



FROM VISION TO ACTION

**BUILDING A GLOBALLY COMPETITIVE MEDICAL
DEVICES INDUSTRY IN INDIA**

29th Feb, 2024

White Paper

“Unlocking the Next Wave of Growth for the Medical Devices Sector”

Foreword by Secretary General, ASSOCHAM



Mr. Deepak Sood
Secretary General

The field of medical technologies stands at the forefront of innovation, driving profound transformations in healthcare delivery and patient outcomes. This white paper serves as a comprehensive exploration of the dynamic landscape of medical technologies, offering insights into the latest breakthroughs, challenges, and the unprecedented impact these innovations have on the healthcare ecosystem.

As we navigate through the pages of this paper, we embark on a journey through the technology, witnessing the convergence of cutting-edge research, data-driven solutions, and transformative devices. The relentless pursuit of excellence by scientists, engineers, and healthcare professionals has given rise to a plethora of groundbreaking technologies.

The government assumes a central role in steering the course of healthcare innovation. This report underscores the crucial role played by strategic interventions orchestrated by governmental departments. By incentivizing research and development initiatives, establishing a conducive regulatory environment, and fostering collaborative platforms, the government becomes a centre in advancing medical technologies.

Recognizing the imperative of investing in skill development and infrastructure, the government lays the groundwork for a flourishing ecosystem conducive to medical device innovation. These investments are pivotal in cultivating the necessary expertise and resources that propel the nation towards the forefront of healthcare advancements.

Over the past decade, commendable strides have been made by the government in steering the healthcare industry in the right direction. A notable shift from a cost-based to a value-based and innovation-driven approach has been the focus, marking a paradigmatic transformation in the sector. This report delves into the initiatives and policies that reflect this transformative journey, providing a comprehensive overview of the government's commitment to fostering an environment where innovation thrives, ultimately contributing to the betterment of public health.

The compilation of this report would not have been possible without the collaborative efforts of experts and researchers in the field who have contributed their invaluable knowledge and perspectives.

As we immerse ourselves in the unfolding narrative of medical technologies, let us recognize the potential to shape a future where technology becomes an ever more powerful ally in the noble quest for healthier lives and well-being.

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Executive Summary

The Indian Medical Devices market **is estimated at USD 12.1 Bn in FY22** and has grown at **a healthy pace in recent years** (18% CAGR from FY15-FY22). However, it is **still under-penetrated in terms of its share of the world market (2.14% share of global market)**. This is a consequence of India's low overall spend on healthcare (Total Healthcare Expenditure of India is 3.2% of GDP – much lower than comparable countries) as well as other factors impacting medical device penetration in India.

Future growth of the Medical Devices industry will be based on **3 key Drivers of Healthcare - Accessibility, Affordability and Assurance** (Quality) of healthcare; along with **4 key Enablers for Medical Devices industry - Regulatory Environment, Manufacturing Ecosystem, R&D and Innovations, and Promoting Investments**. Over the past few years, India has witnessed positive transformation in all of the above Drivers and Enablers.

The USD 50 Bn target of Medical Device market size in FY31 is achievable if some of the fundamental challenges and bottlenecks are addressed.

India's Medical Device market **is highly import dependant (imports comprise 70% of overall market)**. Import dependence is **highest in medical equipment (~ 85%)** whereas in the **other segments the import dependence is between 40-55%**. Even within the domestically manufactured devices, **the level of local value addition varies widely** – from High Value Addition in IVD Reagents and Moderate-High in Consumables to Low-Moderate in Implants and Low in Medical Equipment

Medical Device Category	% Share of Imports in Domestic Market	Extent of Local Value Addition for Domestically Manufactured Products
Implants	40%	Low to Moderate
IVD reagents	60%	High
Medical Equipment	85%	Low
Consumables	55%	Moderate to High
Overall	70%	

Along with the USD 50 Bn market size target for FY31 the industry **should aim for a significant reduction in imports from the current levels of 70% and a substantial increase in local value addition in domestically manufactured products.**

Based on interactions with various industry players **specific areas of intervention / support for the industry have been proposed** in this document. These broadly pertain to the following areas:

- **Robust manufacturing Eco-system including Raw Materials /components/ support facilities:** focus on targeted localisation for key components and attracting global component players to India
- **Quality Compliance:** Focus on globally compliant and harmonised quality standards, supporting clinical trials in India and emphasis on PMS (Post Marketing Surveillance)

- **Skill and Capability Building:** Focus on long-term collaborative partnerships with leading institutes, fast-track implementation of NIMER and innovative programs like PRIP, bridge courses and skill development in product development, manufacturing, QA, validation etc.
- **Drive Domestic Demand Creation and Support Promotion of Exports:** ironing out issues related to existing PPO norms for local value addition, increasing share of healthcare spend, infrastructure improvement in PHCs and usage of critical medical equipment in such centers, increased PPP models in Diagnostics sector, support for registration, marketing and promotion of India made products in exports markets (especially regulated markets)

A study of other major medical hubs - China, Singapore, and Ireland, provides the following **learnings from India: focus on cluster-based approach, R&D and innovation led growth, maintaining quality standards, stable and uniform regulations, robust system for IP protection and a well-laid out infrastructure.**

Avalon Consulting has used a **framework for identifying strategic interventions and product level priorities for the Medical Device Industry in India.** A preliminary evaluation of various Medical Device products has been done across 2 dimensions:

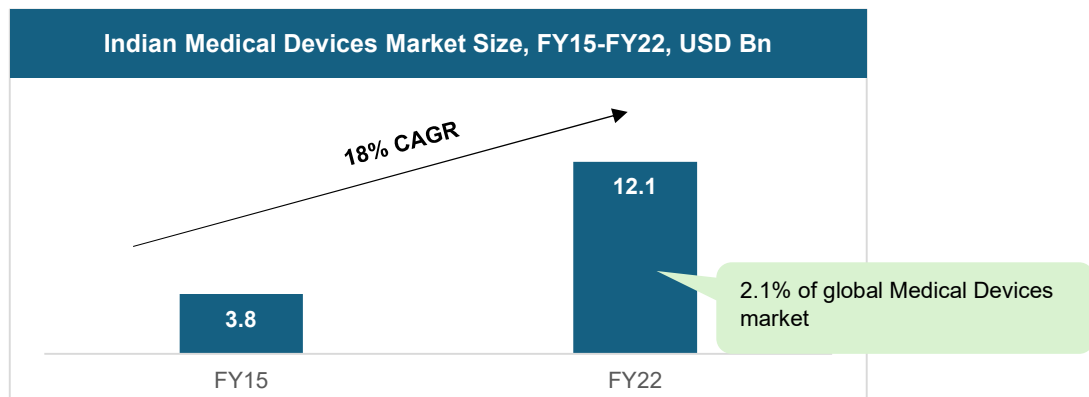
- **Attractiveness for India**
- **India's Ability to Compete**

Based on this, **different products have been prioritised for implementing short-term and long-term actions for driving growth.** This is a preliminary evaluation and needs to be **further discussed between key stakeholders,** leading to a set of specific action points.

