Poised for Takeoff:
MedTech in India

MAY 2026

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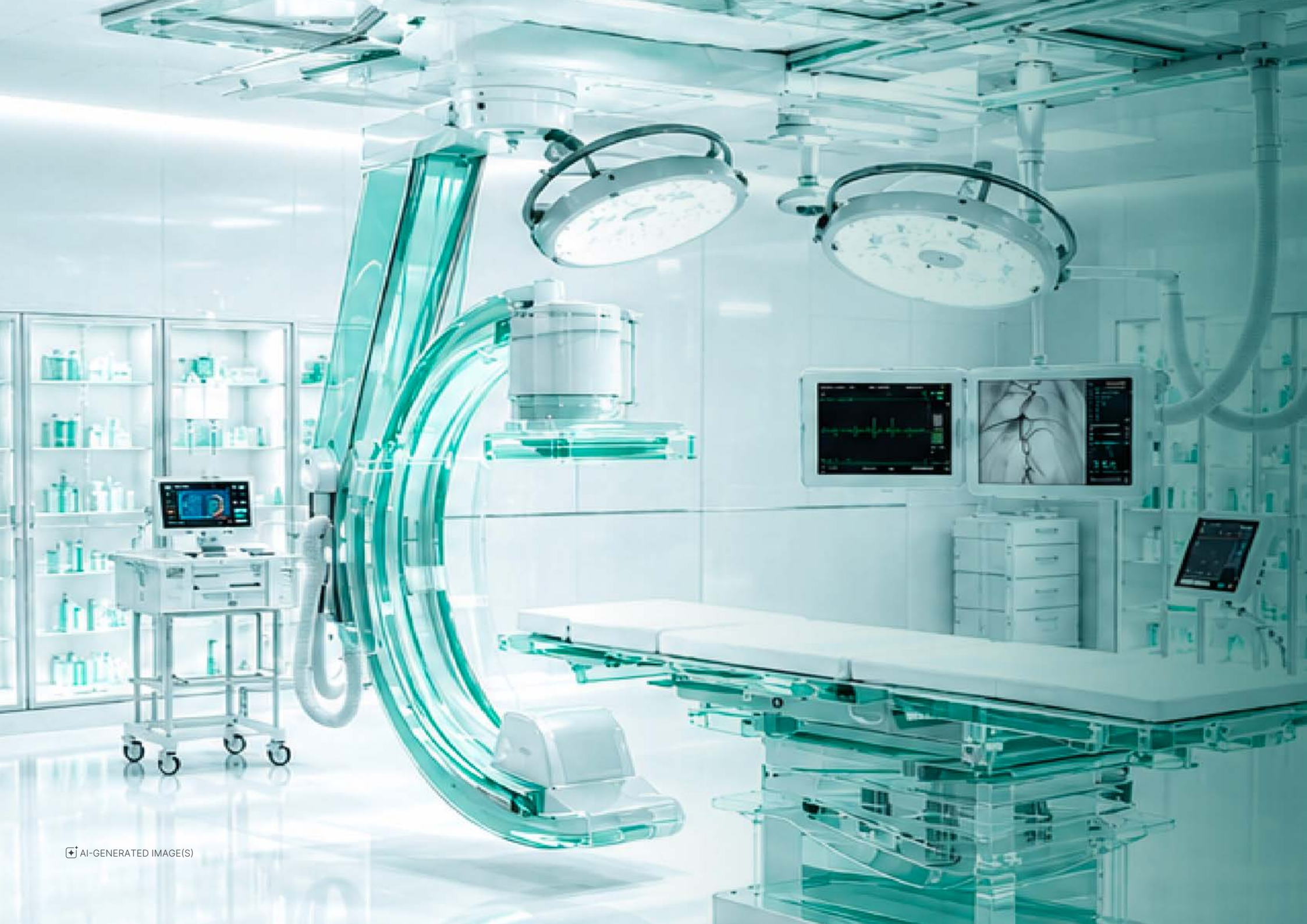

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The Association of Indian Medical Device Industry (AiMeD) represents and advances the interests of India's medical device manufacturers, innovators, and ecosystem partners. As a leading industry voice, AiMeD works to strengthen India's MedTech sector by supporting domestic manufacturing, improving global competitiveness, and helping to shape dialogue across policy, regulation, quality, exports, and market access.

AiMeD brings together diverse stakeholders across the medical device value chain—from MSMEs and start-ups to established manufacturers—to promote affordable, high-quality, India-made medical technologies. Through industry convening, technical inputs, and ecosystem collaboration, AiMeD supports the sector's ambition to build credible local capabilities, reduce import dependence, expand exports, and position India as a trusted global MedTech manufacturing and innovation hub.

The Kalam Institute of Health Technology (KIHT) is India's first institute dedicated to medical technology, created to bridge the gap between healthcare needs, scientific research, and industry-led innovation. KIHT works at the intersection of academia, industry, and public health to identify critical technology gaps, support applied research, and help to translate promising ideas into market-ready medical technologies.

With a focus on affordable, accessible, and locally relevant innovation, KIHT supports India's broader ambition to strengthen domestic MedTech capabilities. By enabling collaboration across researchers, clinicians, manufacturers, and policymakers, KIHT helps to accelerate the development of solutions that can improve patient care, build manufacturing depth, and advance India's role in the global medical technology ecosystem.

Foreword

India is approaching a pivotal phase in the evolution of its MedTech sector, with multiple structural drivers converging to shape the next decade of growth. The sector is witnessing momentum: modern factories, advanced R&D labs, expanding exports, and Indian enterprises steadily moving up the value chain. A ~$16–20 Bn market with ~$4 Bn in exports reflects a shift from aspiration to capability.

Indian manufacturers today demonstrate strength across consumables, diagnostics, implants, critical care, and select high value devices. At the same time, global competitiveness is increasingly associated with capabilities beyond assembly, including components, materials, testing, validation, clinical evidence, and regulatory excellence. Several ecosystem constraints remain, particularly for MSMEs, including sequential approvals, inverted duties, limited testing infrastructure, high certification costs, and constrained access to capital.

These challenges remain addressable. With coordinated policy action—focused on value addition, export readiness, and domestic adoption of Indian innovations, India has the potential to emerge as a MedTech growth story comparable to leading global markets.

This report outlines a set of themes and pathways. For AiMeD, the evolving landscape reflects a focus on quality, trust, and innovation.

The MedTech ecosystem is evolving toward the delivery of world class, patient safe, internationally benchmarked medical technology from India to the world.

As the sector evolves, the next chapter of global MedTech is expected to see greater contribution from emerging hubs, including India.

Shri Rajiv Nath
Forum Coordinator,
AiMED

Foreword

The distance between ideation and impact is traversed not by invention alone, but by the ecosystem that sustains and scales it.

