



# SECTOR IN FOCUS

## Healthcare

# Is Medical Tech Industry truly AtmaNirbhar? ... Well, it sure is on the right path.

## Overview of the Policy

A National Medical Devices Policy 2022 is proposed which aims to facilitate an orderly growth of the medical device sector to meet the underlying objectives of accessibility, affordability, safety and quality, while maintaining a focus on self-sufficiency and innovation. This can be achieved by encouraging domestic production of medical devices in consonance with the Government's 'Atmanirbhar Bharat Abhiyan' and 'Make in India' campaign. The government aspires to reduce import dependence for medical devices from 80% to below 30% in the next 10 years. It also wants to ensure a self-reliance quotient of 80% in Med-Tech by ensuring Make in India with SMART milestones.

On 8<sup>th</sup> July 2022, a draft bill has been released by ministry of Health and Family Welfare which proposes the Regulation of medical devices as a separate category and not as a drug and creating a technical advisory board that is Medical Devices Technical Advisory Board (MDTAB).

## Challenges

- **Inverted duty structure** need to be addressed to make the industry more attractive to investors
- **Lack of skilled manpower** to develop and manufacture medical devices indigenously
- Need substantial push from the govt. to support and promote **startups and MSMEs** in order to help them scale up their businesses
- **Lack of streamlining** of clearances and approvals systems at the state-level **obstructing** the ease of doing business in the sector, **affecting larger investments**
- **Paucity of investment in R&D** by the government for advanced technology products
- **Lack of certification and regulatory processes** in the industry for benchmarking and standardising quality metrics

## Initiatives Taken by the Government

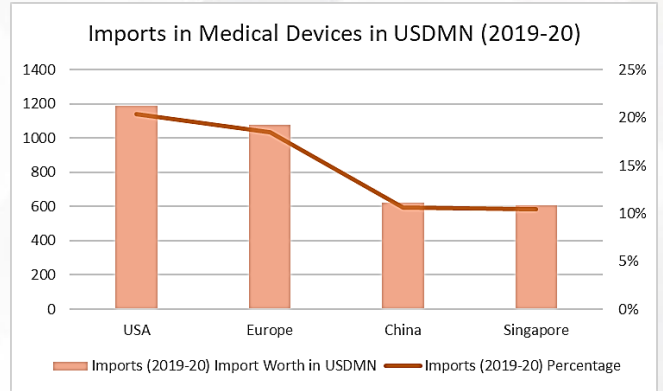
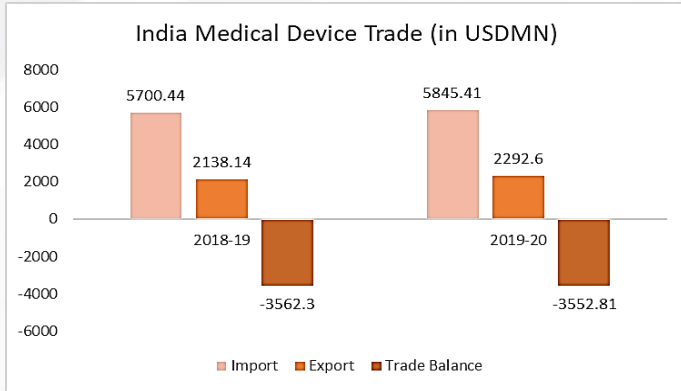
The Government of India (GoI) has taken several steps to ensure the promising growth of a robust network of manufacturing of medical devices in India over the past 5 years that this draft policy aims to reinforce to boost investments in the medical device industry, for example:

1. Separate regulation of medical devices has been a demand from the industry and government think tank NITI Aayog. In line with the same, a draft bill under 'Drugs, Medical Devices and Cosmetics Bill, 2022' has been proposed.
2. In order to attract investments in this sector, the Government had allowed 100% foreign direct investments (FDI) in medical devices sector in 2014 with estimated inflows of around USD 2.17 billion from April 2000 to December 2020, after it became fully implemented in 2019.
3. The Medical Devices Rules (MDR), 2017 regulates Clinical Investigation, Manufacture, Import, Sale, and Distribution of Medical Devices. The devices are classified into 4 classes, in harmony with international guidelines.

## Interventions under this Policy

1. GoI has sanctioned INR 400 crore to set up 4 Medical Devices Parks in Himachal Pradesh, Tamil Nadu, Madhya Pradesh & Uttar Pradesh
2. To boost domestic manufacturing, Government has launched Production Linked Incentive Schemes (PLI 1.0 & PLI 2.0) for medical devices for 4 key target segments & in- vitro diagnostics. Rs. 3,420 crores has been set aside to extend the PLI scheme to the local medical devices sector
3. Through the initiatives introduced in the Medical Devices Policy 2022, startups and SMEs will get an opportunity to collaborate with reputed academic institutions and existing players to develop their technology and product.
4. There is also provision for extended grants for promoting domestic manufacturing in the high-tech segment of the medical devices market.

