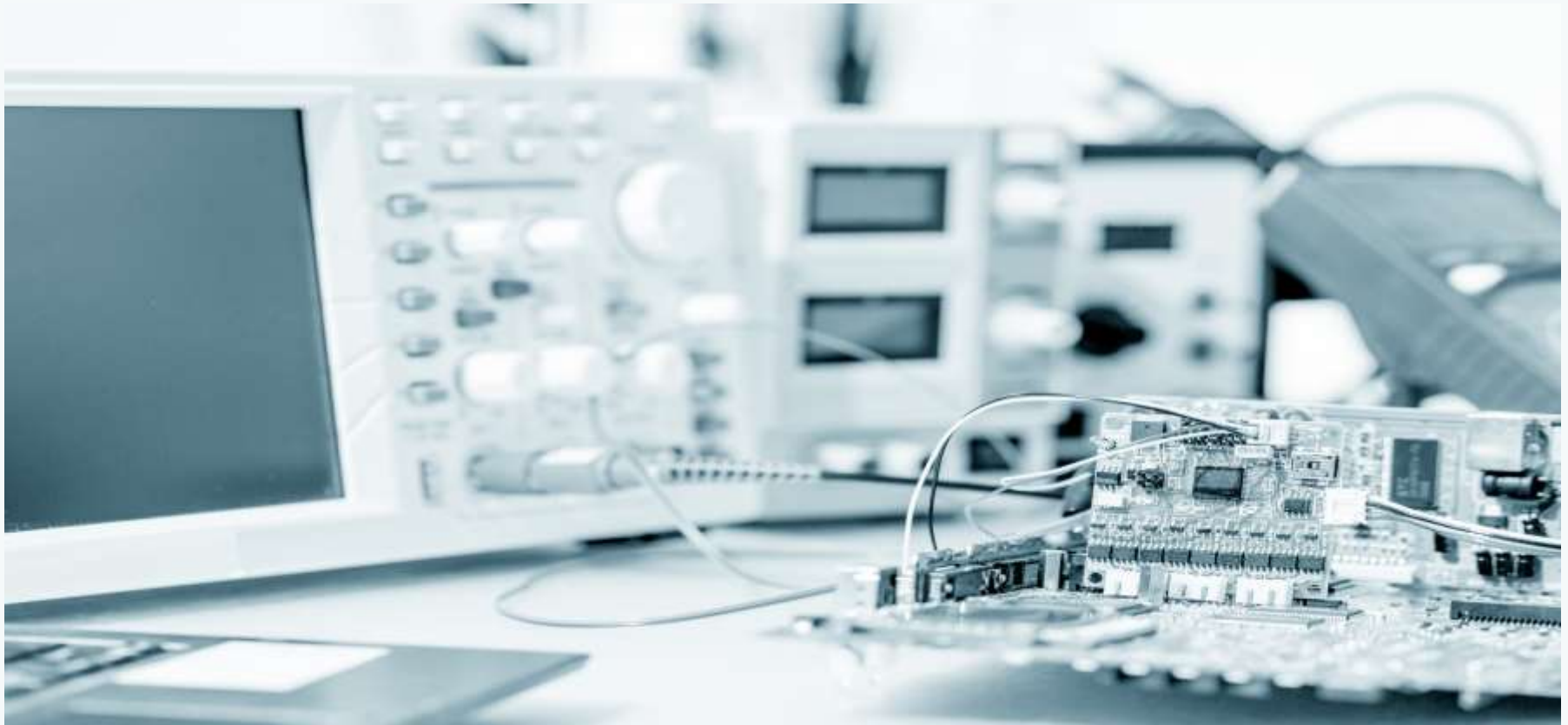


# Medical Devices



March 2024

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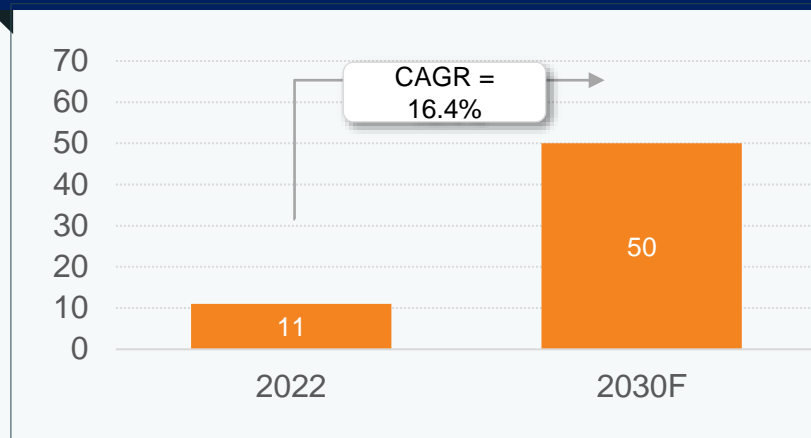
# Table of Contents

<b>Executive Summary</b>	<b>3</b>
<b>Advantage India</b>	<b>4</b>
<b>Market Overview</b>	<b>6</b>
<b>Growth Drivers</b>	<b>12</b>
<b>Recent Trends</b>	<b>17</b>
<b>Export Scenario</b>	<b>23</b>
<b>Manufacturing Cluster</b>	<b>25</b>
<b>Major Investments</b>	<b>27</b>
<b>Key Industry Contacts</b>	<b>31</b>
<b>Appendix</b>	<b>33</b>

# Executive summary

- The size of the Indian medical devices market is estimated at Rs. 90,000 crore (US\$ 11 billion) in 2022 and is expected to grow to US\$ 50 billion by 2030 with a CAGR of 16.4 %.
- The Indian medical device market share in the global market is estimated to be 1.65%.
- India is the 4<sup>th</sup> largest Asian medical devices market after Japan, China, and South Korea, and among the top 20 medical devices markets globally.
- India has an overall 75-80% import dependency on medical devices.
- In 2022-23, India exported medical devices worth US\$ 3.39 billion and imported medical devices valued at US\$ 7.49 billion.
- India's reliance on imported medical devices surged between Nov 2022 and Oct 2023, with a 21% increase in imports totaling Rs. 61,262.84 crore (US\$ 7.237 billion).
- The US, Germany, China, Brazil, Iran, etc. are a few key countries that import Indian medical devices.
- Gujarat, Maharashtra, Karnataka, Haryana, Andhra Pradesh, Telangana and Tamil Nadu are the manufacturing hubs for medical devices in India.
- In December 2023, MedTech Mitra an online platform was launched to support medtech innovators with clinical assessment, regulatory help, and product adoption.