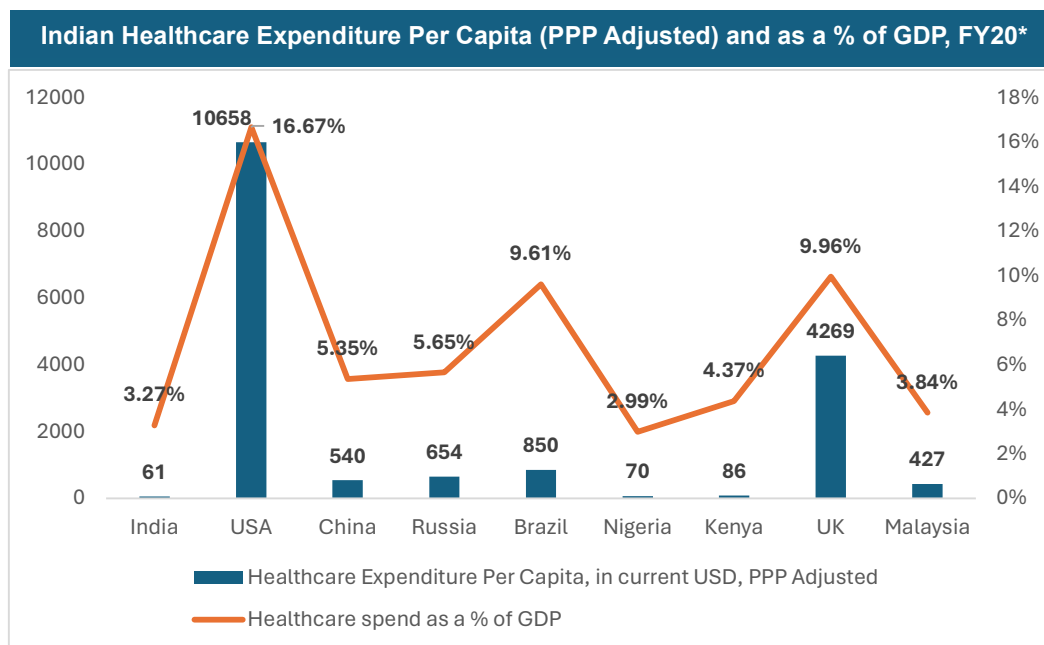
We look forward to further discussions and consultations between industry and government to help build on the strong foundation already prepared over the last few years and to identify specific product and category level actions.

Introduction- The Untapped Potential of the Medical Devices Industry

The Indian Medical Devices market size is **estimated at ~ USD 12 Bn in FY22 and has grown at 18% CAGR over the past 7 years**. Despite a reasonably healthy growth the industry remains under-penetrated in India – reflected in its **low share of global medical devices market**. India comprises only 2.1% of the global Medical Devices market (USD 570 Bn in FY22), although it accounts for 16% of the world’s population. Share of Medical Devices market (FY20) in Total Healthcare Expenditure of India is ~10% (FY20)



Source: a) NATHEALTH report on healthcare, 2016 b) Survey of Medical Devices Clusters by Dept. of Pharmaceuticals, GOI, Feb '23



Source: WHO data

*Note: Data shown for FY20 as subsequent years were impacted by COVID

India's Total Healthcare Expenditure (per capita and as % of GDP) is significantly lower compared even to other developing countries – a fundamental reason for the relatively low size of the medical device market in India.

Indian Medical Devices Sector – Drivers and Enablers

While the industry presents significant untapped potential its future growth will be determined by **3 Key Drivers and 4 Key Enablers**.

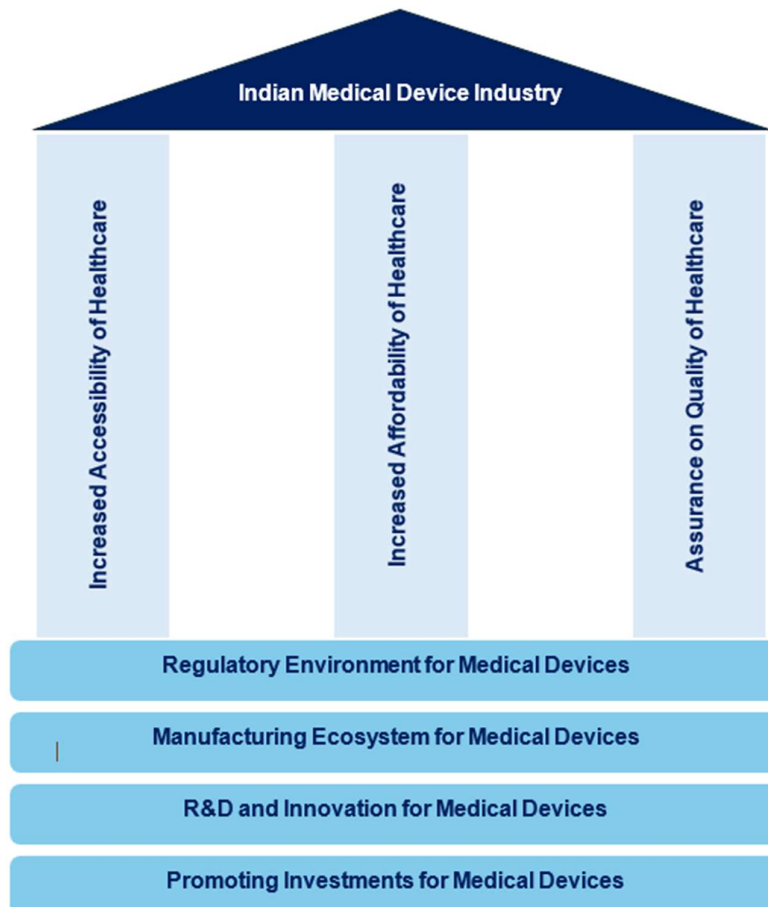
3 Key Drivers:

- Increased **Accessibility** of Healthcare
- Increased **Affordability** of Healthcare
- **Assurance** on Quality of Healthcare

4 Key Enablers:

- **Regulatory Environment** for Medical Devices
- **Manufacturing Ecosystem** for Medical Devices
- **R&D and Innovation** for Medical Devices
- **Promoting Investments** for Medical Devices

The above Drivers and Enablers have witnessed a major positive transformation over the past few years through the collaborative efforts of industry and government. As a result, India is favourably positioned to leverage these factors and drive a significantly higher growth of the industry.



Key Drivers

Drivers	Historical Trends and Ongoing Changes
Increased Accessibility of Healthcare	<ul style="list-style-type: none"> Historically low penetration of hospital beds in India ~ 1.4 beds / '000 population (much lower than other developing countries) Increased investments being undertaken in healthcare delivery systems with overall objective of doubling bed penetration in the near future Govt. focus on basic healthcare through increased share of PHCs and secondary care with the objective of achieving Universal Healthcare in the next few years (increase of ~1000 PHCs in 2022 as compared to 2019) Private sector focus on secondary and tertiary healthcare as well as Diagnostics – with increased capacity creation especially in Tier 2/3 centers Creation of the Ayushman Bharat Digital Mission (ABDM) building a digital backbone for ease of information sharing among healthcare providers, other service providers and patients while ensuring data privacy Increased adoption of PPP models in diagnostics – providing access to quality healthcare in public hospitals Booming Medical Tourism market driving healthcare demand
Increased Affordability of Healthcare	<ul style="list-style-type: none"> High share of Out of Pocket spend on healthcare is ~47% in FY20 and has been declining over the years; historically low penetration of health insurance Share of population covered under health insurance has been increasing over the years; currently around 70% of the population is covered under some form of insurance (~37% share under private insurance, ESIC, CGHS etc. and ~33% under Ayushman Bharat AB-PMJAY) Development of a highly competitive market environment in Diagnostics Services driving down prices of basic and advanced diagnostic tests
Increased Assurance in Quality of Healthcare	<ul style="list-style-type: none"> Healthcare delivery standards have been clearly defined and implemented especially across hospitals, diagnostics, pharma companies etc. Stringent actions against violations of standards Increased role and importance of accreditation and quality certification bodies, for e.g. NABL, QAI etc. Declining share of low quality/unorganised players across various segments of healthcare delivery