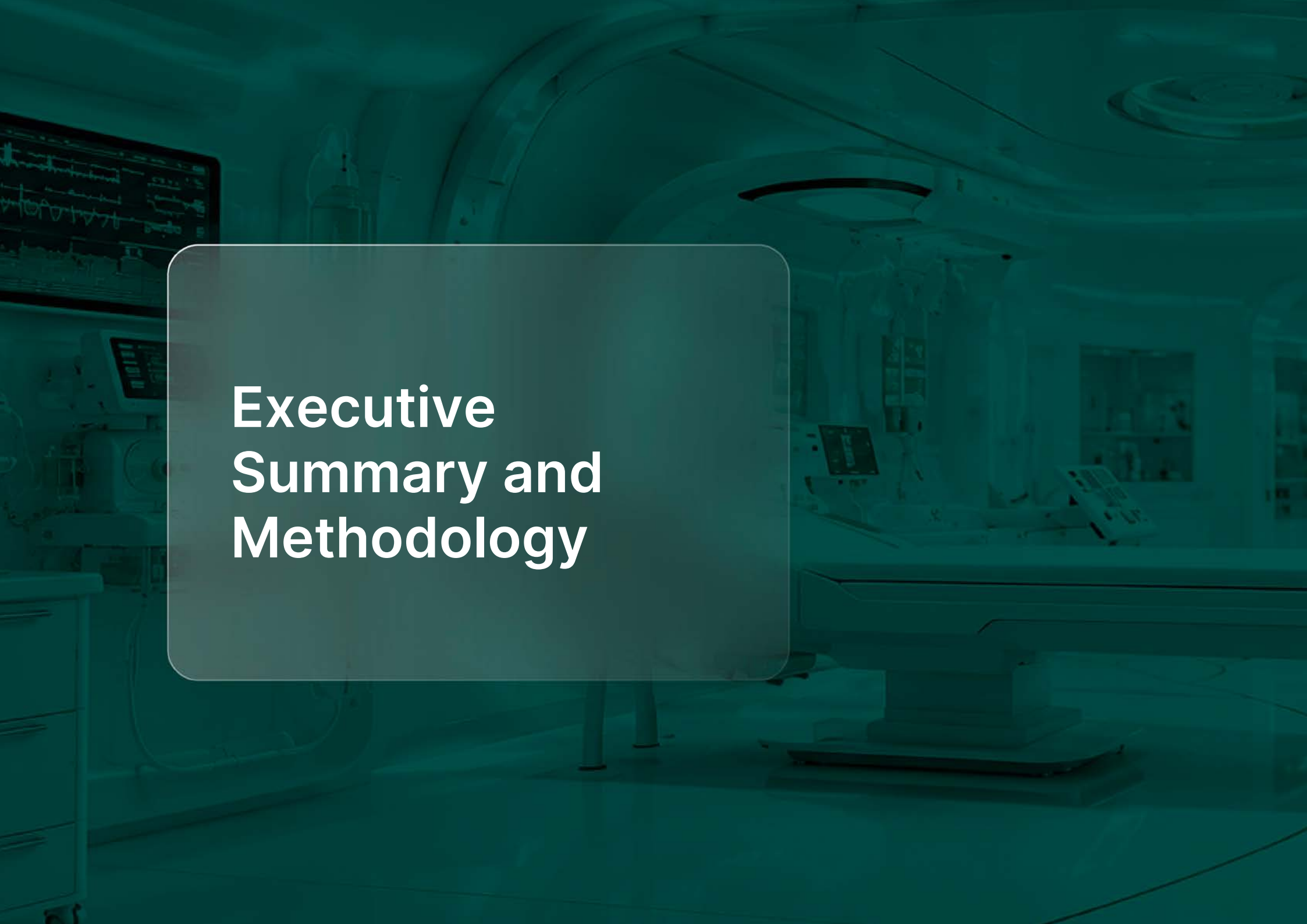
A medical device is not conceived in isolation, it is the culmination of a deeply interdependent and holistic ecosystem, exemplified by the Andhra Pradesh MedTech Zone (AMTZ). Between a clinical need and a product in the hands of a doctor or patient lies a complex and often non-linear continuum—from ideation to commercialisation. This pathway is shaped by iterative design, rigorous validation, regulatory navigation, and sustained collaboration.

India stands today at a pivotal inflection point. The nation has cultivated formidable strengths—entrepreneurial dynamism, engineering acumen, clinical excellence, a vast domestic market, and an expanding manufacturing base. Premier institutions such as the Andhra Pradesh MedTech Zone (AMTZ) and the Kalam Institute of Health Technology (KIHT) have demonstrated how shared infrastructure, advanced testing capabilities, incubation, skilling, and policy facilitation can significantly attenuate barriers and catalyse innovation. Yet, as this report astutely underscores, India's challenge is increasingly one of translation rather than capability. In just seven years, AMTZ has evolved from a visionary initiative into the world's largest integrated medical device manufacturing ecosystem, catalysing innovation, consolidating end-to-end capabilities, and positioning India as a formidable force in the global MedTech landscape.

The dual emphasis on "Make in India" and "Innovate in India" is both prescient and imperative. India is no longer preparing for ascent; it stands at the cusp of accelerated growth, contingent upon cohesive ecosystem alignment. This momentum could be anchored in the strengthening of end-to-end value chains and the indigenisation of critical components, ranging from electronics and sensors to precision materials and advanced manufacturing inputs. Simultaneously, strategic leverage of Free Trade Agreements (FTAs) and calibrated regulatory harmonisation will be essential to unlock expanded access to global markets. Together, these enablers will not only enhance competitiveness but also position India as a resilient and globally integrated hub for medical device innovation and manufacturing.

India's MedTech trajectory will ultimately be defined not by sporadic ingenuity, but by our collective ability to architect a resilient, interoperable ecosystem that transforms innovation into enduring, equitable, and scalable impact.

Dr. Jitendra Sharma
Executive Director,
KIHT



Executive Summary and Methodology

Executive summary (I)

India's MedTech market is at a pivotal inflection point, with the full opportunity estimated at ~$ 20 Bn today

Significant momentum has built up over the past few years:

+ **Rising local share:** domestic manufacturing has more than doubled from ~20% (2022) to ~45% (2025) of domestic demand, growing at ~40% + CAGR
+ **Active policy push:** ~₹3,500 Cr PLI scheme has commissioned 24 projects across 57 products; 4 MedTech parks underway with AMTZ as India's first and most mature anchor
+ **Strong capital flows:** ~₹11,000 Cr deployed across 230+ PE/VC and corporate deals in 2025; India's first dedicated MedTech fund (MedArtha) launched by AMTZ in March 2026
+ **Favourable cost and trade position:** labor cost is 60–80% below US and 40-50% below China, FTAs in various stages with UK/NZ/Oman with potential to provide access to large markets, and global supply-chain rebalancing are unlocking new MNC commitments to India

Looking ahead, a ~$ 80+ Bn opportunity possible by FY2035, through three distinct pillars:

+ **'India for India' (~$8 Bn today → $45–48 Bn by 2035):** Serve growing domestic demand and replacing imports with local products. Equipment and consumables are immediate 'seize now' plays, IVD and devices could be scaled next
+ **'Export-IP led manufacturing' (~$4 Bn today → $16–18 Bn by 2035):** Build own IP-led brands and scale exports
+ **'Contract manufacturing' (nascent today → ~$7 Bn by 2035):** Design, manufacture, and assemble for global MNC OEMs as supply chains diversify; leverage existing strengths in software, sub-assembly, and polymer components

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Executive summary (II)

‘Innovate in India’ could be another powerful growth engine. However, our starting position is a not very strong

+ **India holds ~3% of MedTech patents, with <10% filed domestically;** <1% of US Food and Drug Administration (FDA) approvals (2010–25) are from Indian firms—all via the 510(k) “substantially equivalent” route—indicating limited cutting-edge innovation
+ **Indian MedTech firms spend 2–4% of revenue on R&D,** versus 10–15% in the U.S. and 15–20% in China
+ **Most MedTech MNCs in India are still commercially focused;** only a few—such as GE HealthCare, Siemens Healthineers, and Philips—have scaled end-to-end product design for global markets, unlike pharma where ~50% of top MNCs run innovation-led GCCs in India

Encouragingly, green shoots of innovation are emerging as capital, policy, and ecosystem capabilities increasingly converge.

+ **Public and private R&D funding are converging;** ₹750 Cr ANRF, ₹5,000 Cr PRIP, and ₹1 lakh Cr RDI funds (with MedTech as a focus), alongside PE/VC investment scaling over 6x from $180 Mn (2019) to $1.25 Bn (2025)
+ **Indian firms are emerging as global challengers** in high import-dependent segments—such as Voxelgrids (helium-free MRI), SS Innovations (soft-tissue surgical robot), and Meril (MISSO surgical robot)

Several structural barriers must be addressed to fully realize the potential of both “Make in India” and “Innovate in India.”

+ **Components and RM supply ecosystem:** Key components and raw material remain import-dependent, also an inverted duty structure in select items erodes the viability of domestic manufacturing
+ **Regulatory complexity:** Multiple NOCs, sequential approvals, classification ambiguity, and limited alignment with EU/US FDA frameworks delay approvals and exports; there is no dedicated pathway for breakthrough or innovative devices
+ **Market access friction:** Slow public procurement, technical specifications favoring incumbents, fragmented clinical validation infrastructure, and limited industry–academia collaboration constrain market entry and scale-up
+ **Some perception gaps for MNCs regarding IP protection in India**
+ **Capital and talent gaps:** Scale capital limited especially for MSMEs; domain gaps in advanced imaging, diagnostics, and device design

Executive summary (III)

Realising India's MedTech potential will require coordinated action across four priority themes, with aligned efforts from central government, state government, industry, hospitals and academia

Theme 1: Build an Atmanirbhar value chain ecosystem

+ Incentivise global Tier-1 component and raw material suppliers to **establish manufacturing bases in India, and rationalise inverted duty structures** on critical inputs such as detectors, sensors, and medical-grade plastics
+ Consider developing a **hub-and-spoke testing and validation infrastructure** aligned with FDA and EU MDR standards
+ Consider mandating **~50% domestic value addition in government providers** and domestic device pilots with leading hospitals

Theme 2: Strengthen policy and regulatory enablement to accelerate approvals and exports

+ **Single-window digital approval portal** with defined SLAs; notified bodies for Class C device inspections
+ Pursue **MRAs with ASEAN/EU** and accept FDA/CE clinical data with defined local bridging studies
+ **Fast-track pathways for breakthrough and indigenous devices;** secure preferential rules of origin in FTAs (ASEAN/EU/GCC) and enable low-cost export credit

Theme 3: Attract MedTech OEMs and Contract Development and Manufacturing Organisations (CDMOs) to India through structured engagement