**Medical Devices Market in India (2022-2030, in US\$ billion)**



**Medical Devices Export Market in India (2022-25, in US\$ billion)**



*Note: CAGR-Compounded Annual Growth Rate, E-Estimated, F-Forecasted*

*Source: Government Website, WHO and AMTZ Report 'Medical Device - Manufacturing in India - A Sunrise 2017*

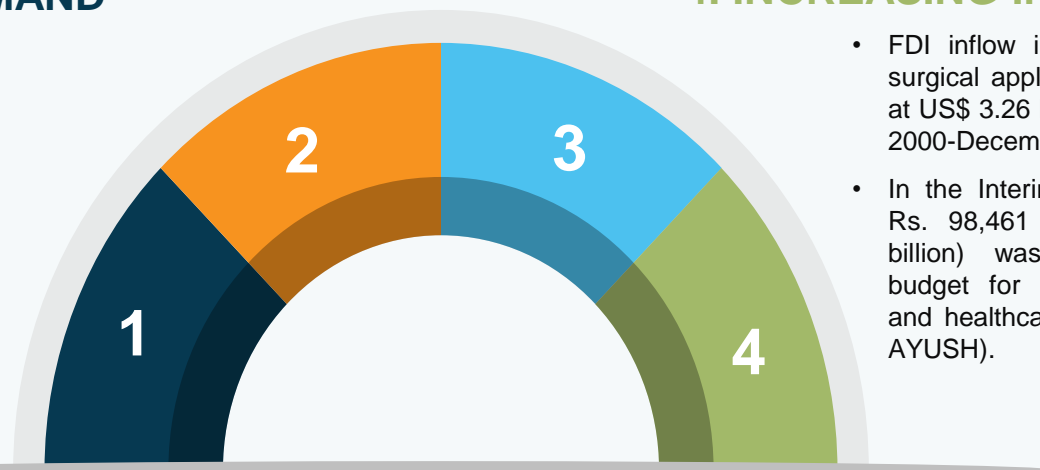


## 2. OPPORTUNITIES IN EXPORT

- The Indian medical device export market is driven by 75-80% imports from countries such as the US, China and Germany.
- India and Russia have set the bilateral trade target at US\$ 30 billion by 2025. Trade is expected to increase by an additional US\$ 5 billion per annum, with opportunities in pharmaceuticals & medical devices, minerals, steel, and chemicals.
- Medical devices are a highly attractive export area for US firms.

## 1. INCREASING DEMAND

- Rising number of medical facilities will boost the demand for medical devices in the market.
- The medical technology sector in India is projected to reach US\$ 50 billion by 2030.
- Various government initiatives such as 'Production Linked Incentive (PLI) Scheme for Medica Devices 2020' and establishing medical parks will augment demand.



## 3. POLICY SUPPORT

- In November 2023, six strategies have been formulated as part of National Medical Policy to maximize the sector's potential, along with a detailed action plan for their execution.
- 100% FDI is allowed in the medical devices sector In India. Categories such as equipment and instruments, consumables and implants attract the most FDI.
- In May 2023, Export Promotion Council for Medical Devices was established under the Department of pharmaceuticals, with its headquarters in Noida.

## 4. INCREASING INVESTMENT

- FDI inflow in the medical and surgical appliances sector stood at US\$ 3.26 billion between April 2000-December 2023.
- In the Interim Budget 2024-25, Rs. 98,461 crore (US\$ 11.85 billion) was allocated as a budget for the pharmaceutical and healthcare sector (including AYUSH).



# Medical devices market is split into 4 key categories in India

Under the medical device and IVD regulations, the Health Ministry of India has divided medical devices into the following four categories:

## CLASS B (LOW MODERATE RISK)

- Medical devices such as endoscopic forceps, vial adapters, suction cups and catheters, Sengstaken-Blakemore tube, feeding tubes, gastrointestinal tubes, etc. are included in this category.

## CLASS C (MODERATE HIGH RISK)

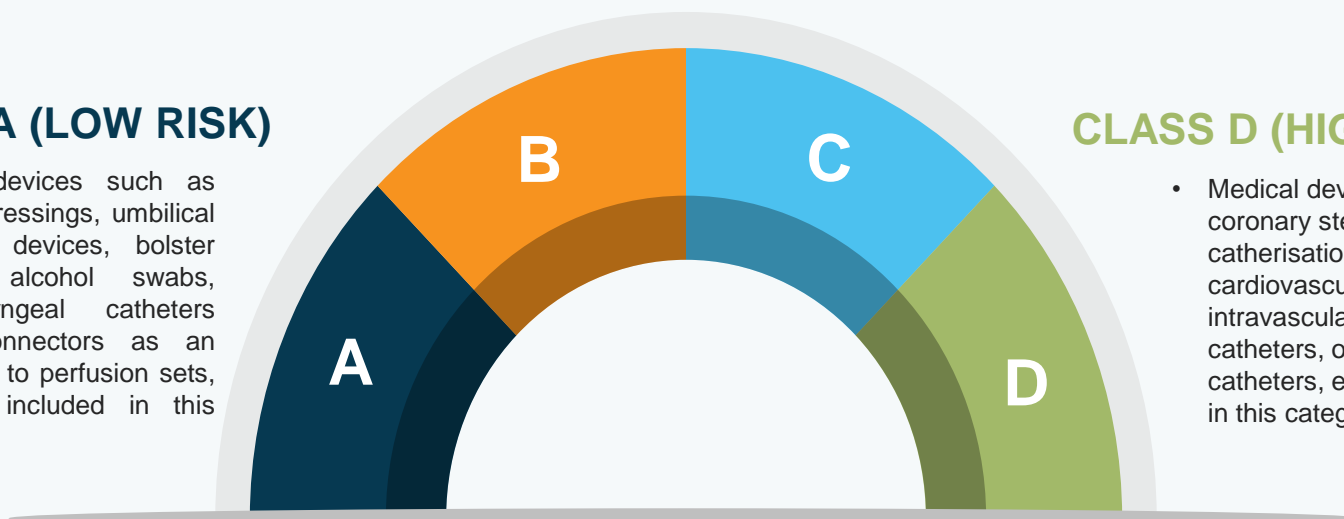
- Medical devices such as anesthesia conduction filter, introducer sheath, microcatheter, imaging catheter colonic stents, pancreatic instruments, etc. are included in this category.

## CLASS A (LOW RISK)

- Medical devices such as surgical dressings, umbilical occlusion devices, bolster sutures, alcohol swabs, nasopharyngeal catheters and Y-connectors as an accessory to perfusion sets, etc. are included in this category.