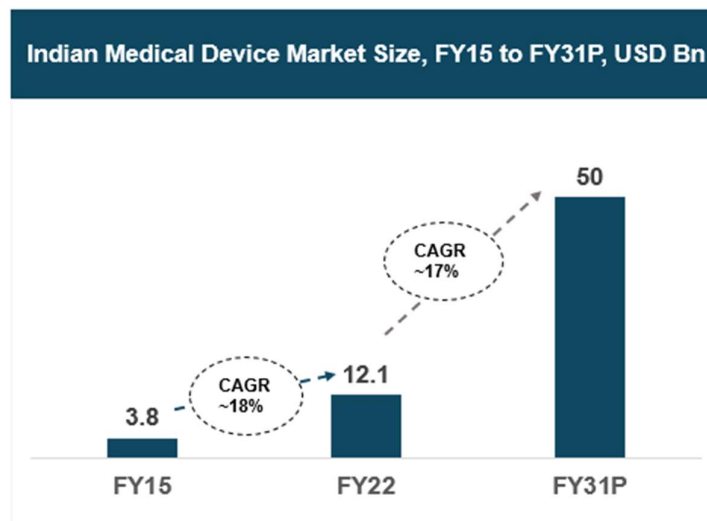
Key Enablers

Enablers	Historical Trends and Ongoing Changes
Regulatory Environment for Medical Devices	<ul style="list-style-type: none"> Historically, only a limited number of medical devices were regulated under Drugs & Cosmetics Act with oversight from DCGI A series of regulatory policy changes have been undertaken in the past few years especially MDR (Medical Device Rules) 2017 and Medical Devices Policy 2020 and 2023 (under discussion for implementation) All medical devices have been brought under regulation based on a risk-based classification (low/ moderate / high risk) Quality standards are being harmonised between BIS and global standards (ASTM etc.); QMS standards being implemented for relevant categories Guidelines on clinical data requirements are being clarified Clear identification of relevant regulatory authority (CDSCO / State Level Authority etc.) for product registration, imports, local manufacturing etc.
Manufacturing Ecosystem for Medical Devices	<ul style="list-style-type: none"> Historically local manufacturing was limited to mainly low technology products (mainly consumables etc.) Over the past few years, various challenges impacting manufacturing are being addressed e.g. anomalies in inverted duty structure are being rectified The PLI scheme for Medical Devices has been well received by industry; it has helped encourage manufacturing with increased local value addition in several categories e.g. High-end diagnostics Radiotherapy Medical Devices, Nuclear Imaging Devices, implants, etc. 26 companies have overall applied for PLI covering a total of 168 products, including Radiotherapy Medical Devices such as Linear Accelerators, Rotational Cobalt Machine, etc., Radiology & Imaging Medical Devices such as CT Scan, MRI, Ultrasonography, etc., Anaesthetics & Cardio-Respiratory Medical Devices such as Dialyzer, ECG, etc., Implants such as Heart Valves, Stents, PTCA Balloon Dilation Catheters, etc. PLI scheme for Medical Devices Clusters has also been proposed for implementation in various states; significant success witnessed by AMTZ as a world class model which can be emulated Implementing the PPO (Public Procurement Order) which prioritises procurement from domestic manufacturers with specified levels of local value addition
R&D and Innovation for Medical Devices	<ul style="list-style-type: none"> Historically there has been a lack of a multidisciplinary vision for training and development in medical devices; evident in the significant skill gap which has been hampering innovation As a result there was relatively low activity in product innovation as well as patent filing in Medical Devices from India Over the past few years there have been several initiatives formulated by the govt. to promote innovation e.g. proposed establishment of NIMER , PRIP scheme etc. along with continued development of medical device related education in NIPER etc. Provision of financial assistance for building labs and innovation hubs at medical device clusters; financial assistance for Testing Labs etc. Funding agencies like BIRAC are also playing an important role in this regard Encouraging industry academia and cross functional academic collaboration (e.g. AIIMS, IISc, IITs etc.) Given India's inherent advantages (talent pool) along with govt. focus in this area, there is increased participation of the major Medical Device

	players to invest in R&D in India – this includes both large MNCs and Indian companies
Promoting Investments for Medical Devices	<ul style="list-style-type: none"> • Overall, PE/VC investments in Medical Devices in India increased to USD 628 Mn in FY22 a 3.5X jump compared to FY19; reflecting increased confidence of private players in the sector • Majority of these investments were in IVD equipment, implants and other equipment • The Gross Block of a sample set of 15 major Medical Devices players increased from INR 3,335 Cr to INR 5,421 Cr from FY18 to FY21 at a CAGR of 17.5%.

The positive changes witnessed across each of the above Drivers and Enablers have helped lay the foundation for growth of the Medical Devices industry in India.

The government and the key stakeholders believe that the **Medical Devices industry can reach USD 50 Bn by 2030, implying a 15% CAGR over the next 9 years.** Achieving this level of growth would have **a transformative impact on the industry in terms of - driving increased investments, local manufacturing and job creation along with export growth.**



Source: Avalon Consulting Research & Analysis

The USD 50 Bn target for medical devices industry is achievable but requires sustained impetus over a significant time period. Even with a USD 50 Bn market size in FY31, the share of medical devices market in healthcare spend would be reasonable (between 12-15% of healthcare spend).

Particulars	Unit	Financial Year		
		FY20	FY31 (Case 1)	FY31 (Case 2)
Medical Device Market Size	USD Bn	8.69	50	50
India's GDP (in current prices)	USD Bn	2,670	8,433	8,433
THE* as a share of GDP	%	3.27%	4%	5%
THE*	USD Bn	87.31	337	422
Medical Devices market share as % of THE*	%	9.95%	15%	12%

Note:

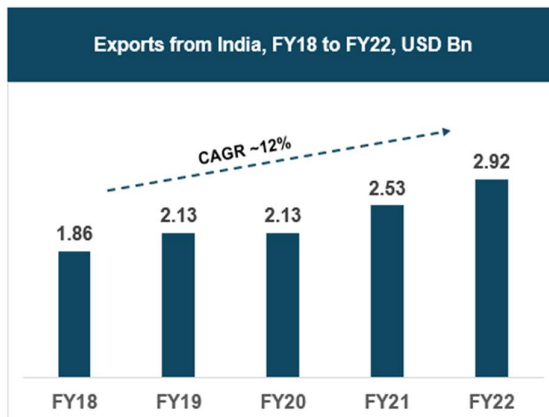
Nominal GDP growth from FY22 to FY31 taken at 11% CAGR (including inflation)

As per National Health Accounts, prepared under the aegis of Ministry of Health and Family Welfare,

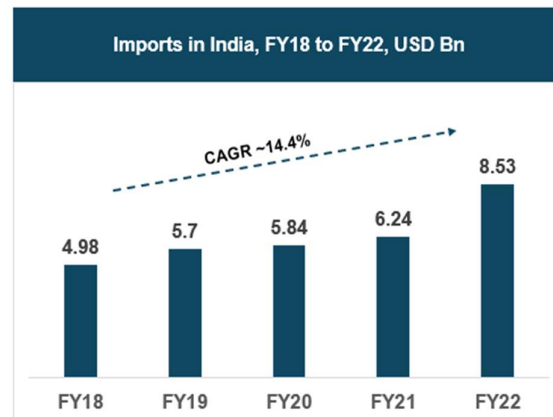
*THE (Total Health Expenditure) includes current and capital expenditures incurred by Government and Private Sources including External funds

However, there are a few fundamental challenges and bottlenecks to be addressed for the above potential to be achieved.

India's Trade in Medical Devices



Source: EEPC India



Source: EEPC India

Top 10 countries for export of Medical Devices, FY22
USA
China
Germany
France
UAE
Singapore
Brazil
Netherlands
Nepal
Nigeria

Top 10 countries for import of Medical Devices, FY22
USA
China
Germany
Singapore
Netherlands
Japan
Malaysia
Switzerland
Hong Kong
South Korea

Medical Device imports have grown at 14% CAGR between FY18 and FY22. The size of imports is at least 3X compared to exports in FY22 and is also growing at a faster pace ; emphasising the need for increasing domestic manufacturing.