# Made in India medical devices are coming ...



## Importance of Make in India

While there are over 6,000 medical devices available worldwide, barely 1/6th of them are made in India and just 23 were notified by the government under the Drugs and Cosmetics Act, 1940, until last year.

India has 75-80% import dependency particularly in higher-end equipment such as cancer diagnostics, medical imaging, ultrasonic scans, and PCR technologies with the US and Europe being the largest export markets. The high import dependency makes the medical device supply chain in India vulnerable in a global crisis as seen in the peak of the pandemic with shortage in ventilators, oxygen concentrators etc.

Medical Devices are categorised based on the level of manufacturing technology required. Currently the Indian Manufacturers are only focused on low-end technology consumable products such as syringes, needles, bandaging, and so on. Owing to the increased demand during the pandemic, local players ventured into manufacturing oxygen concentrators.

Global players such as GE Healthcare, Philips, and Medtronic have set up their R&D and innovation centres in India and have started manufacturing a few components locally. Many start-ups and SMEs such as InnAccel, EzeRx, Tricog Health, Pandorum Technologies among others, are working towards leveraging new-age technology for designing, developing and testing medical devices that solve priority healthcare problems.



## APMTZ: A case study

Andhra Pradesh Medtech Zone Ltd is India's first dedicated medical device park.(AMTZ) was set-up in 2016 in Vishakhapatnam by the Government of Andhra Pradesh with warehousing, specialized laboratories, and testing centers such as the Center for Biomaterial Testing, Center for Electromagnetic Compatibility and safety testing, Centers for Lasers, Center for 3-D Printing, MRI Magnets, Molds, Gamma Irradiation, and many other industrial service centres. It houses more than 150 independent manufacturing units. Within AMTZ the **Bio Valley Incubation Council**, funded by the Department of Biotechnology, and the **Kalam Institute of Health Technology** is also located. AMTZ started to make rapid testing kits for COVID-19 and planned to begin the manufacture of ventilators in April 2020.

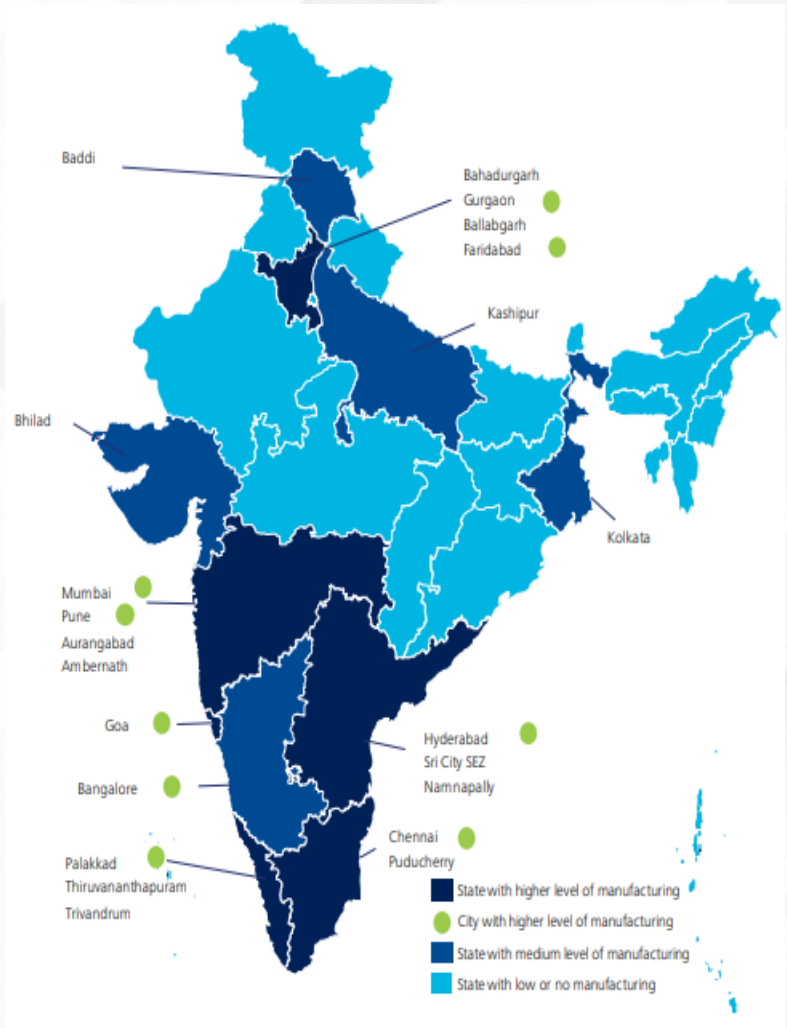
# A sector that can generate forex earnings of \$10–15 billion by 2025

## State-level ecosystem

While indigenous manufacturing is yet to scale up in India, Maharashtra and Tamil Nadu are examples of states that have developed a holistic ecosystem to boost the indigenous medical devices industry. With their manufacturing base, cities of Bangalore, Mumbai and Chennai have also developed R&D centers. Indigenous innovative products are being designed and developed in these R&D centers by MNCs as well as several domestic players. Proximity to R&D facilities and adequate ecosystem support (policy and tax incentives) have led to the organic development of medical devices centers.