+ **Proactively communicate the 'India advantage'** to identified priority players via structured outreach
+ **Set up high-level government taskforce engaging priority OEMs/ CDMOs** with tailored incentive packages (PLI + state incentives + land + utilities + regulatory fast-track)
+ **Link incentives to depth of domestic value addition** rather than final assembly

Theme 4: Strengthen foundational enablers around talent and capital

+ **Attract Indian-origin MedTech professionals;** launch national programs at National Institute of Pharmaceutical Education and Research (NIPER) and AMTZ in imaging, implants, and diagnostics
+ **Co-design industry-relevant curricula with MNCs** covering design, quality, and compliance
+ Revise **PLI thresholds for broader MSME participation;** establish a **dedicated innovation fund** for clinical evidence with outcome-linked financing

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Our findings are grounded in structured primary research and triangulation

More than 30 interviews across manufacturers, MNC and GCC leaders, policy bodies, incubators, and sector experts

Primary research

Structured consultations to capture on-the-ground bottlenecks and opportunities

Industry inputs

Market and company sources

India MedTech reports, company disclosures, company websites and news, and peer-market benchmarks

Government and policy sources

DoP, CDSCO, PIB, DGCI&S and EXIM National Medical Devices Policy 2023, PLI-MD, PRIP, SMDI, KIHT, and MedTech Mitra

Secondary research

Data and insights triangulated via multiple sources and aligned with external evidence; directional views kept as stakeholder perspectives unless fully triangulated

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Key definitions| Four major MedTech segments categorised into 11 sub-segments

Non exhaustive

		India market size ($Bn)	India exports ($Bn)		
Equipment					
Large capital equipment	X-ray, CT, MRI, ultrasound, fluoroscopy, mammography, nuclear imaging, surgical robotics	3.2	1.5	Wipro	Skanray
Monitoring, life support, and critical care	Bedside monitors, ECG, pulse oximetry, ventilators, anaesthesia, pumps, defibrillators, ICU monitoring systems	3.6		Mindray	Allengers
Hospital furniture and surgical instruments	Tables and lights, electrosurgical equipment, sterilisation/ CSSD, physio/rehab equipment, beds and other equipment	1.3		General Electric	Siemens Healthineers
				BPL Medical Technologies	
Implants and other speciality devices					
Orthopaedic and musculo-skeletal implants/devices	Trauma, joints, spine, fixation systems	0.8	0.4	Medtronic	Abbott
Cardiovascular and interventional devices	Stents, balloons, catheters, guidewires, valves, structural heart devices	0.7		Stryker	Olympus
Other implantable and speciality therapeutic devices	Ophthalmic, dental, neurovascular, neuromodulation, ENT, GI/urology speciality devices, hernia mesh, others	1.5		Boston Scientific	Karl Storz Se & Co.
				Coloplast	Meril
IVD					
Central-lab reagents, assays, and test consumables	Reagents, kits, cartridges, calibrators, controls used on lab-based systems	1.5	0.2	Transasia	Molbio
Central-lab analysers, platforms, and lab automation	Chemistry, immunoassay, haematology, molecular analysers; automation systems; installed-base lab platforms	0.2		Roche	Meril
Point-of-care, rapid, and self-testing IVD	Portable analysers, rapid test kits, bedside systems, decentralised testing, home/self-test products	0.4		Agappe	Trivitron
Consumables					
General hospital consumables and disposables	Syringes, needles, gloves, tubing, IV sets, dressings, basic wound care, infection-prevention consumables	1.4	1.9	Polymed	Ramsons Group
Procedure and speciality disposables	Anaesthesia circuits, dialysis disposables, endoscopy accessories, higher-value single-use supplies and others	1.6		HMD	Harsoria
				Lifelong	Medisafe

0-0.5 | 0.5-1 | 1-2 | >2

Total consumption $16 Bn

Total exports $4 Bn

Source: Secondary research; EXIM data; BCG analysis

Right to win assessment methodology | We evaluated the right to win for manufacturing and innovation at each sub-segment level

Manufacturing right to win

Manufacturing track record and scale today
Maturity of domestic production and ability to manufacture at scale with consistent quality

Labour intensity
Magnitude and applicability of labour cost advantage

Ability to create the component ecosystem
Import dependence on key components and breadth of local supplier ecosystem

Access to IP (Indigenous/Partners)
Extent and nature of IP access and depth of engagement with partners

Innovation right to win

Talent and knowledge base
Breadth and depth of capabilities in different domains and ability to commercialise research

Testing and validation infrastructure
Availability and maturity of shared certification and validation infrastructure

Regulatory ecosystem
Policy support and alignment with regulatory systems

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SECTION 1

India’s MedTech Moment is Now


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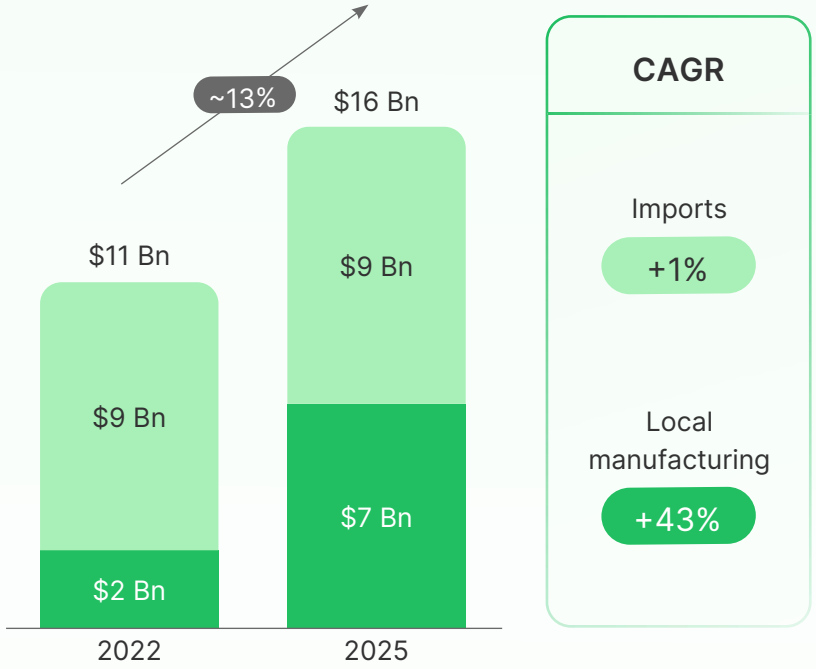
MedTech in India is at an inflection point with a large headroom for growth

Rising local share in domestic demand

India MedTech market



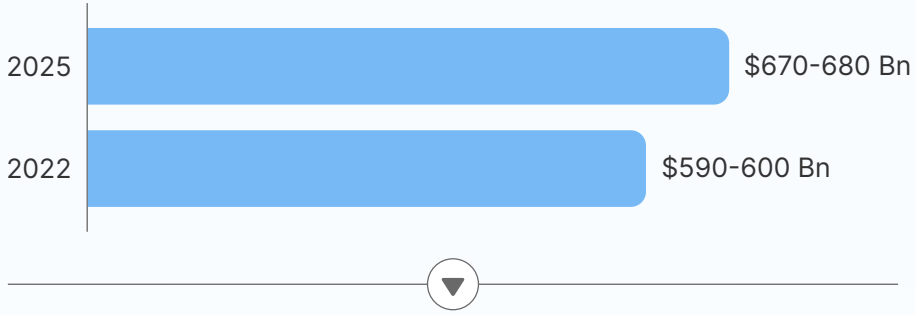
CAGR

Imports
+1%

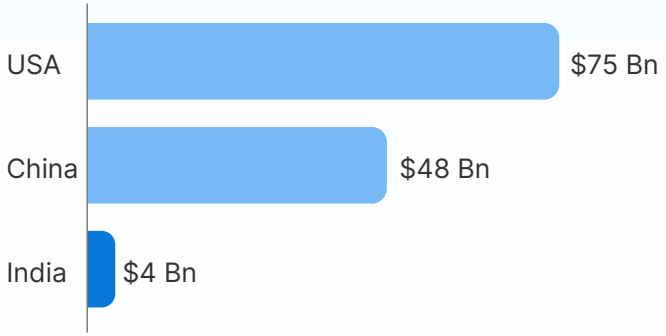
Local manufacturing
+43%

Large headroom to grow exports from India

MedTech market



Global MedTech exports



Global share

~19%
~6%
~1%

Source: Secondary research; EXIM data; BCG analysis

We have seen a marked uptick in activity and momentum in the past few years

Structural demand drivers

Macro foundation:
Fastest-growing major economy, 3.3% of GDP as healthcare spend, high out-of-pocket (OOP) share (45-50%)

Disease burden:
10+ Cr diabetics, 15 lakh cancer cases per year

Insurance coverage:
43+ Cr PM-JAY cards issued, 36,000 hospitals covered of which 40-45% are private