Medical Device Manufacturing in India – A Status Check

Medical Devices industry has been broadly classified into following 4 product categories:

Category	Key Products
Implants	Cardiovascular Stents, Cardiovascular Implants, Orthopaedic Implants, Ophthalmic Implants, Trauma Implants, etc.
IVDs	Reagents: Clinical Chemistry Reagents, Immunochemistry Reagents, Haematology Reagents, Assays, etc.
Medical Equipment	Diagnostic Equipment: Medical Imaging Equipment – X-Ray Machines, Ct Scanners, MRI Machines, Ultrasound Machines, Echocardiography Machines, Etc., Other Diagnostic Equipment - Patient Scales, Stethoscopes, Dopplers, Pulse Oximetry, etc. Treatment Equipment: Defibrillator, Artificial Dialysis Machines and Haemodialyser, Fetal Monitoring Systems, Ventilators, Oxygenators, Linear Accelerators, Baby Warmers, CATH Labs Patient Monitors, etc. IVD Instruments: Immunoassay Analysers such as ELISA Readers, CILA Readers, etc., Clinical Chemistry Analysers Such as Wet Chemistry Analysers, Electrolyte Analysers, etc., Automated and Semi-Automated Haematology Analysers, Flow Cytometry Analysers, Etc., Molecular Diagnostics Instruments such as Real Time-PCR Systems
Consumables	Catheters, Needles, Gloves, Sutures. Renal Care, Syringes, Bandages, IV Cannula, IV Sets, EBCT, Surgical Blades, Blood Bags, Contraceptives, etc.

In the subsequent sections, the current domestic manufacturing status of each of these product categories has been detailed out.

Implants

The market for implants in India is estimated at **USD 1.05 Bn in FY22**, representing **8.7% of the total Indian Medical Devices market size**. The category includes products like prosthetics, body function monitoring, and organ and tissue support etc.

Category	Key Products
Implants	Cardiovascular Stents, Cardiovascular Implants, Orthopaedic Implants, Ophthalmic Implants, Trauma Implants, Intraocular Lenses, etc.

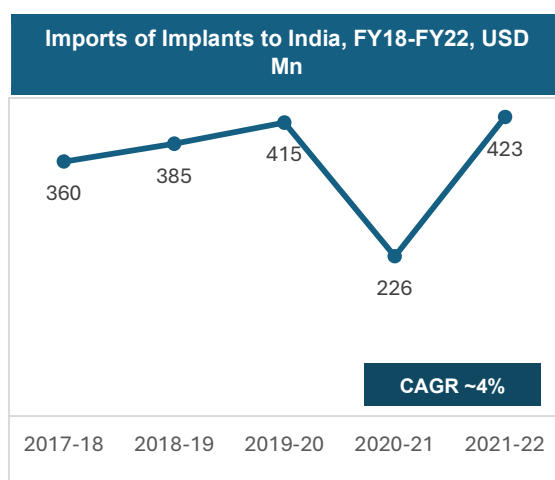
Key trends and Potential Impact driving the Indian Implants sector

Trend	Description	Potential Impact
Higher demand for implants	<ul style="list-style-type: none"> Driven by growing prevalence of various disease e.g. heart failures, osteoporosis, osteoarthritis, cataracts, etc. and focus on aesthetics, in case of dental implants 	<ul style="list-style-type: none"> High growth market with requirement across age categories

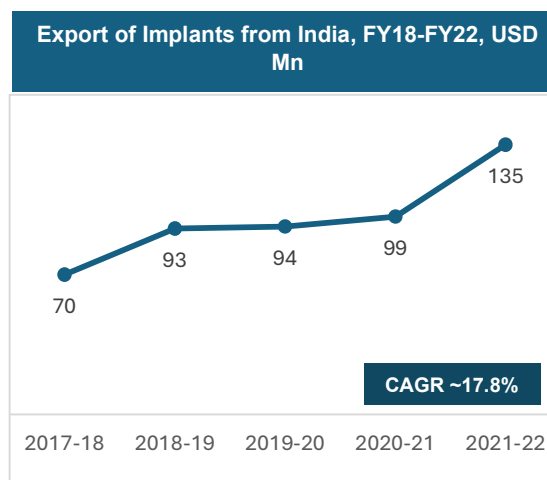
Trend	Description	Potential Impact
Increased presence of local players	<ul style="list-style-type: none"> Number of licensed manufacturers of stents and knee implants in India increased from 8 in 2017 to 56 currently. Over 80 players now operating in this space across categories - stents, knee and hip replacements, intra-ocular lens, etc. 	<ul style="list-style-type: none"> Potentially this category could witness a significant shift away from dominance of MNCs to Indian players

Implants- Extent of Local Manufacturing

India's imports of medical implants went up from USD 360 Mn in FY18 to USD 423 Mn in FY22. Exports have grown almost two-fold in the same time from USD 70 Mn in FY18 to USD 135 Mn in FY22, with a CAGR of ~18% in the last 4 years, showcasing India's growing strength in medical implants manufacturing.



Source: EEPC India, DGCIS



Source: EEPC India, DGCIS

However, challenges still exist for a large-scale local manufacturing of medical implants.

Medical Implants (Share of Demand met through Imports: ~40%)	
<p>Prevalence of Local Manufacturing</p> <ul style="list-style-type: none"> Significant jump in local manufacturing especially in Stents / Orthopaedic Implants; a key driver being the NPPA Price Cap Regulations which created an opportunity for local low-priced players to compete against MNC imports Integration of MSMEs into the value chain; Significant outsourcing through MSMEs e.g. in basic knee and hip implants, basic stents, etc. 	<p>Level of Value-Addition in India</p> <ul style="list-style-type: none"> Moderate to Low Value Addition Mainly assembly activity with significant share of imported components

Prevalence of Local Manufacturing	Level of Value-Addition in India
<ul style="list-style-type: none"> • Some India made products are also being adopted in global markets – however there is a need for improvement in prevalent quality standards to be more globally compliant. 	<ul style="list-style-type: none"> • Lack of availability of raw materials RM for metal components (Cobalt and Chromium) is a challenge. Besides this, some specialised parts and electronic components need imports, where India does not have the required expertise

Overall Conclusions

Medium to long-term horizon for achieving high level of manufacturing self-sufficiency:

- Need to access to high-end technology.
- Scaling up the ecosystem for specific components and electronics parts

IVD Reagents

The Indian IVD reagents market size is estimated at **USD 1.47 Bn in 2022**. The growth of Indian IVD market is mainly driven by the fast-growing diagnostics sector, with a renewed focus on disease detection, treatment, and prevention, especially post the Covid pandemic.

IVD reagents include the following products:

Category	Key Products
IVD Reagents	<ul style="list-style-type: none"> • Clinical Chemistry Reagents for analysing blood chemistry. • Immunochemistry Reagents for testing of infectious diseases • Haematology Reagents for blood cell counts

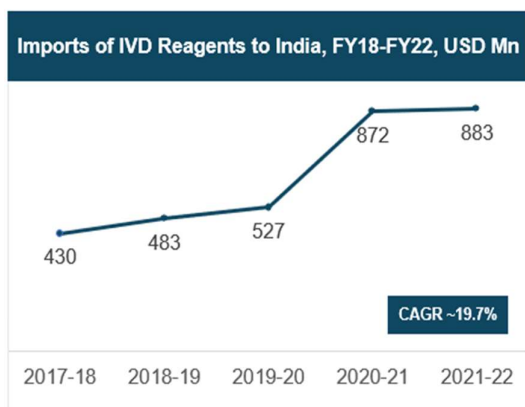
Key trends and Potential Impact driving the Indian IVD Reagents sector

Trend	Description	Potential Impact
Increasing traction Point-Of-Care (POC)	<ul style="list-style-type: none"> • Increased usage of POC Testing e.g. in blood glucose monitoring, infectious disease testing, pregnancy detection and various other types 	<ul style="list-style-type: none"> • Improved patient accessibility • Low testing TAT • Quick disease identification • Fast treatment
Shift Towards Automation & Advanced Technologies	<ul style="list-style-type: none"> • Increasing usage of Molecular Diagnostics, Next-Generation Sequencing (NGS), and Digital Pathology as well as usage of automated analysers 	<ul style="list-style-type: none"> • Improved testing accuracy • Increased testing capacity
Focus on Cost-Effectiveness	<ul style="list-style-type: none"> • The local demand is still largely driven by requirement of low-cost yet effective solutions, thereby nudging players to look at their overall supply chains 	<ul style="list-style-type: none"> • Increased innovation • Increased local manufacturing

