have an ecosystem of important players, including leaders from the medical device sector, the government, and academia. The roadmap should also emphasise innovation and R&D as a key component of the ecosystem supporting the manufacture of medical devices.

It was stated that COVID - 19 created financial difficulties for suppliers and purchasers; as a result, a reliable finance mechanism will need to be given priority in order to foster an innovative environment.

The medical device industry is now in its development, but it may advance through fostering a productive ecosystem, acquiring skills, and supporting factors that make conducting business easier and promote growth. The implementation of legislative and policy reforms, encouragement of research and innovation, provision of financial possibilities, and facilitation of testing and certification to scale up production are all ways to accomplish these aims.

India is prepared for exponential growth through a forward - thinking and cooperative strategy and will become a trusted partner for the globe in medical equipment.

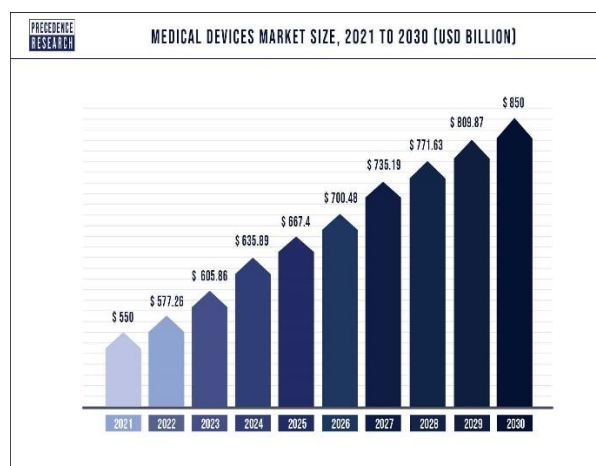
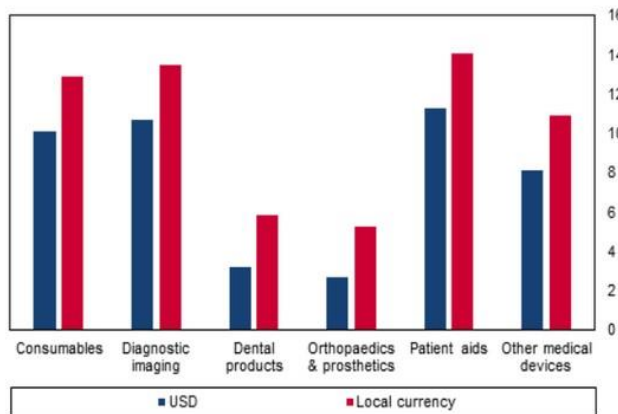


Figure 10: Medical device market size, 2021 to 2030 (USD billion)

Diagnostic Imaging And Patient Aids Will Be The Most Dynamic Product Areas  
Projected Medical Device Market CAGR By Product Area, 2020-2025 (%)



Source: Fitch Solutions

**Figure 11:** Projected medical device market CAGR by product area, 2020 - 2025 (%)

### 3. Conclusion

With an emphasis on "access and equity," medical devices and diagnostics serve as a crucial part of the health care system. A medical gadget is a tool used in the diagnosis, treatment, or amelioration of illnesses in humans or animals. Innovative and local solutions are emerging in the Indian medical device business. To improve public health, the sector does, however, ask for assistance from important stakeholders.

The current study provides an overview of Indian regulatory standards for medical devices. Modern medical care now includes a vast variety of healthcare devices. They frequently relate to the standard of treatment. The use of technology has undoubtedly increased quality in some situations. In other instances, several issues have been linked to devices. The approach to device quality has been heavily reliant on regulation. The law's revision and recently established guidelines will give producers and relevant authorities the necessary direction to handle instances effectively. While these rules and reforms aim to simplify, standardise, and speed up the process of producing and importing medical devices into India, they also come with their own difficulties. Foreign businesses seeking to establish or grow their operations in India's medical sectors would need to have a thorough understanding of the impending regulatory reforms in that country. It is hoped that the regulations and implementation of the recommendations would result in successful outcomes. This article describes the rules that are now in effect for applications for clinical trials, manufacturing licences, and registration certificates for medical devices.

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