## CLASS D (HIGH RISK)

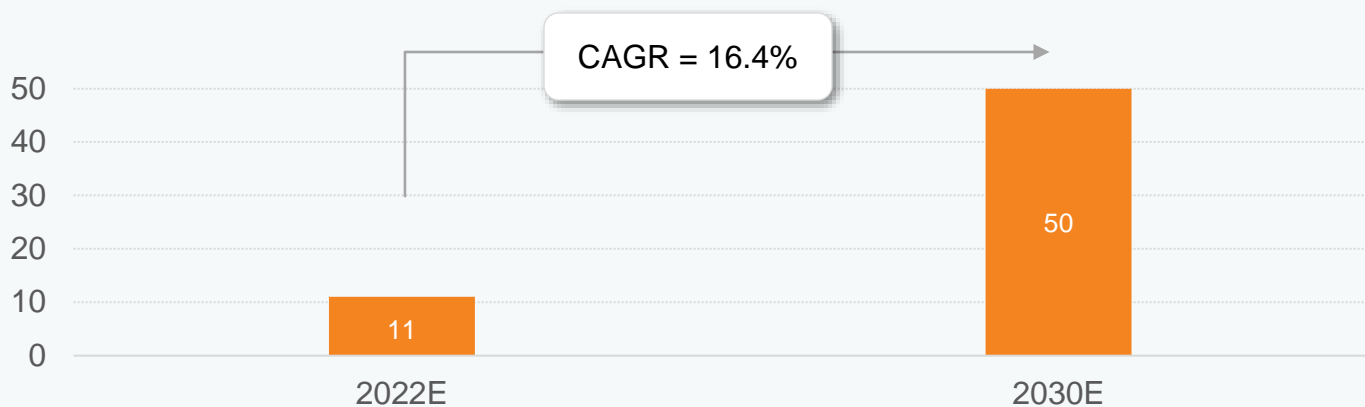
- Medical devices such as coronary stents, cardiac catheterisation kits, cardiovascular, intravascular diagnostic catheters, occlusion catheters, etc. are included in this category.



Source: Drugs Controller General (India) Directorate General of Health Services 2017 Notice

# Growth in medical devices

Medical Devices Market in India (2022-2030, in US\$ billion)



- As of 2022, the medical devices market was estimated to be at US\$ 11 billion in India.
- India is the 4<sup>th</sup> largest Asian medical devices market after Japan, China, and South Korea, and among the top 20 medical devices markets globally. However, it has the potential to surpass its peers in terms of size and scale; this is based on the government's support the sector has received over the past several years.
- India's medical devices market is projected to reach US\$ 50 billion by 2030.
- Between 2022-2030, diagnostic imaging is likely to expand at a CAGR of 16.4%.
- The medical devices sector in India comprises large multinationals and small and mid-sized companies. This sector, which is growing faster amid the pandemic, offers great opportunities for domestic players, particularly engineering MSMEs, to further penetrate the global markets.
- The Government of India (GOI) has commenced various initiatives to strengthen the medical devices sector, with emphasis on research and development (R&D) and 100% FDI for medical devices to boost the market.
- India added significant production capacity for various critical care items such as PPE kits, surgical gloves, sanitisers and N95 masks, and emerged as a significant destination for manufacturing of healthcare products and services.

Source: Government Website, News Articles



# List of medical devices manufacturers... (1/3)

The Indian medical devices market comprises more than 800 manufacturers, of which 65% companies have a turnover of <Rs. 10 crore (US\$ 1.5 million), 25% companies have a turnover of Rs. 10-50 crore (US\$ 1.5-6 million), and 2% companies have a turnover of >Rs. 500 crore (US\$ 73 million).

## List of Medical Devices Manufacturers in India

3M Corporation	ATLAS Surgical	Chemical Resources (Chereso)	GE Healthcare
3S Corporation	B Braun	Coral Laboratories Ltd.	Genex Pharma
Adonis Medical Systems Pvt. Ltd.	Banuline Pharma Pvt. Ltd.	Cura Healthcare Pvt. Ltd.	Gepach International
Aligens International	Bayer AG	Danaher Corp.	GOLDEN Nimbus INDIA Pvt. Ltd.
Ananta Medicare Ltd.	Bigtec Labs	Deluxe Scientific Surgico Pvt. Ltd.	GRIPORTHO Surgicals Pvt. Ltd.
Anchor Plus LLP	Becton Dickinson India	Dynamic Ortho Industries	GST Corporation Ltd.
Antila Life Sciences Pvt. Ltd.	Biocon	East African India Overseas	Gujarat HEALTH Care
Appaswami Associates	BIO Polymer Systems	Ethinext Pharma	Harsoria Healthcare Pvt. Ltd.
Arommac Industries	Biorad Medisys	Eucare Pharmaceuticals Pvt. Ltd.	Hexagon Nutrition Pvt. Ltd.
Arrow Medical Devices,	Biotrol Laboratories Pvt. Ltd.	Fab Pharmaceuticals Pvt. Ltd.	Hindustan Syringes & Medical Devices Ltd.
Arthon Implants Pvt. Ltd.	Boston Scientific Corp.	Flagship Biotech International Pvt. Ltd.	Hiral Labs Ltd.
ASOJ Soft Caps Pvt. Ltd.	Cachet Pharmaceuticals Pvt. Ltd.	GANGAR Electronics	Hi-tech Medicare Devices Pvt. Ltd.

**Source:** Company Websites

# List of medical devices manufacturers... (2/3)

## List of Medical Devices Manufacturers in India

Hospi Line Equipment Pvt. Ltd.	MEDI Tech Devices Pvt. Ltd.	Mrk Healthcare Pvt. Ltd.	Palakkad Surgical Industries Pvt. Ltd.
Impact Labs Pvt. Ltd.	Medicare Hygiene Ltd.	Nandu Chemical Industries	Paramount Surgimed Ltd.
Jk Medirise	Meditek India	Nature's Global Service	Perfint Healthcare
Johnson & Johnson	Medived	Nebula Surgical Pvt. Ltd.	Pharmacrest Company Pvt. Ltd.
Johnson & Smit Co.	Medsorce Ozone Biomedicals	Nice Neotech Medical Systems Pvt. Ltd.	Pharmexcil
Kanam latex Industries Pvt. Ltd.	Medtronic	Nipro Corp	Philips Healthcare
Kenoor Organics Pvt. Ltd.	MEHTA Tubes Ltd.	NIRAJ Industries (P) Ltd.	Prasad Meditech
Lamar Healthcare Pvt. Ltd.	Meril Life Sciences	Nosch Labs Pvt. Ltd.	Preci Turn Pvt. Ltd.
Livealth Biopharma Pvt. Ltd.	Metal Gems	Nulife Global Medical Devices Pvt. Ltd.	Precision Coatings Pvt. Ltd.
MAESTROS Electronics & Telecommunications Systems Ltd.	Microtrack Surgicals	OM Surgical	Premium Serums & Vaccines Pvt. Ltd.
Magnatek Enterprises	Miracalus Pharma Pvt. Ltd.	Opto Circuits	Proactive Health Inc.
Magnus Analytics	Morepen Laboratories Ltd.	Ortho Care	Prognosys HEALTH Care