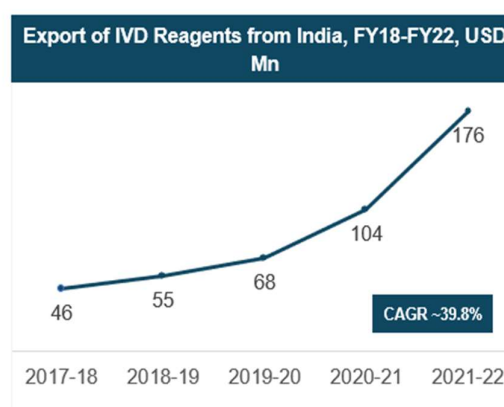
With India still largely being a price-sensitive market, long-term sustenance of these trends will depend on developing local manufacturing capabilities for IVDs as one of the core focus areas, among many others.

IVD Reagents - Extent of Local Manufacturing

India's imports of IVD reagents, was around USD 527 Mn in FY20 and ballooned to USD 883 Mn in FY22. However, despite being lower in value, exports have grown at a higher pace than imports at ~40%.



Source: EEPC India, DGCIS



Source: EEPC India, DGCIS

IVD Reagents
(Share of Demand met through Imports: 55-65%)

Prevalence of Local Manufacturing	Level of value-addition
<ul style="list-style-type: none"> • Push for local manufacturing through PLI scheme which has already attracted 5 companies, including 4 MSMEs for IVD reagents. • Challenges remain pertaining to Price and Quality. Quality standards maintained by global reagent players are currently not matched by Indian manufacturers. Also, importing of chemicals can sometimes be less costly than sourcing locally. 	<ul style="list-style-type: none"> • Value addition of Indian manufacturing is reasonably high, as most of the key chemicals are available locally. • Import dependence is however higher for several specialised chemicals, antibodies, antigens, enzymes, specialised proteins etc. due to their unavailability in India. Similarly Cubitainers is also a highly imported product. These products can be focused on for localisation.



Overall Conclusions

India has the potential to become a global player in IVD reagents, owing to a strong manufacturing base in chemicals and an already existing high level of value addition through local manufacturing, and can achieve self-sufficiency in a short to medium time frame:

- Investment in local manufacturing to for various types of raw materials (enzymes, antibodies, antigens, cubitainers, etc)
- More stringent quality standards and quality control to elevate Indian products to global standards.
- Developing an ecosystem of both large players as well as small players who can contract manufacture for large players – thereby creating global scale capacities for key reagents in India.

Medical Equipment

The market for medical equipment in India is estimated at **USD 6.4 Bn in FY22**, representing **53% of the total Indian Medical Device market size**. Medical equipment are specifically used for diagnosis, treatment of disease or rehabilitation and therapy.

Category	Key Products
Medical Equipment	<p>Diagnostic Equipment: Medical Imaging Equipment – X-Ray Machines, CT Scanners, MRI Machines, Ultrasound Machines, Echocardiography Machines, etc., Other Diagnostic Equipment - Patient Scales, Stethoscopes, Dopplers, Pulse Oximetry, etc.</p> <p>Treatment Equipment: Defibrillator, Artificial Dialysis Machines and Haemodialyser, Fetal monitoring systems, Ventilators, Oxygenators, Linear Accelerators, Baby Warmers, CATH Labs, Patient Monitors, etc.</p> <p>IVD Instruments: Immunoassay Analysers such as ELISA readers, CLIA readers, etc., Clinical Chemistry Analysers such as wet chemistry analysers, electrolyte analysers, etc., Automated and Semi-Automated Haematology Analysers, Flow Cytometry Analysers, etc., Molecular diagnostics instruments such as Real Time-PCR systems</p>

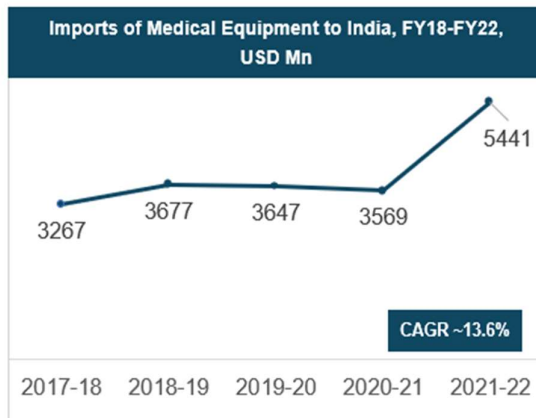
Key trends and Potential Impact driving the Indian Medical Equipment sector

Trend	Description	Potential Impact
Growing Demand for Technologically Advanced Equipment	<ul style="list-style-type: none"> Driven by rising population, increasing healthcare awareness, and technological advancements Need for telemedicine and remote monitoring to drive healthcare adoption in remote areas 	<ul style="list-style-type: none"> Demand growth in smaller towns; Tier 2/3 centers
Government Focus on Creating Integrated Manufacturing Ecosystem	<ul style="list-style-type: none"> Upcoming medical device parks can form the base for component development in high end equipment like Radiology and others 	<ul style="list-style-type: none"> Medical Device parts with integrated infrastructure can be the hub for development of component ecosystem for Equipment e.g. for X-Ray Tubes / High Voltage Generators / Ultrasound Probes/ Detectors / MR Amplifiers / Power Supplies / Coils etc.)

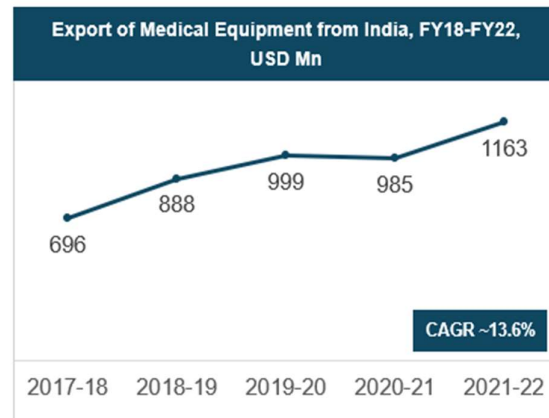
Equipment – Extent of Local Manufacturing

India's imports of medical equipment went up from USD 3267 Mn in FY18 to USD 5441 Mn in FY22, exports have grown almost 1.7x at the same time, showcasing India's growing strength in medical equipment manufacturing. The growth CAGR for both imports and exports have remained similar, pegged at ~13%.

Major equipment players including MNCs and Indian players have set up manufacturing/planning to set up manufacturing in India- especially under PLI scheme.



Source: EEPC India, DGCIS



Source: EEPC India, DGCIS

Medical Equipment (Share of Demand met through Imports: 75-85%)

Prevalence of Local Manufacturing	Level of value-addition
<ul style="list-style-type: none"> • High share of MNC players with limited Indian players • Low scale of local demand Low underlying consumption and healthcare infrastructure penetration reduces the scale of local demand, thereby limiting scope for driving economies of scale through local production • Lack of harmonized quality controls Lack of clarity on specific regulatory issues e.g. QCO directives arising from various ministries regarding sourcing of specific components (applicable to sourcing standalone components rather than as part of the overall equipment) 	<ul style="list-style-type: none"> • Value addition is currently low but is increasing with key components being gradually localised in future (e.g. X Ray Tubes, MR amplifiers, Coils, High Voltage Detectors, Generators, Ultrasound Probes etc.) • Inverted duty structure on imports: Some cases of inverted duty structure still prevalent which impacts competitiveness of local manufacturing • Absence of semiconductor value chain and specific precision components e.g. there is a high share of imports from Japan for components related to IVD devices e.g. precision electronics, advanced optical components, etc.