Infrastructure build:
₹64,000 Cr+ outlay to strengthen hospital capacity

Policy and supply shifts

Infrastructure build:
AMTZ, India's first MedTech park; four other parks approved

Policy shift:
National Medical Devices Policy in 2023 and focus on "Make in India" procurement

Financial incentives:
₹3,420 Cr PLI for Medical Devices - 57 products and 24 projects commissioned

Innovation and investment:
+ **Government incentives** via PRIP and Maha MedTech
+ 100% automatic FDI route
+ MedTech Mitra launched to provide end-to-end support and regulatory guidance

Capital flows

~₹2,000 Cr invested across seven PE deals; ~₹8,660 Cr invested across 90+ VC deals; **~₹280 Cr of corporate and individual capital** infused across 135+ deals in 2025

KKR acquired Healthium for ~₹7,000 Cr and is deploying ₹1,350-1,800 Cr additional capital to scale the platform

India's first dedicated MedTech fund launched by AMTZ and MedArtha capital

Rising exports

Supply chain rebalancing: Deepening MNC commitment to India owing to manufacturing base diversification and favourable tariff positioning

Export boost: FTAs with the UK, NZ, and Oman in various stages of implementation are expected to provide greater access to markets for exports

Domestic players as challengers: Local innovation in high import-dependent categories

Source: World Bank; IMF; National Health Authority (PM-JAY); ICMR; WHO; Ministry of Health and Family Welfare; ABDM Mission; US International Trade Administration; Ministry of Commerce (FTA/CEPA updates); Invest India; industry reports; company disclosures; secondary research; BCG analysis

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"Make in India" and "Innovate in India" **are two distinct opportunities**

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Make in India (Immediate)

Deep dive in section 2

Three archetypes	
India for India	Serve domestic demand and replace imports with indigenised products
Export-IP led manufacturing	Build Indian-origin brands for markets (US/EU, LMICs)
Contract manufacturing	Design, manufacture, and/or assemble for MNCs

Innovate in India (Medium-to-long term)

Deep dive in section 3

Two pathways	
MNC-led innovation	MNCs are increasing the depth of presence in India with GCCs and innovation centres
Indian firm-led innovation	Indian firms are building products to solve Indian problems while setting standards

SaMD bridges 'Make' and 'Innovate' in India: Regulated software for global OEMs, Indian-origin digital devices for global markets

Over the next decade, each opportunity will unfold across MedTech segments

SaMD: Cross-cutting digital layer across device segments[2]

	Equipment	Implants and other speciality devices	IVD	Consumables
Capture strong spaces Double down on strengths and increase depth of expertise	Hospital furniture and surgicals Market: $32 Bn ●		Point of care, rapid and self-testing IVD Market: $27 Bn ●●	General hospital consumables and disposables Market: $114 Bn ● Procedure and speciality disposables Market: $128 Bn ●●
Scale the nascent stars Specific interventions could improve capabilities in the medium term	Monitoring, life support and critical care Market: $130 Bn ●●	Orthopedic and musculoskeletal implants/devices Market: $94 Bn ●●	Central-lab reagents, assays, and test consumables Market: $112 Bn ●	
Invest in select big bets Low RTW currently but big opportunity to consider	Large capital equipment[1] Market: $96 Bn ●	Cardiovascular and endovascular/ intervention devices Market: $92 Bn ●●		

1. Current focus on India and emerging economies, India RTW in developed economies would take a longer period; **2.** SaMD is most directly relevant in equipment, IVD, implants and speciality devices, and is a strong India right-to-win given its deep software, AI, data and engineering talent base. In consumables, it appears selectively as a software layer for clinical decision support, monitoring, usage guidance and workflow optimization
Note: Market numbers are 2030 global estimates; RTW: Right to win

● Manufacturing RTW ● Innovation RTW

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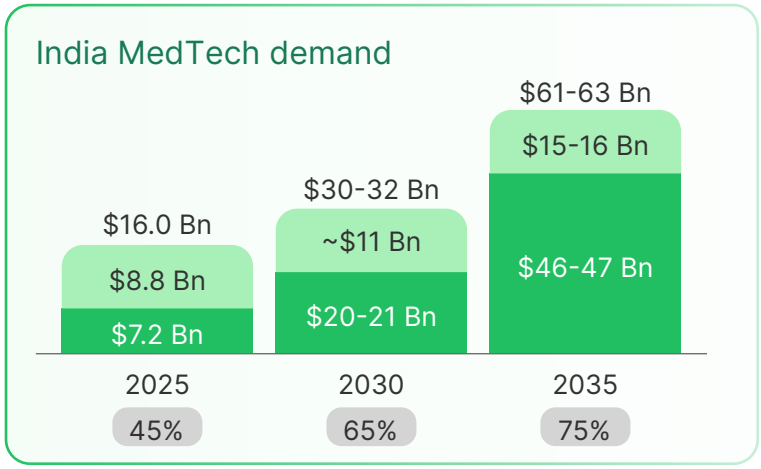
Together, a $41-44 Bn opportunity by 2030 growing to $83-89 Bn by 2035

India for India



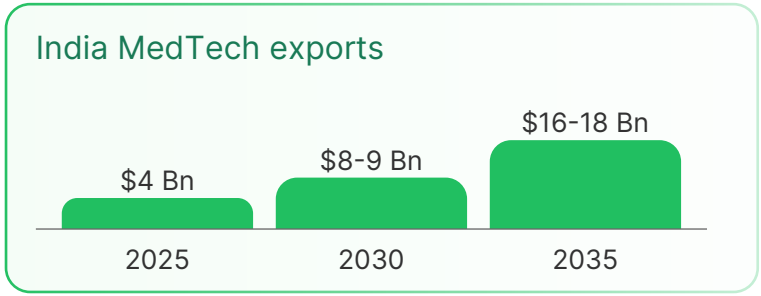
CAGR

~5-6%

20-21%

Domestic share in consumption (%)