*Source: Company Websites*

# List of medical devices manufacturers... (3/3)

## List of Medical Devices Manufacturers in India

Prognosys Medical Systems	Sai Krishna Pharmaceuticals/Kings Global Biotech Ltd.	Swiss Parenterals Pvt. Ltd.	Wellmed International Industries Pvt. Ltd.
Raajratna Metal Industries Ltd.	Samay Surgical	Terrace Pharmaceuticals Pvt. Ltd.	West-coast Pharmaceutical Works Ltd.
Roche	Skarray	Thea-Tex Healthcare (India) Pvt. Ltd.	Xcellance Medical Technologies Pvt. Ltd.,
Radiant Pharma	Schiller	Trivitron Healthcare	Yashica Pharmaceuticals Pvt. Ltd.
Remi Laboratories	Sceptre Medical India Pvt. Ltd.	Udaipur Health Care Pvt. Ltd.	Zenova BIO Nutrition Pvt. Ltd.
Relysis	SGPHARMA Pvt. Ltd.	Unilab Chemicals and Pharmaceuticals Pvt. Ltd.	-
RHR Medicare Pvt. Ltd.	SHAILI Endoscopy	United Poly ENGINEERING Pvt. Ltd.	-
Rishabh Exim	Shaimil Laboratories	Vaansari Marketing Services	-
Ruby Surgical & Allied Products Pvt. Ltd.	Smith & Nephew	Vascular Concepts	-
Saboori Collezione International Pvt. Ltd.	Siemens	Verve Human Care Laboratories	-
Saboori Collezione International Pvt. Ltd.	SON'S & Daughter's	Vinod Medical Systems Pvt. Ltd.	-
Sahjanand Medical Technologies	Swipha Exports Pvt. Ltd.	Vins Bioproducts Ltd.	-

*Source: Company Websites*



# 100% FDIs and various government initiatives boosting demand ...(1/2)

## 1

### 100% FDI

- 100% FDI under the automatic route for both brownfield and greenfield setups in the sector is expected to boost the industry. Strong FDI inflows also reflect confidence among global players on the Indian medical devices market.
- Over the last five years (2015-20), India received US\$ 600 million, with key investments from countries such as Singapore, the US, Europe and Japan.
- Categories such as equipment and instruments, consumables and implants have attracted the most FDIs.
- From April 2000-December 2023, FDI inflow in the medical and surgical appliances sector stood at US\$ 3.26 billion.

## 2

### Incentive Schemes

- Under the PLI scheme for Medical Devices, till now, a total of 26 projects have been approved, with a committed investment of Rs. 1,206 crore (US\$ 147 million) to enable growth and innovation in the MedTech industry and make India as the global hub for manufacturing and innovation in the coming years.
- In August 2022, the Promotion of Medical Devices Parks scheme allocated Rs. 400 crore (US\$ 48.14 million) from 2020-21 to 2024-25, offering Rs. 100 crore (US\$ 12.04 million) to four States/Union Territories for Common Infrastructure Facilities in new Medical Devices Parks.
- In July 2022, the government tabled a draft for the new Drugs, Medical Devices and Cosmetics Bill 2022, to assure and offer thorough legal protections to ensure that the medical items sold in India are reliable, efficient, and up to required standards.
- To boost domestic manufacturing of medical devices and attract huge investments in India, the Department Of Pharmaceuticals launched a PLI scheme for domestic manufacturing of medical devices, with a total outlay of funds worth Rs. 3,420 crore (US\$ 468.78 million) for the period FY21-28.
- The government also approved applications for nine eligible projects that are expected to lead to a total committed investment of ~Rs. 729.63 crore (US\$ 100.01 million) by the companies Siemens Healthcare Private Limited, Allengers Medical Systems Limited (AMSL), Allengers OEM Private Limited (AOPL), Wipro GE Healthcare Private Limited, Nipro India Corporation Private Limited, Sahajanand Medical Technologies Private Limited, Innvolution Healthcare Private Limited, and Integris Health Private Limited, and generate ~2,304 jobs.

Source: Government Website, News Articles

## 3

### Introduction of Medical Parks

- In March 2024, Dr. Mansukh Mandaviya, Union Minister for Chemicals & Fertilizers and Health & Family Welfare inaugurated 27 new Bulk Drug Park projects and 13 Manufacturing Plants for Medical Devices under the PLI Scheme. The medical device parks are expected to reduce manufacturing costs as these will be equipped with the necessary infrastructure where companies can plug and play.
- In August 2022, the Department of Pharmaceuticals greenlit the "Promotion of Medical Device Parks" programme from FY21-25 with a total financial investment of Rs. 400 crore (US\$ 48.97 million), with a maximum support under the programme of Rs. 100 crore (US\$ 12.24 million) for each Medical Device Park.
- The scheme reflects the spirit of co-operative federalism where the Central Government and State Governments will partner to develop the Medical Device parks for better performance of the sector.
- A vast medical device park is planned to open in Noida, bringing in a total investment of Rs. 5,250 crore (US\$ 705.38 million) by the government and employ 20,000 people.
- In September 2021, the government-sanctioned a proposal worth Rs. 5,000 crore (US\$ 674.36 million) to build a medical devices park in Himachal Pradesh's industrial township Nalagarh in the Solan district.
- In September 2021, the government approved the construction of a medical devices park near the Noida International Airport at Jewar in Sector 28.

## 4

### Commercialisation in the medical devices and diagnostics space

- In November 2021, the Indian Council of Medical Research (ICMR) collaborated with Indian Institutes of Technology (IITs) to establish 'ICMR at IITs' by setting up Centres of Excellence (CoE) for Make-in-India product development and commercialisation in the medical devices and diagnostics space.
- The ICMR-DHR CoEs at IITs will create a pipeline of innovative medical devices and start-ups that will incentivise and motivate local manufacturing in India and provide holistic support to the technologies/products nearing commercialisation.

## 1

### Introduction of Medical Device (Amendment) Rules 2020

- In 2017, the Central Drugs Standard Control Organisation (CDSCO) published the 'Medical Devices Rules 2017', which came into effect in 2018 and comprised regulatory structures that were required to obtain registration and licence by importers and manufacturers of medical devices.
- In February 2020, two new amendments were introduced, i.e., a new chapter for registration of medical devices by their respective manufacturers and importers, and exemption of the 37 categories of already regulated or notified medical devices from the requirement of registration introduced by the new chapter.

## 2

### National Medical Devices Promotion Council

- In January 2020, the government set up a National Medical Devices Promotion Council to promote local manufacturing of high-end medical devices and attract investments in the sector.
- The council would be headed by the secretary of the Department for Promotion of Industry & Internal Trade (DPIIT).
- In August 2022, the Department of Pharmaceuticals reconstituted the National Medical Devices Promotion Council (NMDPC) under the Chairmanship of the Secretary of the Department of Pharmaceuticals.

## 3

### Revised Public Procurement Order (PPO)

- On March 25, 2021, the Department of Pharmaceuticals released a revised notice on the Public Procurement Order (PPO) incorporating 19 medical devices in the revised guidelines of the PPO, which is expected to improve domestic medical devices manufacturing (and strengthen 'Make in India') and reduce import bills by ~Rs. 4,000 crore (US\$ 538.62 million).

Source: Government Website, News Articles

## 4

### Introduction of 'Health and Wellness ATMs'

- To expand the primary healthcare industry and clinical centers in the country, in July 2021, the government of Uttar Pradesh announced to introduce automatic medicine dispensing machines. The state health department has been initiated to design an action plan and install 'Health ATMs', which are walk-in medical kiosks with combined medical devices for fundamentals, basic laboratory testing, emergency offerings, cardiology, neurology, pulmonary testing, gynaecology, etc., operated by a medical assistant in all 75 districts of Uttar Pradesh.