Overall Conclusions

While there is considerable interest and participation in domestic manufacturing the horizon for achieving high levels of local manufacturing and competitiveness would be long term:

- Significant investment would be required for scaling operations and fostering a robust value chain to increase the competitiveness of local manufacturers
- Strategic interventions would be required to build the required skill sets and knowledge to undertake R&D and technologically advanced operations

Consumables

Medical Consumables is a critical segment comprising a range of disposable and reusable products used for diagnosis, treatment, and patient care. Overall market size is estimated at **USD 3.25 Bn in 2022, constituting ~27% of the overall Medical Devices market in India.**

Category	Key Products
Disposable Items	Needles, Syringes, Catheters, Swabs, Gauze, Wound Dressing, Bandages, etc.
Surgical Supplies	Scalpels, Sutures, Anaesthesia Supplies, Dialysis Supplies
Diagnostic Tools	Test Strips, Blood Collection Tubes, Culture Plates, Etc
Personal Protection	Gloves, Masks, PPE Kits, etc.

Key trends and Potential Impact driving the Indian Consumables sector

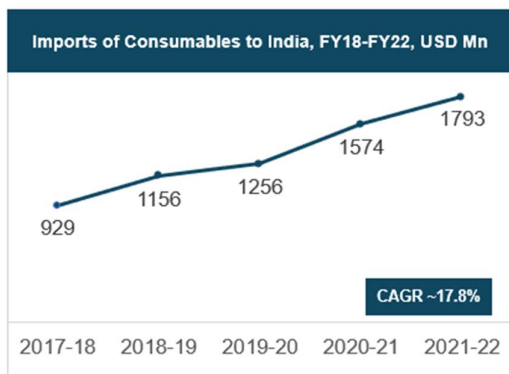
Indian manufacturers drive the production and market share in the consumables and disposables segment. Major manufacturing is being done in India for products like catheters, perfusion sets, extension lines, cannula, feeding tubes, needles, syringes, etc.

Consumables and disposables comprised 47.14% of India's medical device exports in FY22, demonstrating the segment's significant contribution.

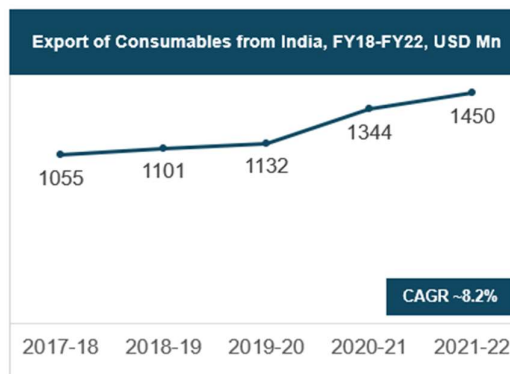
Trend	Description	Impact
Increasing number of hospitals in India	Number of hospitals in India, both public and private, is increasing, with a major focus on providing healthcare accessibility in rural areas. Increasing access to medical facilities, translates to a higher demand for medical consumables	<ul style="list-style-type: none"> • Higher demand of consumables • Growth potential for local manufacturing
Ageing population and disease prevalence	Elderly in India 2021 report estimates 137.9 million elderly people living in India. 23% of the population suffers from multi-morbidities and around 1 in 12 senior citizens suffer from diabetes. The rise of comorbidities and diabetes is expected to boost the consumables sector	<ul style="list-style-type: none"> • Higher demand of consumables like needles, syringes, catheters, etc.

Consumables- Extent of local manufacturing

India's imports of consumables doubled from USD 929 Mn in FY18 to USD 1793 Mn in FY22, whereas exports grew slightly from USD 1055 Mn in FY18 to USD 1450 Mn in FY22. Although India was a net exporter of consumables in FY18, the scenario changed by FY22, with imports exceeding exports.



Source: EEPC India, DGCIS



Source: EEPC India, DGCIS

Consumables
(Share of Demand Met through Imports: 50-60%)

Prevalence of Local Manufacturing	Level of value-addition
<ul style="list-style-type: none"> Dominated by domestic players Major local manufacturing in IV sets, catheters, perfusion sets, extension lines, cannula, feeding tubes, needles, syringes, etc. Import price challenge Cheap imports especially from China impacting the price competitiveness for Indian players. Non-compliance of best practices on usage of consumables, raising concerns on patient safety and product efficacy, also demand 	<ul style="list-style-type: none"> Manufacturing of low-end consumables Manufacturing in India is mainly for the relatively simpler design and technology; Indian players are significant exporters in these products. Some local manufacturing has also commenced for certain high end products like specialty catheters (CVC, PICC etc.) Lack of availability of raw materials India still relies on imports for certain specialised raw materials and consumables that are not available domestically, like fabrics for dialysers, or products which require specialised manufacturing processes such as mid-line catheters or arterial cannulas.

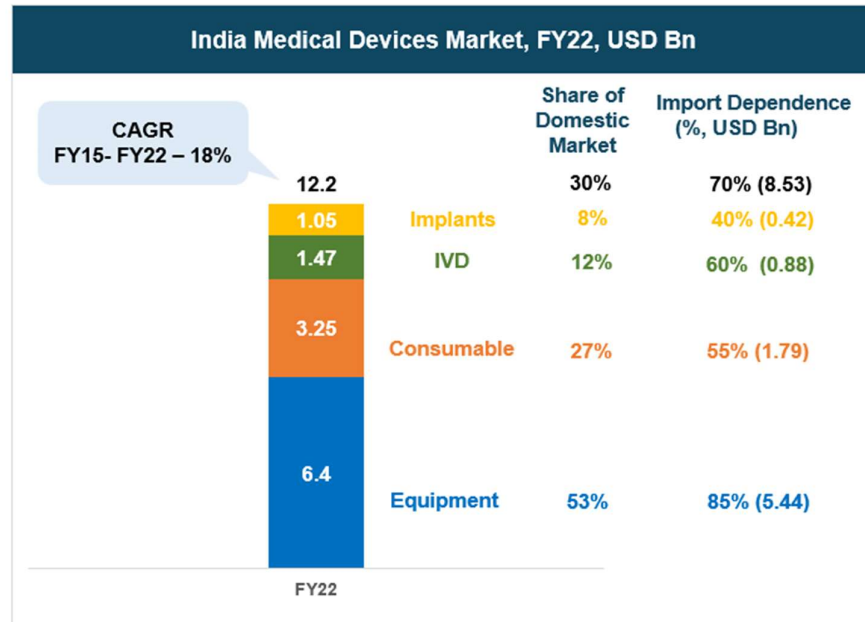


Overall Conclusion

India has the potential to achieve self-sufficiency in consumables in the medium term (5-7 years)

- A robust network of hospitals, clinics, nursing homes, spread across both rural and urban India, will continue to drive market growth.
- Stronger regulatory measures to prevent flooding of market by low-quality imports, and re-usage of disposables.
- Investment requirement to set up facilities for manufacturing specialised raw materials, to reduce import dependence.