## Advantages of Make in India

- Increased investments and revenue generation for the exchequer with medical devices sector open to 100% FDI through the automatic route
- Promotes “Atmanirbharta” as Indigenous production would mean **reduction in cost** of acquiring the machine which would ultimately lower the cost of the test to the patient making the **services affordable**.



## What would make this a Win-Win Situation?

- According to industry estimates, the devices segment is expected to generate foreign exchange earnings of \$10-15 billion by 2025
- Medical Devices industry will create a multiplier effect **on employment generation**, along the lines of the overall healthcare sector.
- The domestic players, who constitute around 65% of the medical device manufacturers in India, focus on low-cost, low-technology devices such as consumables and disposables catering to local consumption with limited exports. There is a need for long-term funding and large investments in **pure research and innovation** from the government in medical devices along with private sector partnerships (PPP) and collaboration.
- There is a strong need to build an atmosphere of **promoting innovators** and creating a local work force. A good example is "Sahajanand Laser Technology – SUSHRUTA Innovation Awards" which is being awarded since the last 5 years by the National Bio medical Engineering Society (NBES) with support of Department of Science and Technology.

# The reforms needed

- The medical devices space has been identified as a sunrise sector. Small manufacturers need support as they struggle to meet the high labor and electricity costs. The industry also seeks **tax incentives and flexible labor laws** to achieve economies of scale and remain competitive.
- There is a need for continuous **skilling and re-skilling of human resources** in tandem with the latest technological innovations.
- Providing CENVAT/Duty credit on raw materials instead of **inverted duty structure** as the present arrangement favors import of finished goods than raw materials /components, weakening the case for indigenous manufacturing.
- To integrate all the key stakeholders involved with the regulatory process, an online **Single Window Clearance System** for Licensing of Medical Devices will be quite useful for filing applications for a medical device manufacturing licence, an import licence, and clinical research.
- To increase the **exports**, we can concentrate on **SAARC countries**.
- The Indian devices are not as per **USFDA mark** we can concentrate on having all the devices as per USFDA mark

## Conclusion

As the country moves ahead with its vision to promote indigenous manufacturing under the initiative "AtmaNirbhar Bharat", the policies and regulatory reforms must favour the big and small medical device manufacturers in the advanced tech category of products. The government has taken many progressive initiatives to remove obstructions for businesses to scale up, which is also attractive for foreign investors. The new proposed manufacturing clusters across the country will give a multitude of opportunities for local players to innovate and manufacture with easy access to skilled manpower. It is important to find cost-optimised solutions for manufacturing to ultimately improve accessibility and affordability of the devices to all strata of healthcare.

## Overview

The Indian Medical Device Market is valued at around \$11 Billion and is expected to grow at the rate of 35.4%, reaching \$50 Billion by the year 2025. This makes India the fourth largest market after Japan, China, and South Korea for medical devices in Asia. The Indian Diagnostics Market is currently valued at around \$9 Billion and is expected to grow at a CAGR of around 10% over the next 5 years.

Although India is heavily import-dependent in the medical devices market, the exports by India to other countries is expected to reach \$10 Billion by 2025. 65% of the manufacturers in India operate in the consumables and disposables segment and mainly cater to the local market with minimal exports. Most of the high-tech medical device market is driven by large multinationals. There are six main clusters for medical device manufacturing in India namely Gujarat, Andhra Pradesh, Maharashtra, Haryana, Telangana and Tamil Nadu.

Through progressive government initiatives, FDI inflows received a much-needed boost. From April 2000 to June 2021, the medical and surgical appliances sector has attracted an FDI inflow of \$2.23 billion.

While indigenous manufacturing is yet to scale up in India, Maharashtra and Tamil Nadu are leading examples of states that have developed a holistic ecosystem to boost the indigenous medical devices industry. With their manufacturing base, cities of Bangalore, Mumbai and Chennai have also developed the presence of R&D centers.

# Three ways to increase the export potential of Medical Device Industry?

## How to make Medical device Industry less import dependent?



**Anurag Singh**  
Managing Director

India's ambition to become a global leader in the medical devices industry cannot be achieved in a straightforward manner. There must be a multipronged approach towards it, which will include identification of core competencies, focus of research, innovation and manpower skilling, along with creating a brand identity for locally manufactured products.