## 5

### National Medical Devices Policy, 2023

- The Union Cabinet approved the National Medical Devices Policy, 2023 on April 26, 2023.
- The National Medical Devices Policy, 2023 is expected to facilitate an orderly growth of the medical device sector to meet the public health objectives of access, affordability, quality, and innovation.
- The policy is expected to help the Medical Devices Sector grow from the present US\$ 11 billion to US\$ 50 billion by 2030.





# Notable trends in the medical devices sector...(1/5)

## 1

### Big Data

- Numerous companies have been utilising predictive analytics models by gathering key patient vital signs, along with other observations from devices, to make decisions about the overall health of patients
- For example, in 2019, Medtronic and IBM created a mobile personal assistant application that provides real-time glucose insights for individuals with diabetes. This management system helps understand the links between glucose readings, lifestyle choices and drug administration and thereby, aids patients to make an informed decision about their medication

## 2

### New Devices

- In January 2024, The Centre introduced the National Single Window System (NSWS) to simplify the import, clinical trials, and testing procedures for medical devices.
- In July 2022, Godrej Appliances launched the new InsuliCool product range – Godrej InsuliCool and Godrej InsuliCool+, which are innovative cooling solutions especially designed for insulin storage, in order to address the challenge faced by diabetic patients with respect to insulin storage at recommended temperatures.
- In November 2021, Cipla launched ‘Spirofy’, India’s first pneumotach based portable, wireless spirometer.
- In October 2021, Andhra Medical College announced the pilot test for a artificial technology platform to monitor lung condition. The artificial intelligence platform is expected to increase the accuracy of identifying the next appropriate intervention in the treatment.
- In July 2021, Abbott announced that it has launched a pea-sized, life-saving device for babies with hole-in-the-heart malformations. The company has launched the device in India with emphasis on centres having an active neonatal intensive care unit (NICU).

*Source: Government Website, News Articles*

# Notable trends in the medical devices sector...(2/5)

## 3

### Robotics

- In July 2022, the Rajiv Gandhi Cancer Institute and Research Center (RGCI) in New Delhi received its first-ever Made-in-India Surgical Robotic System, the SSI-Mantra, which was developed by med-tech startup SS Innovations.
- Medtronic has launched a Surgical Robot Experience Center (SREC) in Gurugram, Haryana, the first of its kind in South Asia. The SREC will be focused on the education and training of surgeons in robot-assisted surgery.
- Selective Compliance Articulated Robot Arm (SCARA) robots can be easily mounted on a tabletop and fit well in small confined spaces; this is typical of a medical device manufacturing facility.
- In February 2021, Siemens Healthineers introduced Corindus, a robotic system, to drive cardiovascular interventions with robotic assistance in India.

## 4

### Startups

- In December 2023, Health Minister Mansukh Mandaviya introduced MedTech Mitra, an online platform to support medtech innovators with clinical assessment, regulatory help, and product adoption. It will be managed by ICMR and CDSCO, overseen by NITI Aayog's Atal Innovation Mission.
- The medical devices market is evolving at a fast pace on the back of constant innovations and research that are making medical devices affordable and accessible. Several Indian start-ups and SMEs have entered the medical devices market and are contributing with innovative solutions. With the entry of start-ups in this sector, new investments are being observed in the market.
- BeatO, a supplier of diabetes treatment, has raised US\$ 33 million in a Series B fundraising, which was headed by Lightrock India. HealthQuad and current investors Orios Venture Partners, Blume Ventures, and Leo Capital also participated.
- Indian Institute of Technology (IIT) Delhi has developed a national center for medical technology development in an effort to help medical device startups produce their goods in a facility that has received ISO certification and secure the necessary certifications.

**Note:** AiMeD: Association of Indian Manufacturers of Medical Devices, PPE: Personal Protective Equipment, RT PCR: Reverse Transcription Polymerase Chain Reaction

**Source:** Government Website, News Articles

# Notable trends in the medical devices sector...(3/5)

## 5

### Wearables

- Wearables such as glucose monitors, exercise trackers and wearables for mental health are becoming popular among consumers in India because of their ease of usage
- In July 2022, Ultrahuman announced its latest wearable: the Ultrahuman Ring, which can track users' metabolism, measure movement, sleep and other body dynamics in real-time.
- India's wearable market grew 47% YoY in 2022, shipping 100 million units. In the Q4 of 2022, boAt maintains the lead with 23.9% shares, Noise stood second at 11.2%, OnePlus (10.2% share), Fire-Boltt (8.7% share), realme (2.5% share), others (43.5% share).

## 6

### Educational Programmes

- To fulfill the demand for trained professionals, several educational institutions are offering/introducing courses to provide training and research in the medical devices field.
  - National Institute of Pharmaceutical Education and Research introduced a course - Master in Technology in medical devices
  - IIT Hyderabad is offering Bachelor in Technology in biomedical engineering that will train students to design medical devices, develop 3D images and create bio-sensors on a chip.
- In June 2021, Lupin Limited announced the launch of its Digital Asthma Educator platform for guiding patients on the correct technique of using inhalers.

**Note:** AiMeD: Association of Indian Manufacturers of Medical Devices, PPE: Personal Protective Equipment, RT PCR: Reverse Transcription Polymerase Chain Reaction  
**Source:** Government Website, News Articles

## 7

### COVID-19

- According to AiMeD, before the outbreak of COVID-19, there were only 20 firms manufacturing 62 lakh PPE kits per year, but within 2-3 months, the number of manufacturers listed with AiMeD increased to 140 with 25.55 crore annual capacity.
- As of June 1, 2023, India's cumulative Covid-19 vaccination coverage has crossed 2.20 billion doses.
- Hindustan Syringes & Medical Devices Ltd, in April 2023, has achieved another milestone of supplying 1.75 billion syringes of the total 13.3 billion COVID-19 vaccines administered globally.
- In June 2021, the National Anti-profiteering Authority (NAA) directed tax officials to ensure rate cut on Goods and Services Tax (GST) for COVID-19-related medical supplies to offer consumers tax relief on supplies.
- In June 2021, medical devices manufacturer Meril announced that it has received approval from the Indian Council of Medical Research (ICMR) for its COVID-19 self-use rapid antigen test kit.
- In April 2021, due to the unusual spike in covid infections and an increased number of patients requiring hospitalisation, the government allowed faster custom clearance for up to three months to import medical devices including nebulisers, oxygen concentrators, oxygen canisters, cryogenic cylinders, oxygen generators and ventilators.
- Similarly, the number of Indian firms manufacturing ventilators increased from 8 to 17, mask manufacturers from 30 to 108, swab manufacturers from zero to five, sanitiser manufacturers from 35 to 49, and RT PCR kit manufacturers from zero to eight
- Hindustan Syringes and Medical Devices Ltd., the world's largest manufacturer of auto-disable syringes that are used for vaccination, planned to scale up production to 1 billion syringes a year (from 700 million) in the first-half of 2021, to push COVID-19 vaccination. In March 2021, the company announced its plan to produce 8,200 syringes per minute—40% more than its current capacity of 5,900 syringes per minute.
  - In April 2021, Hindustan Syringes and Medical Devices (HMD) announced to invest >Rs. 100 crore (US\$ 13.47 million) to increase its syringe production capacity from 2.5 billion to >3 billion syringes by the next quarter.
  - In October 2021, HMD achieved a milestone by supplying 500 million 0.5 ml AD syringes to the government to accelerate the vaccination drive and contribute to India's Atmanirbhar (self-reliance) mission.
  - The company further plans to achieve annual capacity of 3.5 billion syringes by March 2022.