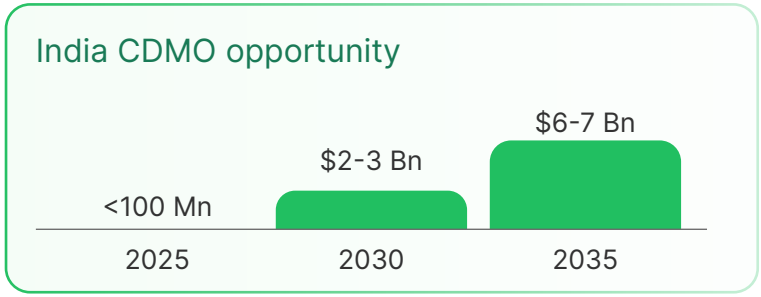
Export-IP led manufacturing



CAGR

15-16%

Contract manufacturing



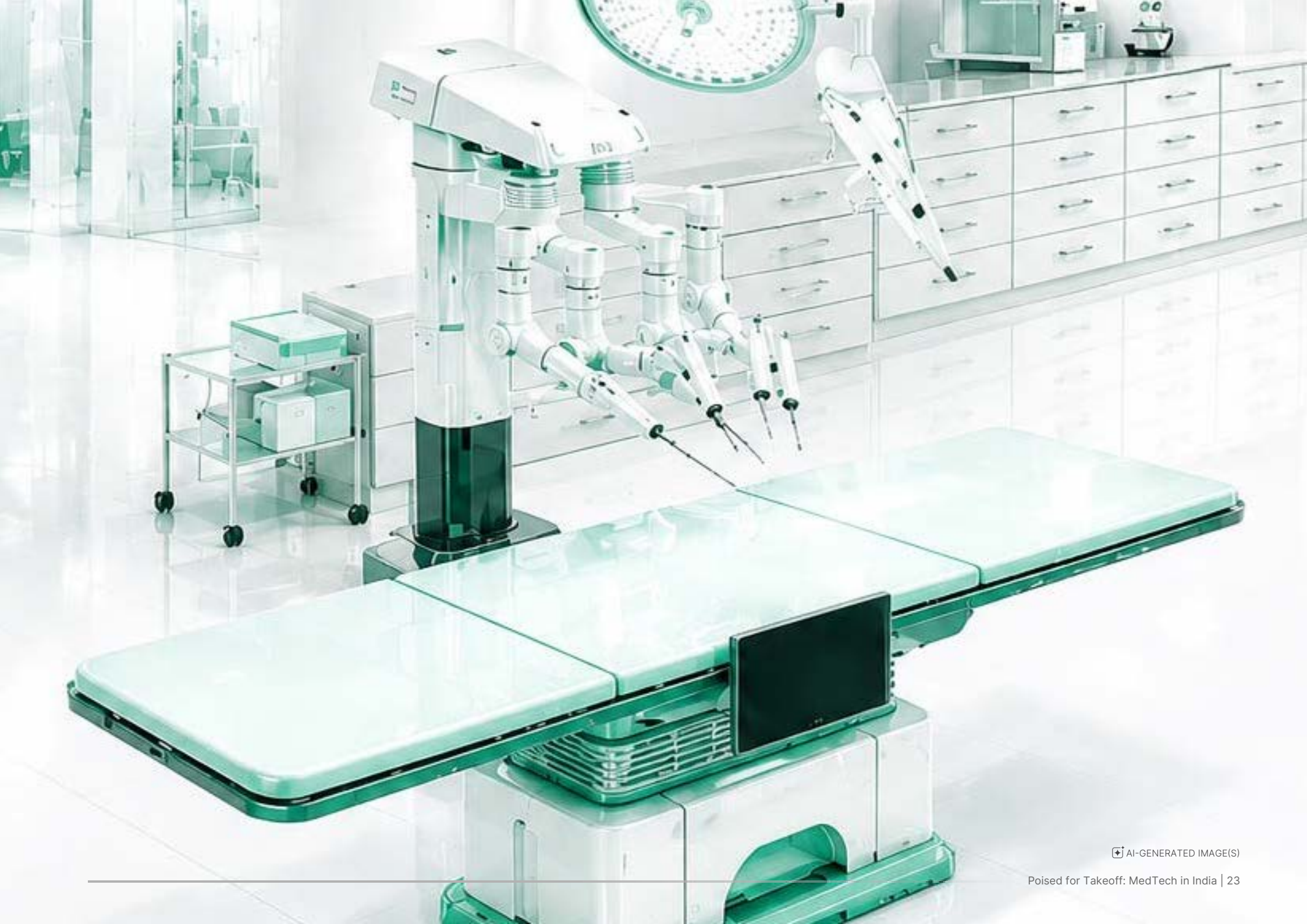
Imports | Local manufacturing

+ **Indian MedTech companies are entering new, high-value segments** (e.g., implants and imaging) which is expected to substitute imports and improve share of local manufacturing

+ **Export growth to hasten** in the coming decade
  - India's cost and talent advantage is expected to play out in the industry

+ **Contract manufacturing capability** currently limited to a few small players and is expected **to grow exponentially** owing to recent success stories in the electronics space

Source: Secondary research; EXIM data; Expert interviews; BCG analysis



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SECTION 2

Capturing the “Make in India" Opportunity


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Three distinct pillars of the “Make in India” opportunity...

Make in India

	1 India for India	2 Export IP-led manufacturing	3 Contract manufacturing
Description	+ Serve India demand and replace imports with indigenised products + IP created in-house or via partnership with MNC	+ Build Indian-origin products and scale exports globally (US, EU, and LMIC) + IP and manufacturing housed in India for domestic firms or globally for MNCs	+ Design, manufacture, assemble, and/or test, and certify for MNCs + IP with OEM
TAM	**$8 Bn** (2025) ▶ **$45-48 Bn** (2035)	**$4 Bn** (2025) ▶ **$16-18 Bn** (2035)	Nascent (2025) ▶ **$7 Bn** (2035)[1]

1. Calculated as 3% of the global CDMO market
Source: Secondary research; BCG analysis

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...building on multiple structural advantages

Key dimension	India	US	EU	Mexico	China
Operating costs	Labour 60–80% below US; competitive land and energy costs	Skilled labour $6–13K/mo; med. facility build $4–7 Mn	Labour $3.5–8K/mo across EU-5; energy elevated by EU ETS/ CBAM exposure	Labour ~30–50% of US; depending on cluster and skill band	Costs rising but 30–50% below US on labour
Tax environment	~17% eff. rate/~25% for new entrants[1].; PLI adds 5% on incremental sales	~21% federal + state; limited MedTech incentives	20–35% across EU-5; Ireland 12.5–15%	~30% headline; maquiladora regime provides partial relief via VAT/duty deferrals	~25% standard; ~15% for qualifying high-tech enterprises
Trade/tariffs	10-25% US baseline tariff; growing FTA network	No import duty for domestic-to-domestic; retaliatory export risk	<15% baseline; retaliatory duties active	USMCA-compliant goods duty-free to US; non-compliant face 10–25%	35–55%+ US tariffs; EU procurement curbs; highest trade friction
Supply chain	Long lead times to US/EU; port infra improving; China+1 momentum	Domestic proximity; highest logistics maturity	Strong intra-EU logistics; short lead times to EU customers	Adjacent to US; 1–3 day ground freight; USMCA-integrated	Mature logistics but concentration risk; tariff + geopolitical disruption
Supply ecosystem	70–80% devices still imported	30–40% manufacturing offshore; deep ecosystem for high-end devices	20-30% devices imported extra-EU; strong Class III and IVD	Assembly-focused with >80% of devices imported	Only 15–20% imported; end-to-end capability
Quality and regulatory maturity	MDR 2017 standalone regime; digital licensing live; still maturing	FDA is the benchmark; robust QSR/cGMP infrastructure	EU MDR/IVDR in force; NB bottlenecks expected to ease; high bar	COFEPRIS aligned with FDA; capacity constraints in reviews	NMPA reforms ongoing; IP enforcement concerns persist
Geopolitical risk	Stable democracy; China+1 beneficiary; non-aligned posture limits bloc risk	Amongst the lowest sovereign risk; tariff policy volatility is the main variable	Stable institutional framework; Russia-Ukraine proximity a tail risk	USMCA stabilises trade; cartel security concerns in some regions	US-China decoupling; export controls tightening
Ease of doing business	CPI 39/100 (rank 91); bureaucracy improving but land/ permits slow	CPI 64/100; strong rule-of-law; regulatory certainty	CPI 53–77 for EU-5; transparent governance; clear IP	CPI 27/100 (~rank 141; last OECD members); security and corruption present real risk	CPI 43/100 (rank 76); opaque regulatory env.; IP risk elevated

Manufacturing attractiveness | Advantaged Competitive Challenging

1. Qualifying companies under 115BAB (sunset 31-Mar-24)
Source: Dept. of Pharma, GoI–PLI MD Scheme; Invest India; IBEF Medical Devices Report 2025; Tax Foundation–Corporate Income Tax Rates in Europe 2026 (Apr 2026); India Income Tax Dept–Section 115BAB/115BAA; Secondary research; BCG analysis

India
for India

Export-IP led
manufacturing

Contract
manufacturing

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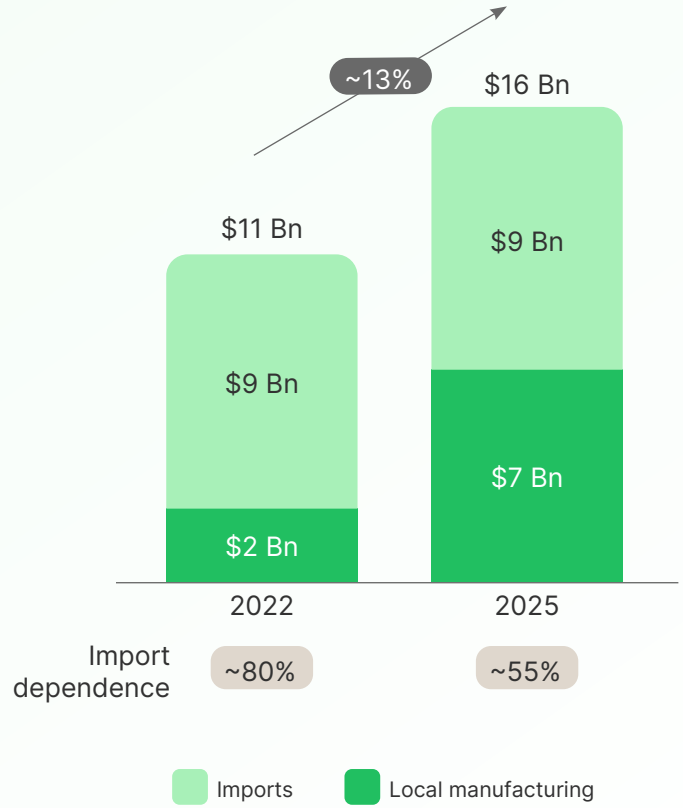
Significant uptick in share of domestic manufacturing in local consumption

Share of local manufacturing has increased from 20% to 45%...