### **Identifying Core Competencies**

The medical devices vertical that has seen the fastest growth and the greatest number of startups in India is wearable devices. They use Artificial Intelligence and have a market beyond the patients seeking treatment. Although there is dominance of global brands such as Samsung and Apple, Indian manufacturers like BoAt are able

to give them a stiff competition due a greater inclination of the youth towards these products and incorporation of advanced technology at par with the global giants.

The medical device industry and the electronics industry go hand-in-hand because electronic devices get embedded into medical devices. The Indian Government is taking many initiatives like the National Policy on Electronic Devices 2019, that focus on establishing India as the global hub for electronics system design and manufacturing. The true value will be in finding the convergence point between the medical devices and electronics industry where both these industries can grow in synergy with each other and push the local players to move from the low-and-medium technology segment to high technology segment.

### **Brand Identity**

Another important aspect is to consider the brand identity that "Made in India" drives at a global stage. How do we ensure that this brand for medical devices is recognised? A stringent system of benchmarking, certifications and quality assessments is required to make sure that the medical devices/products created under the "Made in India" brand are of globally acceptable standards and attract investments. The role of research and development in this case is very big. Through continuous efforts towards innovation and skilling, the industry needs to reform itself to produce at par with international standards.

### **Cluster-Based Approach**

As in the case of the Medical Devices Park established in Andhra Pradesh, the cluster-based approach is the best way to address the needs of the medical devices industry today, especially if the goal is to be completely "Atmanirbhar."

It is seen worldwide that such a setup works best for industries like Medical Devices because it is a multidisciplinary industry. A multitude of things are required from researching and designing to manufacturing that can be fulfilled in a cluster setup like Medical Parks. Such clusters also give the manufacturers and researchers from all verticals an opportunity to work and create products in tandem with each other, giving rise to innovation and collaborative growth. Technologies like 3D printing and Gamma irradiation can also be explored for new and varied applications in the industry.

# Medical Device Industry in India: A Snapshot

## Indian Players

- The Indian manufacturers primarily deal in the Class A and B markets that are relatively less technologically advanced.
- Most of the Indian manufacturers of these devices are Micro, Small & Medium Enterprises (MSMEs) with an average turnover of \$450-500 million.
- Some of the largest players in the Indian domestic medical devices market are Allied Medical, Trivitron Healthcare, Transasia Biomedicals, and so on.
- Initiatives under the 2022 policy will help SMEs such as InnAccel and Tricog Health, besides other, to accelerate growth.

## International Players

- The manufacturing value chain for high-end medical devices (Class C and D, as per the Global Harmonization Task Force Rules) is driven majorly by large international players with extensive service networks established in India.
- At present, almost all the top 40 players in the medical devices industry have a presence in the country.
- Some of the largest players in this segment are Philips, GE Healthcare, Siemens, Medtronic etc.
- In consumables, instruments, and appliances, multinational firms account for 40 percent to 50 percent of the market, while all other sub-segments account for 80 percent to 90 percent.

## Start Up Ecosystem

The medical devices industry in India is getting a much-needed makeover through new startups that cater to a diverse market. Companies like BeatO and Forus Health are moving away from the conventional consumable products and introducing advanced diagnostic technology. However, there are several challenges in scaling up these operations-

- Poor infrastructure support in manufacturing
- Underdeveloped logistics and supply
- Inadequate focus on research and development
- Lack of skilled manpower

## Major news developments

- A welcome step has been taken by the Union health ministry to launch the ICMR/ DHR Policy on Biomedical Innovation and Entrepreneurship. This Policy is to encourage the multi-disciplinary collaboration and promote a start-up culture at Medical Institutes across the country by encouraging Make-in-India, Start-Up-India, and Atmanirbhar Bharat initiatives.
- Innovation Imaging Technologies has established a facility in Bengaluru to manufacture 240 catheterisation laboratories in the next 12 months. As lifestyle diseases are on the rise, the company wants to build robust infrastructure to treat cardio-vascular diseases.
- In October 2021, Hindustan Syringes and Medical devices upgraded their manufacturing and supplied 500 million 0.5 ml AD syringes to the government to accelerate the vaccination drive
- The government approved applications for nine eligible projects that are expected to lead to a total committed investment of Rs. 729.63 crore (\$100.01 million) and generate around 2,304 jobs. These are Siemens Healthcare, Allengers Medical Systems, Allengers OEM, Wipro GE Healthcare, Nipro India Corporation, Sahajanand Medical Technologies, Innvolution Healthcare, and Integris Health.
- Transasia Bio-Medical, an in-vitro diagnostic company, plans to invest Rs. 150 crore (\$21 million) to set up a manufacturing unit in Sultanpur, Telangana to manufacture high-end analysers

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## About Primus Partners

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