Overall Import Dependency of Medical Devices Market



Source: Avalon Consulting Research & Analysis

Medical Device Category	% Share of Imports in Domestic Market	Extent of Local Value Addition for Domestically Manufactured Products
Implants	40%	Low to Moderate
IVD reagents	60%	High
Medical Equipment	85%	Low
Consumables	55%	Moderate to High
Overall	70%	

Along with the USD 50 Bn market size target for FY31 the industry **should aim for a significant reduction in imports from the current levels of 70% and a substantial increase in local value addition in domestically manufactured products.**

Proposed Areas of Intervention / Support Required by Medical Devices Industry – Preliminary Thoughts

Discussions with industry players have elicited a few areas of active intervention / support required for development of the Medical Devices industry. These cut across manufacturing, regulatory, skill development, driving demand etc. ***These are preliminary areas identified and need to be further debated between govt. and industry.***

Desired Outcome	Proposed Areas of Intervention / Support Required by Industry
Robust manufacturing Eco-system including Raw Materials /components/ support facilities etc.	<ul style="list-style-type: none"> • Focused long-term strategy similar to PMP (Phased Manufacturing Program) in mobile phones will encourage component localisation • Focus on localization of key components which require significant investments e.g. X-Ray Tubes / High Voltage Generators / Detectors / MR Amplifiers / Power Supplies / Coils etc. • Focus on other components which are also “low hanging fruits” and simpler to indigenise e.g. antibodies, antigens, and other inputs for IVD reagents. • Addressing specific RM challenges in implants and consumables. • Identify key global component manufacturers and undertake active outreach to them to ‘Make in India’. • Target global EMS players which are already in India – partner with device companies and invite them to set up facilities in Medical Park Cluster
Quality Standards	<ul style="list-style-type: none"> • Achieving globally compliant and harmonised quality standards • Regulations prohibiting re-use of consumables. • Support clinical investigation in India for new medical equipment. • Increased focus on Post Market Surveillance (PMS) by regulatory authorities
Skill and Capability Building	<ul style="list-style-type: none"> • Structured, long-term collaborative partnerships between industry and academia must significantly expand, for example, Govt. institutes e.g. IITs, AIIMS, NIPER etc. for product and technology development • Fast-track implementation of the proposed new center for medical devices research - NIMER • Fast-track implementation of innovative programs like PRIP (Promotion of Research and Innovation in Pharma and MedTech Research) or related initiatives • Strengthen IP laws and fast-track patent grants to promote indigenous technology development. • Establish dedicated innovation hubs alongside upcoming Medical devices clusters with shared facilities and incubation centres. • Focused bridge courses and skill development in product development, manufacturing, QA, Validation etc. • Increasing the number of biomedical engineers in India
Drive Domestic Demand Creation and Support Promotion of Exports	<ul style="list-style-type: none"> • Further clarity required on the local value addition norms to qualify under PPO – calibrate further based on industry feedback to encourage domestic players. • Increase healthcare spending to 5% of GDP. • Increasing the underlying infrastructure in PHCs and promoting the usage of critical medical devices in such centers • Increased focus on PPP basis for medical equipment, especially in the Tier 2/3 city hospitals • Support to industry for marketing and promotion of India made products in exports market; financial support for markets with complex product registrations / high registration costs

Learnings from Other Major Medical Device Hubs

Several countries like Ireland, Singapore, China, etc. have made major strides in the Medical Devices manufacturing space and can thus provide a vision and roadmap for the Indian Medical Device manufacturing sector. Ireland has focussed on a cluster-based growth, with policies encouraging establishment of Medical devices clusters in the country. Singapore however has grown by laying an emphasis on Research and Development and growth by leveraging technology.

China, on the other hand, has received a strong push from the government to improve local manufacturing, keep imports at low levels and push for exports. The following table gives a brief idea on the 3 countries and their strategies for growth:

Factors	Ireland	Singapore	China
Key Growth Theme	Cluster-based growth	R&D and Technology-driven growth	Growth through Government push
Talent Availability	<ul style="list-style-type: none"> Ireland has a significant talent pool, with around 40,000 working in the ~300 Medical devices companies. There is also industry-academia alignment with universities that offer specific courses in medical technology, such as University of Galway. 	<ul style="list-style-type: none"> Already a Medical devices hub for the ASEAN area, with a large pool of talent at its disposal and consistent government efforts to upskill workers through programs like SkillsFuture. \$100 million in budgeted support from the government to help businesses scale and invest in skill development. 	<ul style="list-style-type: none"> Government promotes cross-functional strategic collaboration between various companies, through industry associations, networking events, etc., leading to knowledge cum technology exchange and talent development
Government Support	<ul style="list-style-type: none"> Policies aimed at creating and promoting Medical devices clusters around the nation, where institutions, government agencies, and businesses involved in the value chain are all at proximity to each other. Low tax rate of 12.5% for businesses with annual revenue under USD 750 million. 	<ul style="list-style-type: none"> Strong emphasis on regulation and implementation, with Class A to Class D medical devices and standards aligned with the Global Harmonization Task Force (GHTF) 	<ul style="list-style-type: none"> Govt. procurement policies favouring procurement of medical devices from local manufacturers. Regulatory push towards fast-tracking medical device patents
Research and Development	<ul style="list-style-type: none"> Encouragement through grants and 25% tax credit for R&D purposes 	<ul style="list-style-type: none"> Top 25 medical device MNCs established their R&D facilities in Singapore, along with best-in-class universities. Placed second in the Global Innovation Index (2022) for economies in Asia 	<ul style="list-style-type: none"> Ministry of Science and technology supported Mindray and Lepu to build Diagnostic and Heart Disease Research Centres Shanghai launched 5 industrial parks which will promote biomedical innovation research

Factors	Ireland	Singapore	China
Intellectual Property (IP) Protection	<ul style="list-style-type: none"> Strong legal framework with patents, trademarks, copyrights, and trade secrets protected. Efficient enforcement mechanisms through courts and customs authorities. Active participation in international IP treaties (e.g., WTO's TRIPS Agreement) 	<ul style="list-style-type: none"> Robust legal framework with comprehensive IP laws and enforcement mechanisms. Efficient Intellectual Property Office of Singapore (IPOS) 	<ul style="list-style-type: none"> Evolving legal framework with increasing emphasis on IP protection. Government efforts to improve enforcement and align with international standards, but potential challenges remain
Market Access	<ul style="list-style-type: none"> Easy access to the European market and other developed economies due to EU regulations and trade agreements 	<ul style="list-style-type: none"> Strategic location for Southeast Asia and access to regional markets through free trade agreements 	<ul style="list-style-type: none"> Large domestic market with significant growth potential. - Access to global markets through increasing trade partnerships

Thus, the pathways adopted by these countries provide various pointers for India:

- Cluster-based approach for Medical Devices Manufacturing with easy access to academia and government agencies.
- Free Trade Zones to attract foreign investments.
- Emphasis on R&D and skill development while working with international organizations.
- Stable regulatory standards that are applied nation-wide.
- Quality Standards compliant with international standards.
- Robust system for protection of Intellectual Property.
- A well-connected network infrastructure, including roadways, railways, waterways and airways.

A Framework for Identifying Strategic Interventions Across Medical Device Products

Avalon Consulting has developed an assessment framework to identify strategic directions that can be taken for certain key medical devices within various product segments from an Indian context. The evaluation comprises the following dimensions:

- **Attractiveness for India (Is the product “Attractive” for India?)**
- **India’s Ability to Compete (What is India’s Competitive Advantage / Right to Win in the product?)**

Attractiveness for India

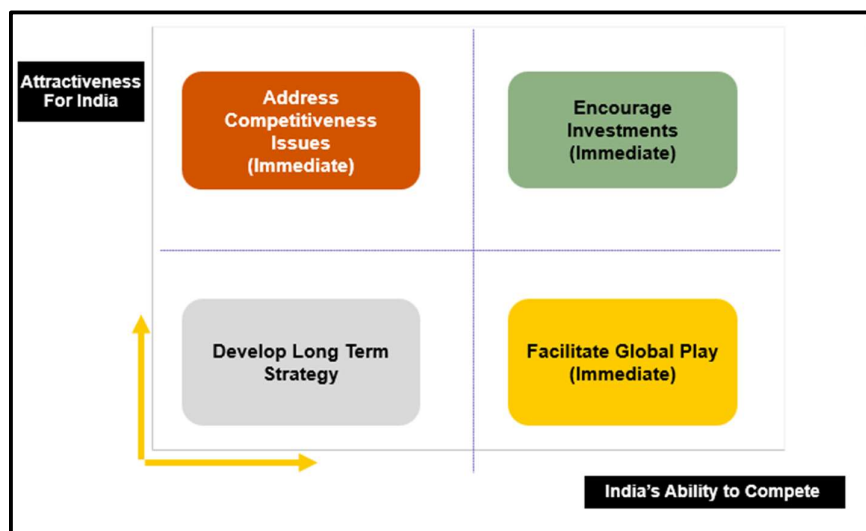
- **Potential for import substitution** – What is the extent of imports?
- **Need for Improving Self-Sufficiency** – How critical is the product for India’s healthcare needs AND /OR what is the extent of dependency on imports?
- **Potential for Exports** – What is the extent of exports?