**Note:** AiMeD: Association of Indian Manufacturers of Medical Devices, PPE: Personal Protective Equipment, RT PCR: Reverse Transcription Polymerase Chain Reaction  
**Source:** Government Website, News Articles

## 8

### Initial public offering (IPO)

- In April 2023, Healthvista India, the parent company of the healthtech startup Portea Medical, received approval from the Securities and Exchange Board of India (SEBI) for its initial public offering (IPO). The IPO comprises a fresh issue of equity shares worth Rs. 200 crore (US\$ 24 million) and an offer for sale (OFS) of up to 56,252,654 shares worth Rs. 800 crore (US\$ 95.9 million).
- On September 27, 2022, QMS medical allied services proposed to open its IPO of Rs. 5,687 lakh (US\$ 6.93 million) on the NSE Emerge platform.
- In September 2021, Sahajanand Medical Tech filed its Draft Red Herring Prospectus (DRHP) with SEBI for its Initial Public Offering (IPO) worth Rs. 1,500 crore (US\$ 202.31 million).
- In June 2021, Skanray Technologies filed its draft red herring prospectus (DRHP) with SEBI for its initial public offering (IPO) worth Rs. 400 crore (US\$ 53.70 million). The IPO is expected to include sale of secondary share, wherein its promoters and Ascent Capital (an existing private equity investor) are expected to sell a part of their stake.

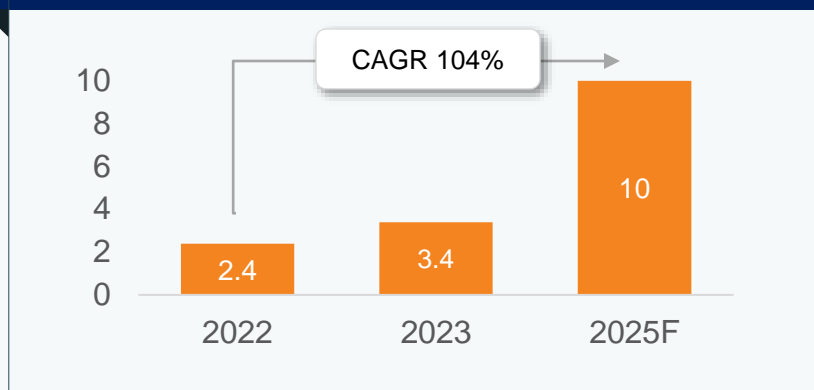
**Note:** AiMeD: Association of Indian Manufacturers of Medical Devices, PPE: Personal Protective Equipment, RT PCR: Reverse Transcription Polymerase Chain Reaction  
**Source:** Government Website, News Articles

# Export Scenario



# Export scenario of medical devices in India

Medical Devices Export Market in India (2022-25, in US\$ billion)



Key Export Countries

The US	France
Germany	Singapore
China	Turkey
Brazil	The Netherlands
Iran	Belgium

- In 2022-23, India exported medical devices worth US\$ 3.39 billion and imported medical devices valued at US\$ 7.49 billion.
- India has a 75-80% import dependency on medical devices, with exports of US\$ 2.4 billion in FY22, which is expected to increase at a CAGR of 51% to reach US\$ 10 billion by 2025.
- To increase the export of medical devices in the country, the Ministry of Health and Family Welfare (MOHFW) and Central Drugs Standard Control Organisation (CDSCO) implemented the following initiatives:
  - The entities are re-visiting and implementing the Schedule MIII, which is a draft guidance on good manufacturing practices and facility requirements.
  - System for export labelling.
  - Clinical evaluation and adverse reporting clarification.
  - State licencing authority to extend free sales certificate validity from 2 years to 5 years to allow exports.
  - Create a list of manufacturers with export licencing and make this list easily accessible to different regulatory authorities worldwide.
- The Medical Devices Virtual Expo 2021 showcased Indian products and enabled direct interaction between Indian suppliers and buyers/importers from participating countries. Also, 300 foreign buyers from the healthcare sector participated in this event.

*Note: F-Forecasted*

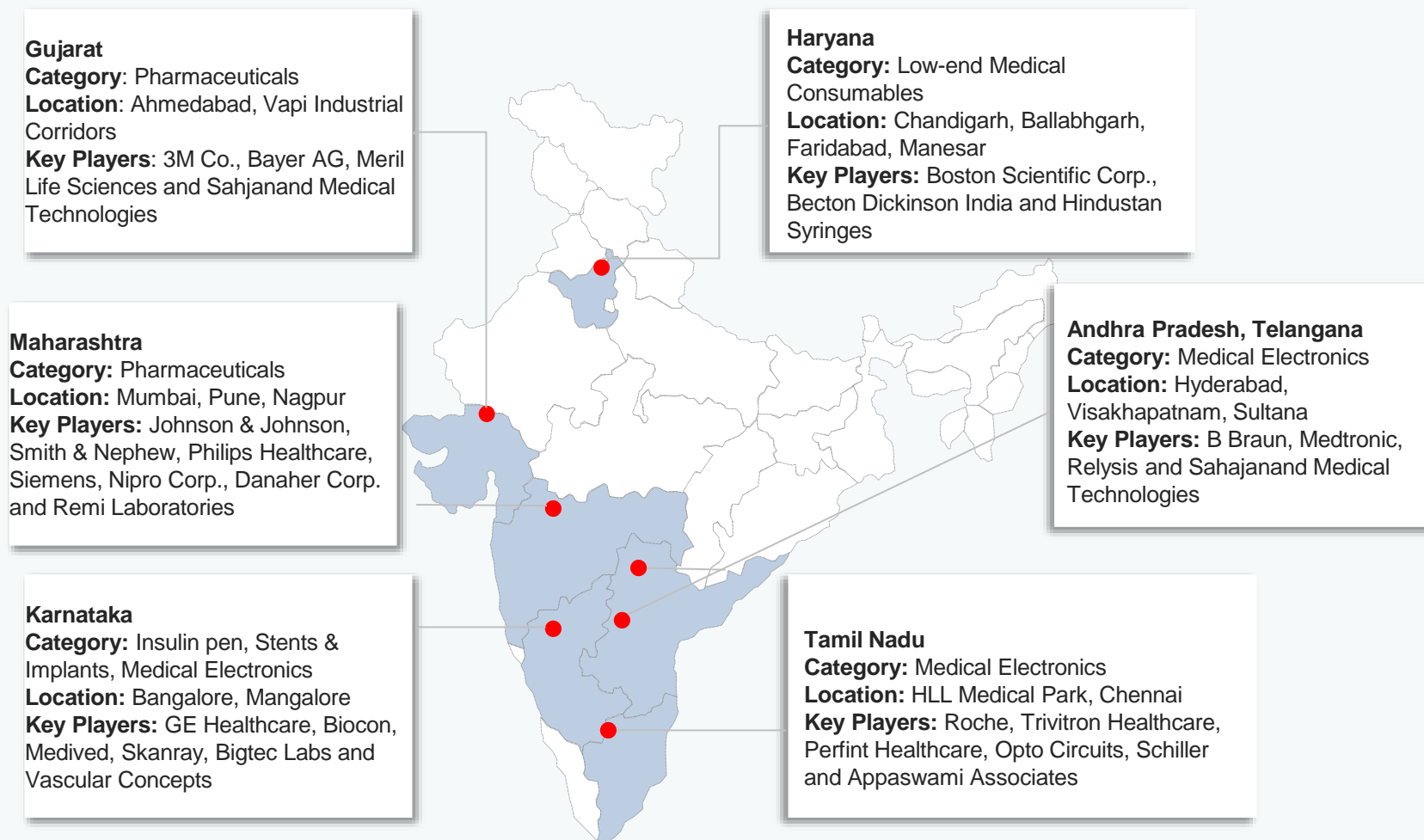
*Source: Government Website, News Articles*