Indian MedTech market

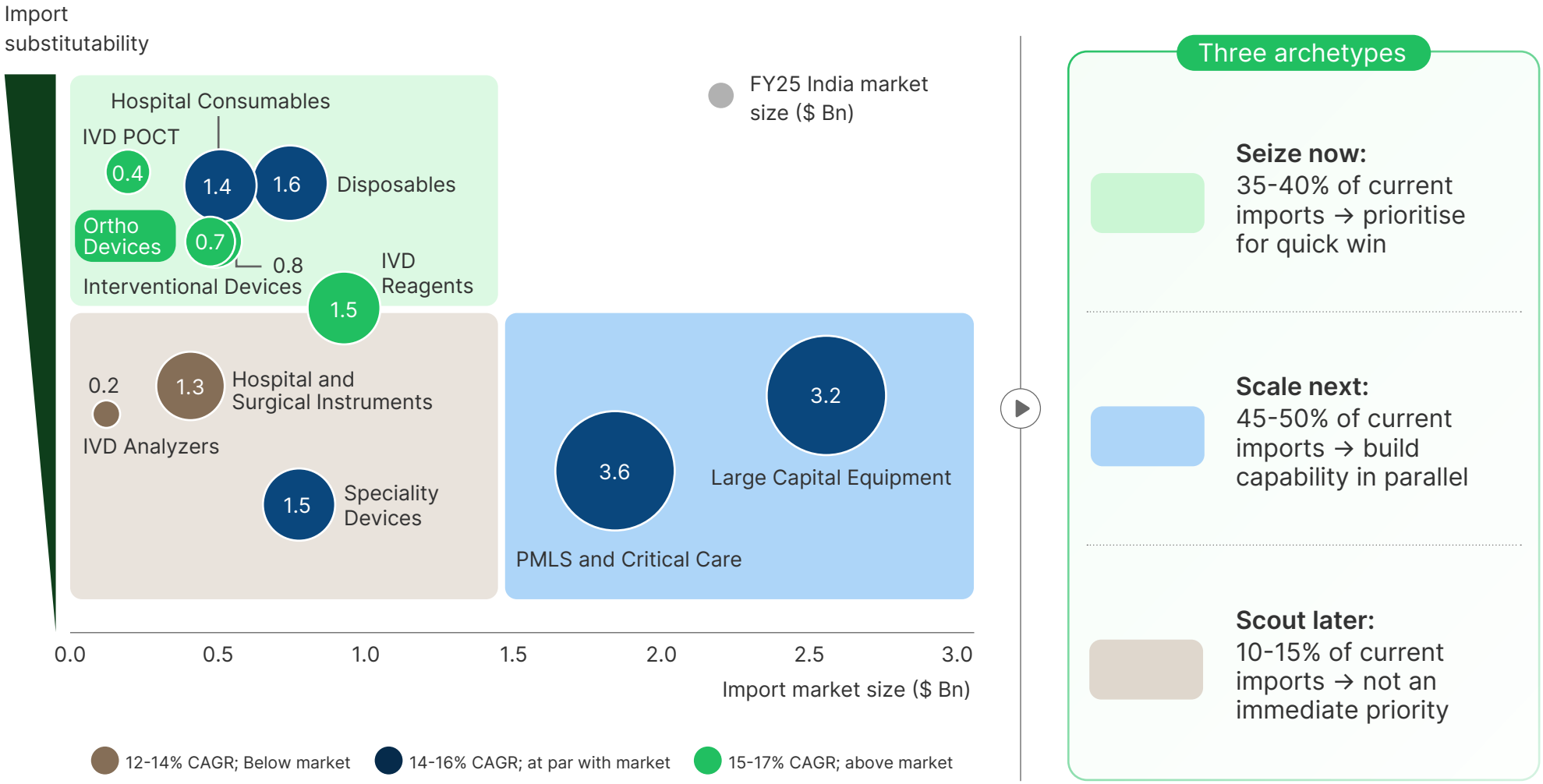


...visible across categories, with equipment and consumables leading

Category	% Import share 2022	% Import share 2025
Equipment	90-95%	60-65%
Consumables	80-85%	50-55%
IVD	55-60%	35-40%
Implants and other special devices	30-35%	25-30%

Source: Department of Pharmaceuticals - Government of India Annual Report FY25, PBI Press Release, Industry reports, Secondary research; BCG analysis

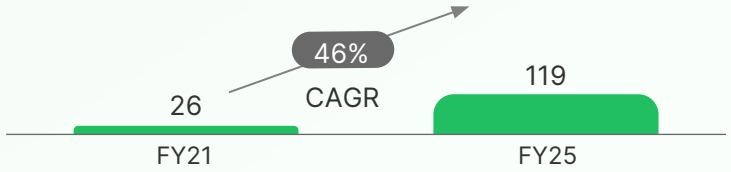
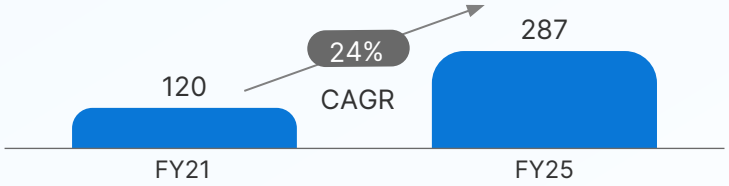
Focus on fast-growing, highly-substitutable segments in the near-term and move to higher-value segments over time



Note: India market CAGR 14-15%
Source: DoP Annual Report FY2024-25, Secondary research; BCG analysis

Many firms are leveraging in-house R&D, manufacturing scale, and product diversification to enable higher local share of domestic consumption (I)

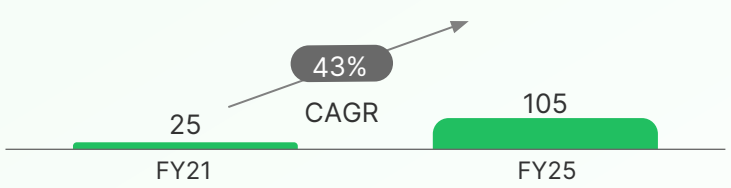
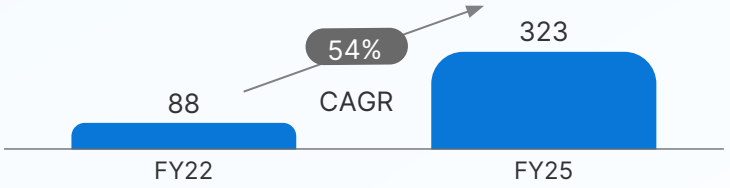
Non exhaustive

Company	Biotek	B L Lifesciences
Revenue (₹ Cr.)		
FY25 EBITDA (₹ Cr.)	**31** (26%)	**46** (16%)
Levers deployed for import substitution	+ **In-house capability buildout:** Manufacturing facility in Ahmedabad producing 1,00,000+ ortho instruments and implants per year across arthroscopy, trauma, and spine + **Import substitution in sports medicine:** Domestically manufactures ACL-PCL reconstruction implants (fixation buttons, ligament anchors, screws)	+ **Domestic manufacturing buildout:** Three facilities in Greater Noida with 10,000 clean rooms for cardio, critical care, and blood banking devices + **Bimodal manufacturing and distribution model:** Manufactures own-branded products and exclusively distributes premium international brands (US/EU) across 11 Indian offices
Archetype	**Seize now:** Orthopaedic devices	**Scale next:** PMLS and critical care

Source: Secondary research; Company reports; company news; BCG analysis

Many firms are leveraging in-house R&D, manufacturing scale, and product diversification to enable higher local share of domestic consumption (II)

Non exhaustive

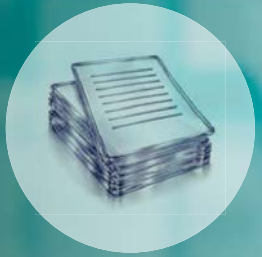
Company	XcelLance	Innvolution
Revenue (₹ Cr.)		
FY25 EBITDA (₹ Cr.)	**41** (39%)	**~5** (1.5%)
Levers deployed for import substitution	+ **Scaled in-house manufacturing:** 50+ product lines covering full OR needs (electrosurgery, OT lights, tables, laparoscopy) from facility in Navi Mumbai + **Domestic scale:** Market leader in electrosurgery and vessel sealing; exports to 60+ countries	+ **Integrated Cath Lab and consumables platform:** Drug-eluting stents, balloon catheters, and guidewires – all manufactured in-house + **Multi-site domestic manufacturing:** Three facilities across Bengaluru, Visakhapatnam (AMTZ), and Jaipur; new dedicated Cath Lab manufacturing facility launched at Vizag AMTZ in 2024 to scale imaging capacity
Archetype	**Scout later:** Hospital and surgical Instruments	**Scale next:** Capital equipment and cardio devices