India’s Ability to Compete

- **Availability of Critical Inputs for Production** – What is the current level of RM availability in India?
- **Access to Technology and Skills** – Does India have access to technology, the required skills to develop these products and are there IP challenges?
- **Global Market Access** – How difficult it is to tap export markets for these products – are product registrations challenging or expensive? Are there other entry barriers for exports?

Based on the above assessment and inputs from experts within the Indian medical devices sector, each of the key products have been fitted into a 2X2 matrix as indicated below:

“Attractiveness -Ability to Compete” Framework – a Visual Representation



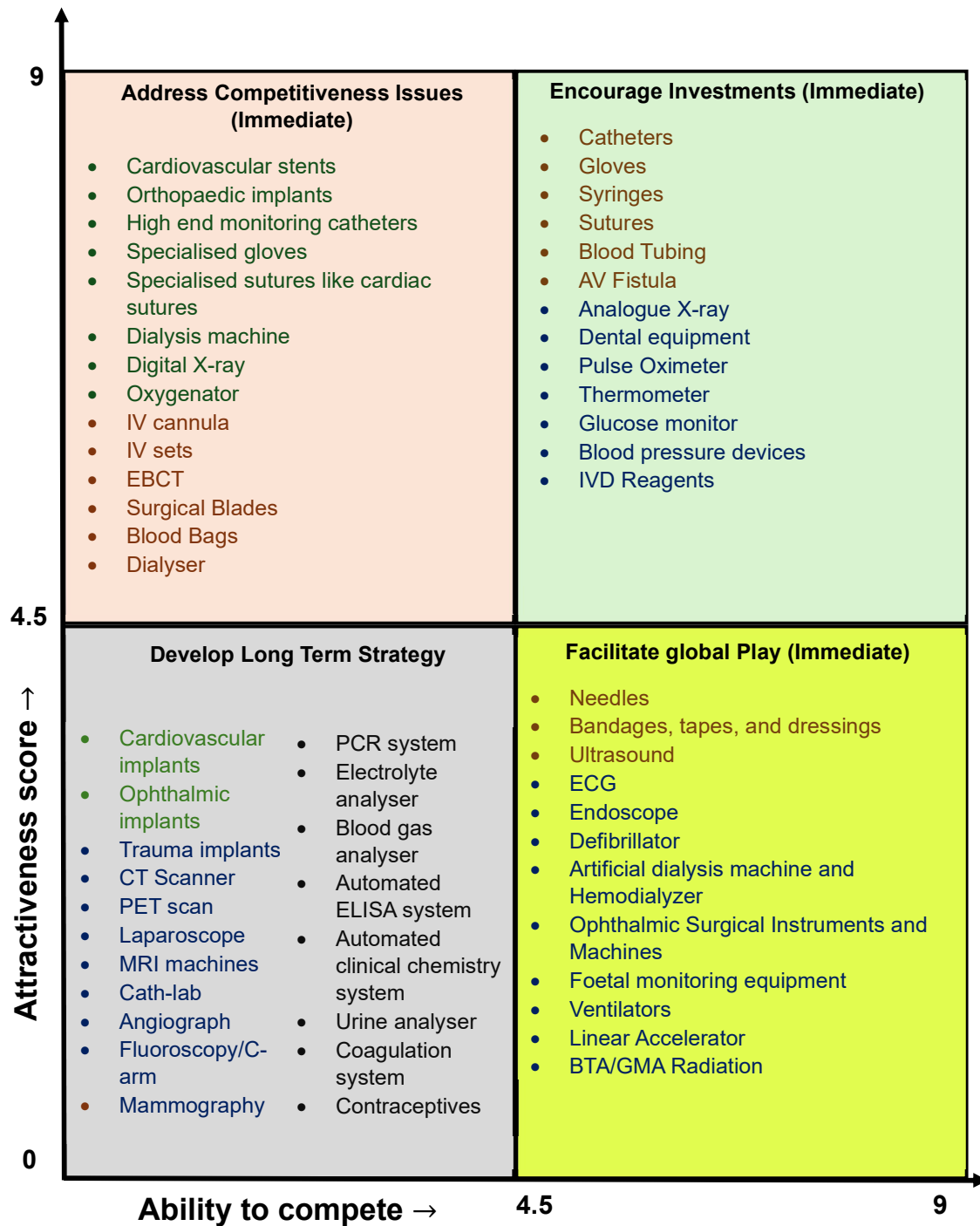
Source: Avalon Consulting Research and Analysis

Note: Scoring framework used for the above evaluation is presented in the annexure.

There are broadly 4 strategic interventions that can be taken, as also indicated in the representation above at a high level, for products falling in any of the quadrants in the 2X2 attractiveness-do ability framework as tabulated below:

Attractiveness for India	India's Ability to Compete	Strategic Intervention
High	High	<ul style="list-style-type: none"> • Low hanging fruits for localisation • Should be immediate focus for encouraging investments
High	Low	<ul style="list-style-type: none"> • India has a low competitiveness for these medical devices • Measures to be taken to increase overall competitiveness
Low	High	<ul style="list-style-type: none"> • Focus on exports / global play
Low	Low	<ul style="list-style-type: none"> • Build a long-term strategy for product-focus and capability development

For certain key medical devices across product segments, the above framework applied based on extensive interactions with the industry is highlighted in the next page.



The above evaluation provides a starting point for developing a granular data-driven decision making on how to prioritise products / categories for support and intervention by government. We look forward to further discussions and consultations between industry and government to help build on the strong foundation already prepared over the last few years and to further identify focus areas and priorities for the Medical Devices industry.

About ASSOCHAM

The Associated Chambers of Commerce & Industry of India (ASSOCHAM) is the country's oldest apex chamber. It brings in actionable insights to strengthen the Indian ecosystem, leveraging its network of more than 4,50,000 members, of which MSMEs represent a large segment. With a strong presence in states, and key cities globally, ASSOCHAM also has more than 400 associations, federations, and regional chambers in its fold.

Aligned with the vision of creating a New India, ASSOCHAM works as a conduit between the industry and the Government. The Chamber is an agile and forward-looking institution, leading various initiatives to enhance the global competitiveness of the Indian industry, while strengthening the domestic ecosystem.

With more than 100 national and regional sector councils, ASSOCHAM is an impactful representative of the Indian industry. These Councils are led by well-known industry leaders, academicians, economists, and independent professionals. The Chamber focuses on aligning critical needs and interests of the industry with the growth aspirations of the nation.

ASSOCHAM is driving four strategic priorities - Sustainability, Empowerment, Entrepreneurship and Digitisation. The Chamber believes that affirmative action in these areas would help drive an inclusive and sustainable socio-economic growth for the country.

ASSOCHAM is working hand in hand with the government, regulators, and national and international think tanks to contribute to the policy making process and share vital feedback on implementation of decisions of far-reaching consequences. In line with its focus on being future-ready, the Chamber is building a strong network of knowledge architects. Thus, ASSOCHAM is all set to redefine the dynamics of growth and development in the technology-driven 'Knowledge-Based Economy'. The Chamber aims to empower stakeholders in the Indian economy by inculcating knowledge that will be the catalyst of growth in the dynamic global environment.

The Chamber also supports civil society through citizenship programmes, to drive inclusive development. ASSOCHAM's member network leads initiatives in various segments such as empowerment, healthcare, education and skilling, hygiene, affirmative action, road safety, livelihood, life skills, sustainability, to name a few.

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