# Manufacturing Clusters



# Manufacturing cluster for medical devices



Source: WHO and AMTZ Report 'Medical Device - Manufacturing in India - A Sunrise 2017', Government Website

# Major investments in medical device sector... (1/4)

## Key Highlights

- On December 2023, Agappe, Kerala's leading diagnostic technology brand, unveils its first indigenously manufactured HX series hematology equipment and Mispa i200 Immunology CLIA analyzer, marking a new era in diagnostics era.
- In November 2023, LTTS partnered with Nvidia to create AI-driven, software-based designs for endoscopy devices, aiming to improve image quality and scalability. This collaboration was disclosed in a regulatory filing by the engineering services firm.
- In October 2023, Primary Healthtech Pvt. Ltd., a start-up founded by Indian Institute of Technology (IIT) Guwahati alumni, created MobilabTM, a POCT device for early diagnosis of various chronic diseases.
- In April 2023, Union Cabinet approved a policy for the Medical Devices Sector, outlining six strategies and an action plan to boost growth from US\$ 11 billion to US\$ 50 billion in five years.
- In August 2023, Union Health Minister Mr. Mansukh Mandaviya said that India is poised to become a global center for medical technology and devices, while addressing the India MedTech Expo 2023.
- In May 2023, Medtronic announced an investment of approximately Rs. 3,000 crore (more than US\$ 350 million) to expand the Medtronic Engineering & Innovation Center (MEIC) in Hyderabad. MEIC is Medtronic's largest research and development (R&D) center outside of the US.
- In May 2023, Omron Healthcare, a Japan-based manufacturer and distributor of personal healthcare products, announced that it will set up a medical devices manufacturing plant in Tamil Nadu at a cost of Rs. 128 crore (US\$ 15.5 million).
- In March 2023, Siemens Healthineers, a medtech company that is into precision medicine, transforming care delivery, improving the patient experience and digitalizing healthcare, announced that it would invest Rs. 1,300 crore (US\$ 157.2 million) at Bommasandra in Bengaluru to set up a full-fledged campus.
- As of March 2021, 40 companies signed up to establish their facilities in the Medical Devices Park of Sultanpur, Telangana. In total, the park received a commitment of >Rs. 1,200 crore (US\$ 165 million) with a potential to generate 6,500 jobs.
- In August 2022, Wipro GE Healthcare announced that it had partnered with medical device maker Boston Scientific to offer comprehensive, cutting-edge cardiac interventional care solutions in India.
- By 2022, the Gautam Budh Nagar, Noida, is expected to have Northern India's first medical tools and system manufacturing park. The park is likely to be developed in Sector 28 of the Yamuna Expressway Industrial Development Authority (YEIDA) Space by the Yamuna Expressway Authority. In March 2021, YEIDA is expected to introduce a mission scheme worth ~Rs. 5,000 crore (US\$ 685.35 million), of which Rs. 100 crore (US\$ 13.71 million) is likely to be funded by the central authorities.
- In September 2021, the government approved a medical devices park in Oragadam (Tamil Nadu) that is expected to attract an estimated investment of Rs. 3,500 crore (US\$ 472.05 million) and offer direct and indirect employment to ~10,000 people.
- Metal Component Engineering Limited ("MCE" or the "Group"), based in Singapore, invested in MedTel, an India-based company, and formed a strategic partnership with its healthcare unit, GainHealth.

## Major investments in medical device sector... (2/4)



- The first indigenously-developed RT-PCR kit for testing monkeypox was launched by TransAsia at the Andhra Pradesh Medtech Zone (AMTZ) in August 2022.
- In April 2021, the company announced that it has established a medical devices manufacturing plant in Visakhapatnam.
- In March 2021, TransAsia Bio-Medical Ltd., a Mumbai-based in-vitro diagnostic company, announced plans to invest Rs. 150 crore (US\$ 21 million) to set up a manufacturing unit at the Medical Devices Park in Sultanpur, Telangana.
- The company plans to manufacture state-of-the-art high-technology analysers in the unit to address biochemistry, immunology, hematology, and molecular testing, in addition to COVID-19, HIV, dengue, and TB testing for domestic and export markets.



- In November 2022, Sunways India Pvt. Ltd. received a minority stake and Rs. 122.67 crore (US\$ 15 million) from the InvAscent-managed India Life Sciences Fund III (ILSF III). The pharmaceutical company intends to use the money to accelerate its acquisitions, capacity augmentation, and worldwide expansion goals.
- In February 2021, Sunway Group, a Mumbai-based medium-sized pharmaceuticals company, signed a deal to acquire Inor Medical Products Ltd. (manufacture and seller of orthopaedic implants and instruments).
- As part of the contract, Sunway has also agreed to acquire Inor Medical's facility based in Valsad, Gujarat. The deal value of the transaction was not disclosed.



- In March 2023, SMT was selected as the exclusive distributor of Penumbra's peripheral and coronary vascular thrombectomy technologies in select domestic geographies in India.
- In December 2022, SMT won the India Pharma award for excellence in R&D for the development of Peripherics, a new-age in-house developed Paclitaxel Drug Coated PTA Balloon.
- Sahajanand Medical Technologies (SMT), in April 2022, opened the first phase of its Rs. 250 crore (US\$ 30.2 million) global hub for manufacturing and R&D at Telangana government-promoted Medical Devices Park in Sultanpur, near Hyderabad.
- In March 2019, Sahajanand Medical Technologies (SMT), a manufacturer of coronary stents, announced an investment worth Rs. 250 crore (US\$ 34 million) to establish a stent manufacturing facility in Telangana.
- This facility will be Asia's largest stent manufacturing facility with a capacity to produce one million stents and two million balloon catheters per year.
- The facility is expected to be ready by 2020 and will generate employment for 1,200-2,000 people.