Source: Secondary research; Company reports; company news; BCG analysis

India
for India

Export-IP led
manufacturing

Contract
manufacturing

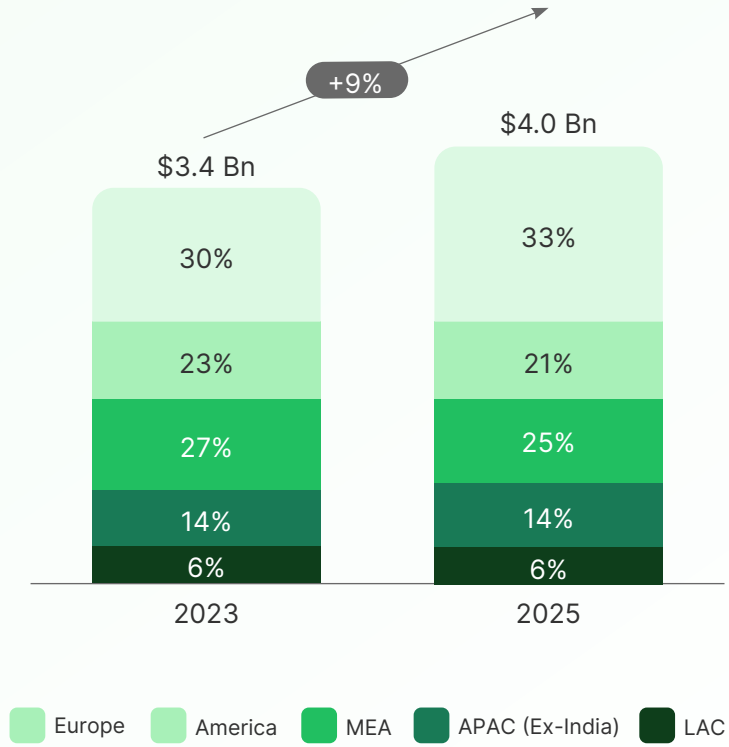


AI-GENERATED IMAGE(S)

India's MedTech exports are scaling; however share remains small

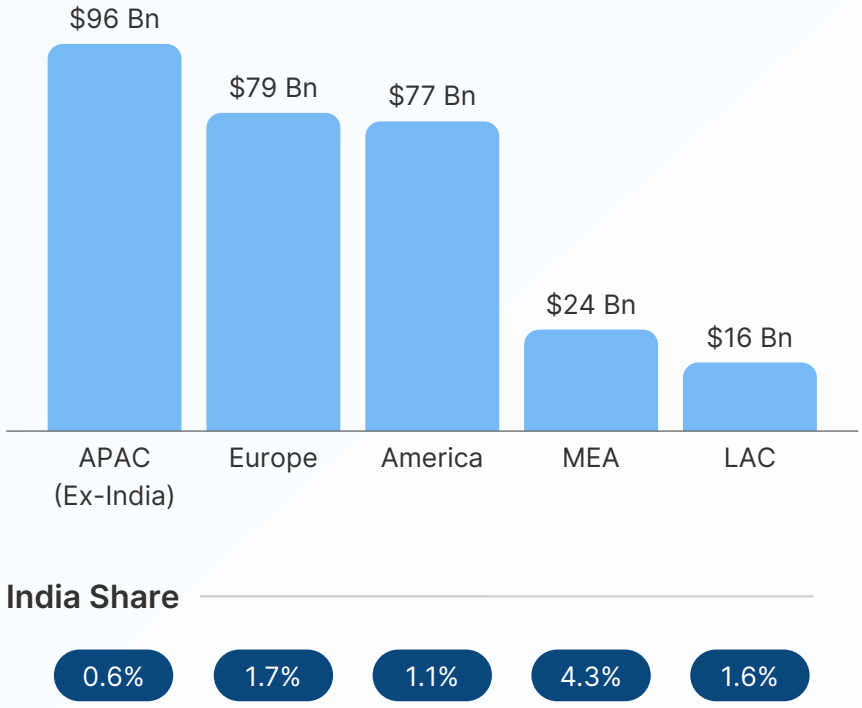
Export growth is concentrated in developed markets i.e., Europe and NAMR

India exports by region



India represents <5% of imports for every major region

2025 Import market by region



India Share

0.6%	1.7%	1.1%	4.3%	1.6%

Source: DoP Annual Report FY2024-25, EPCMD Medical Devices Export-Import Data Analysis for FY2024-25; Secondary research; BCG analysis

Export champions are scaling fast, leading with globally competitive offerings, and building strong go-to-market capabilities (I)

Non exhaustive

Company	Meril	SMT
FY25 revenue (₹ Cr.)	**~4,900** (~61% from exports)	**1,025** (~69% from exports)
EBITDA (₹ Cr.)	**~1,270** (26%)	**124** (12%)
Export strategy	+ **Channel depth:** More than 25 subsidiaries (including the US, the EU, and Latin America) for sales and service; established Meril Academy training centres to drive adoption + **Product competitiveness:** MISSO (India's first indigenously-developed surgical robot) launched globally; expanding into segments including endosurgery and diagnostics	+ **Channel depth:** Direct operations and distribution network across more than 70 countries; top five by DES market share in Germany, the Netherlands, Poland, and Italy; manufacturing in India (Surat, Hyderabad) and Thailand (Nonthaburi) + **Product competitiveness:** Pioneered Asia's first indigenously developed coronary stents; 102 patents with 71 pending + **Clinical evidence for market access:** 72 clinical studies; GPO partnerships in Europe anchored in trial data
Archetype	**Fast growing:** Orthopaedic and cardio implants and IVD	**Fast growing:** Implants

Source: Secondary research; Company reports; Company news; BCG analysis

Export champions are scaling fast, leading with globally competitive offerings, and building strong go-to-market capabilities (II)

Non exhaustive

Company	Polymed	Transasia
FY25 revenue (₹ Cr.)	**1,670** (~70% from exports)	**1,450** (~35% from international operations)
EBITDA (₹ Cr.)	**452** (27%)	**305** (21%)
Export strategy	+ **Channel depth:** Over 900 distributors with direct presence in more than 125 countries; set up local subsidiaries in Italy, China, and Egypt + **M&A to expand reach:** PendraCare (cardiac catheters) and Citieffe (ortho trauma) in FY25	+ **Channel depth:** Mix of direct operations and distributor network across more than 100 countries; subsidiaries in 11 countries including Germany, Czech Republic, Turkey, and the US; IVD manufacturing facility in Vishakhapatnam + **Product competitiveness:** First Indian company to manufacture and export state-of-the-art blood analysers; CE and US FDA-certified portfolio; manufacturing in India and Europe + **Key acquisitions:** More than 10 acquisitions to build integrated R&D and manufacturing capabilities for international markets (including France, the Czech Republic, and the US)
Archetype	**High volume:** Consumables	**Fast growing:** IVD

Source: Secondary research; Company reports; Company news; BCG analysis

Export champions are scaling fast, leading with globally competitive offerings, and building strong go-to-market capabilities (III)

Non exhaustive

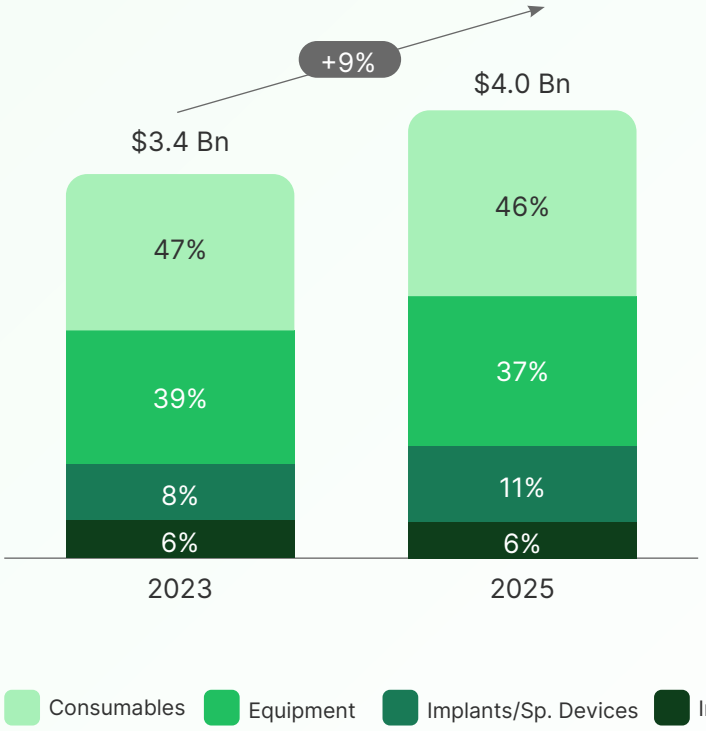
Company	Healthium
FY25 revenue (₹ Cr.)	**870** (~50% from exports)
EBITDA (₹ Cr.)	**115** (13%)
Export strategy	+ **Channel depth:** Exports to more than 90 countries including the US, Germany, France, Italy, Brazil, the GCC, and Egypt via a distributor network; six manufacturing facilities certified to US FDA, EU MDR standards + **Product competitiveness:** Largest non-captive surgical needles manufacturer globally by volume; more than 100 patents across the US, Europe, and India; expanding arthroscopy segment internationally in FY25 + **Key acquisitions:** Acquired Paramount Surgimed to broaden the advanced surgery portfolio for international markets
Archetype	**High volume:** Consumables