Source: Transasisa Bio-medical Ltd. Website, News Articles

# Major investments in medical device sector... (3/4)

## Medtronic

- In December 2023, Medtronic made history by gaining FDA approval for its innovative PulseSelect Pulsed Field Ablation System for treating atrial fibrillation.
- Medtronic partners with Cosmo Intelligent Medical Devices, a Cosmo Pharmaceuticals subsidiary, to enhance healthcare through AI-driven innovation with the GI Genius endoscopy module for global patients and caregivers.
- Medtronic bolstered its presence in India by investing approximately Rs. 3,000 crore (US\$ 362.8 million) to expand Medtronic Engineering & Innovation Center in Hyderabad.
- In May 2023, Medtronic announced an investment of approximately Rs. 3,000 crore (more than US\$ 350 million) to expand the Medtronic Engineering & Innovation Center (MEIC) in Hyderabad. MEIC is Medtronic's largest research and development (R&D) center outside of the US.
- In November 2021, Medtronic India Private Limited launched the Arctic Front Cardiac Cryoablation Catheter System for treatment of Atrial Fibrillation (AF).
- The facility will be Medtronic's largest R&D facility, outside of the US, generating ~1,000 jobs in the next five years. The investment is planned over the next five years and is aimed at making Hyderabad the hub for medical devices in India.

## SIEMENS Healthineers

- Siemens Healthineers is betting on the use of Artificial Intelligence(AI) in healthcare services. It is seeing increased AI adoption in India and aims to innovate and build a stronger R&D muscle in India, according to Mr. Dileep Mangsuli, Executive Director and Development Centre Head, Siemens Healthineers.
- In August 2023, Manipal Academy of Higher Education (MAHE), Manipal and Siemens Healthineers signed a Master Research collaboration (MRA) for continued strengthening of future cooperation between both organizations in achieving shared outcomes for the stakeholders.
- In March 2023, Siemens Healthineers announced that it would invest Rs. 1,300 crore (US\$ 157.2 million) at Bommasandra in Bengaluru to set up a full-fledged campus.
- In September 2021, Siemens Healthineers announced that molecular testing kits will be manufactured in its Vadodara, Gujarat, unit.
- In September 2021, Siemens Healthineers extended its collaboration with SyntheticMR, with a new license agreement for distribution of the company's (SyntheticMR) products.
- In October 2020, Siemens Healthineers, a global medical technology company, announced plans to invest Rs. 1,300 crore (US\$ 177 million) over the next five years in Bengaluru, Karnataka, to make India one of its four key digital innovation hubs worldwide.

Source: News Articles

## Major investments in medical device sector... (4/4)



- As announced in August 2023, Omron Healthcare India Pvt. Ltd., a subsidiary of Japanese company Omron Healthcare Co. Ltd., which is in the supply of home healthcare monitoring devices in India, is planning to double its revenue in 3-5 years.
- In August 2023, Omron Healthcare India announced a collaboration with supermodel, film producer, and fitness enthusiast Mr. Milind Soman to enhance awareness around adopting home monitoring as an essential constituent of the health regime.
- In July 2023, Omron Healthcare Manufacturing India began the construction of its new plant in Chennai with a groundbreaking ceremony.
- In May 2023, Omron Healthcare, a Japan-based manufacturer and distributor of personal healthcare products, announced that it will set up a medical devices manufacturing plant in Tamil Nadu at a cost of Rs. 128 crore (US\$ 15.5 million).
- Japan-headquartered Omron Healthcare, which established its Indian arm in 2010, is drawing growth plans for India that may include setting up a manufacturing unit in India and expanding its retail footprint.
- By the end of 2021, the company plans to have 10 retail outlets in India and plans to create a center in Warangal as part of its expansion into Southern India, where it anticipates a potential contribution of 40% of its sales in FY20. The company expects a Rs. 220 crore (US\$ 30 million) turnover in India during that period.
- In October 2021, the company announced to strengthen its telehealth and remote patient monitoring operations to boost digital experience for its customers. In line with this, OMRON introduced innovative features in its app such as 'Health Gift' option and BP Diary for its users.

Source: News Articles

# Key Industry Contacts



# Key industry contacts

	Agency	Contact Information
	Association of Medical Device industry (AIMED)	901-902, Narain Manzil, 23, Barakhamba Road, New Delhi - 110001 Tele: 91-129-4289000 / 4061151 E-mail: <a href="mailto:forumcoordinator@aimedindia.com">forumcoordinator@aimedindia.com</a> Website: <a href="http://www.aimedindia.com">www.aimedindia.com</a>
	Medical Technology Association of India	B-17, Infocity, Sector-34, Gurgaon, Haryana 122001 Tel: 91-124 4382629 E-mail: <a href="mailto:info@mtaiindia.org">info@mtaiindia.org</a> Website: <a href="https://mtaiindia.org/">https://mtaiindia.org/</a>
	Association of Diagnostics Manufacturers of India	C-123, Phase-1, Okhla Industrial Area, New Delhi - 110020 Tel: 91-11-41727222 / 41084222 E-mail: <a href="mailto:president@admi-india.org">president@admi-india.org</a> / <a href="mailto:secretary@admi-india.org">secretary@admi-india.org</a> / Website: <a href="https://admi-india.org/">https://admi-india.org/</a>

Source: Transasisa Bio-medical Ltd. Website, News Articles





# Glossary

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- AiMeD: Association of Indian Manufacturers of Medical Devices
- CAGR: Compound Annual Growth Rate
- CSDCO: Central Drugs Standard Control Organisation
- FDI: Foreign Direct Investment
- GOI: Government of India
- Rs.: Indian Rupee
- JPY: Japanese Yen
- Ltd: Limited
- MOHFW: Indian Ministry of Health and Family Welfare
- PLI: Production Linked Incentives Scheme
- Pvt Ltd: Private Limited
- R&D: Research and Development
- SCARA: Selective Compliance Articulated Robot Arm
- US\$ : US Dollar
- Wherever applicable, numbers have been rounded off to the nearest whole number

# Exchange rates

**Exchange Rates (Fiscal Year)**

Year	Rs. Equivalent of one US\$
2004-05	44.95
2005-06	44.28
2006-07	45.29
2007-08	40.24
2008-09	45.91
2009-10	47.42
2010-11	45.58
2011-12	47.95
2012-13	54.45
2013-14	60.50
2014-15	61.15
2015-16	65.46
2016-17	67.09
2017-18	64.45
2018-19	69.89
2019-20	70.49
2020-21	73.20
2021-22	74.42
2022-23	78.60

**Exchange Rates (Calendar Year)**

Year	Rs. Equivalent of one US\$
2005	44.11
2006	45.33
2007	41.29
2008	43.42
2009	48.35
2010	45.74
2011	46.67
2012	53.49
2013	58.63
2014	61.03
2015	64.15
2016	67.21
2017	65.12
2018	68.36
2019	69.89
2020	74.18
2021	73.93
2022	79.82
2023	82.61
2024*	83.09

*Note: \*- Until February 2024*

*Source: Foreign Exchange Dealers' Association of India*

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