Source: Secondary research; Company reports; Company news; BCG analysis

Consumables lead exports and higher-value segments are the next growth engines

Indian MedTech exports by segment— three distinct growth tiers are emerging

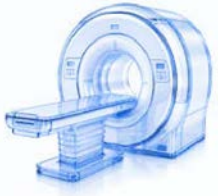
India exports by segment



Segment	CAGR
Consumables	5.1%
Equipment	3.57%
Implants/ Sp. Devices	18.82%
IVD	6.65%

High-volume:
Disposables and consumables

Fast-growing:
IVD diagnostics and implants/ sp. devices



Strategic:
Capital equipment and higher-value devices

Source: DoP Annual Report FY2024-25, EPCMD Medical Devices Export-Import Data Analysis for FY2024-25; Secondary research; BCG analysis

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India
for India

Export-IP led
manufacturing

Contract
manufacturing

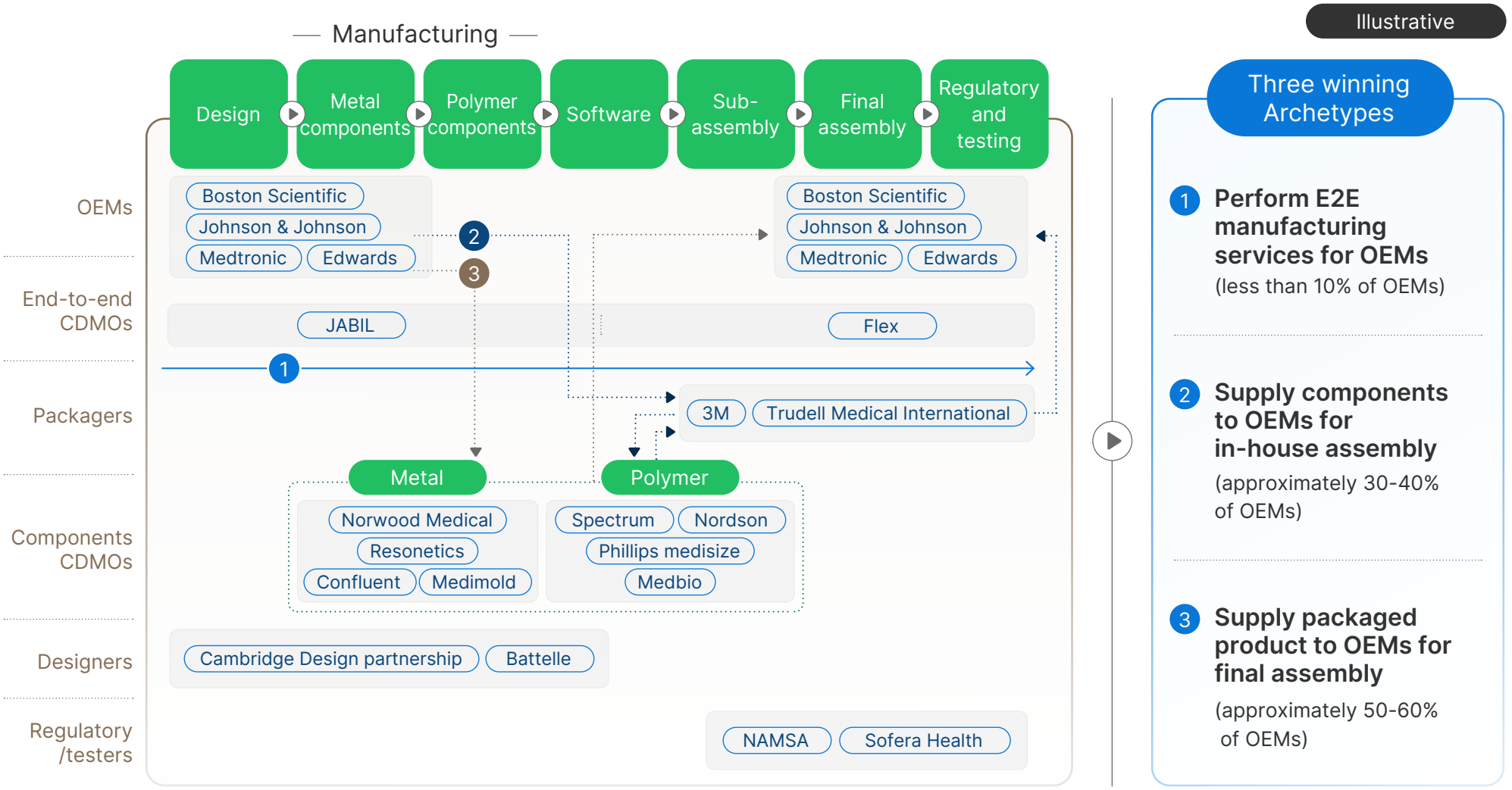
AI-GENERATED IMAGE(S)

MedTech CDMO is a $110-120 Bn market, growing at approximately 8% CAGR

	Equipment	Implants and other speciality devices	Consumables	In Vitro Diagnostics
Description	Equipment to aid in the diagnosis and monitoring of medical conditions (external use only)	Apparatus, implants, and related article used to diagnose, prevent, or treat	Non-durable medical supplies, including disposables	Diagnostic testing performed outside of the body to detect diseases, infections, etc.
End market:				
Size (2025)	$158 Bn	$252 Bn	$165 Bn	$106 Bn
Growth (N5Y)	5%	6%	6%	4%
Outsourcing:				
Size (2025)	**~$28 Bn**	**~$45 Bn**	**~$37 Bn**	**~$8 Bn**
% of end market	**15-20%**	**15-20%**	**20-25%**	**5-10%**
Outsourcing trends and others	Increasing interest in outsourced service contracts in combination with manufacturing	Increasing interest in value-added services, e.g., design to manufacture, supply chain management, etc.	Increasing interest in value-added services, especially for digital products (e.g., Advanced Wound Care)	Increasing growth in underlying volumes and maturity of high-volume capital and consumables products in the market

Source: BCG analysis; Expert Interviews

Component and sub-assembly outsourcing represent 80-90% of the market



Most OEMs anchor on hybrid models, limiting full end-to-end outsourcing

Source: Secondary research; Industry interviews; BCG analysis

Global CDMOs win through integrated capabilities and deep OEM partnerships (I)

Company	FIHealth & biotech	Tecomet
FY25 revenue ($ Mn)	1,25,916[1]	680
FY25 EBITDA ($ Mn)	6,597 (5%)[1]	N/A
Facility size	230+ campuses, 24 countries	Approx 1 Mn sq. ft., 14 facilities, 5 countries
Success mantra	+ **Electronics manufacturing services scale as entry ticket:** Leverages the largest manufacturing base (9,00,000 employees, 230+ sites) for sub-assembly, and component manufacturing for medical devices + **Flex capacity model:** Not a dedicated CDMO; rapidly spins up medical production on existing infrastructure	+ **Full in-house metals value chain:** Largest orthopaedic contract manufacturer covering multiple manufacturing modalities under one roof + **PE-backed serial M&A:** Symmetry Medical $450 Mn, 3D Medical, Mountainside, and Beere; merging with Orchid to form 24-site platform
Key clients	Medtronic, Sotera, Varian	Stryker, DePuy Synthes, Zimmer Biomet

1. Parent company financials
Source: Secondary research; Company reports; Company news; BCG analysis

Global CDMOs win through integrated capabilities and deep OEM partnerships (II)

Company	Jabil	Integer
FY25 revenue ($ Mn)	29,802[1]	1,854
FY25 EBITDA ($ Mn)	2,120 (7%)[1]	377 (20%)
Facility size	35 healthcare sites, 12 countries	2.5 Mn sq. ft., ~20 manufacturing sites, and 10 R&D centres
Success mantra	+ **E2E services at scale:** Largest healthcare manufacturing solutions provider covering all parts of the value chain + **Landmark OEM absorption:** Acquired 14 J&J plants and 6,000 employees in 2018, the largest OEM-to-CDMO manufacturing transfer in MedTech history	+ **High-value sub-components specialist:** Manufactures key components of cardia, vascular, and neuro devices + **Deep OEM lock-in:** Approximately 60% of sales under long-term agreements and approximately 700 patents, creating high switching costs; disciplined M&A to expand vertically (Precision Coating, $152 Mn in 2025)
Key clients	Ethicon, Johnson & Johnson	Abbott, Boston Scientific, Medtronic

1. Inclusive of non-MedTech CDMO financials
Source: Secondary research; Company reports; Company news; BCG analysis

Indian players can leverage strengths in software and sub-assembly before scaling to complex services

STEP 1

Build upon areas of existing competitive advantage for India

Continue the current momentum by building on competitive advantages in polymer components, software, and sub-assembly

Establish strategic partnerships with MedTech OEMs to secure anchor contracts, enable technology transfer, and accelerate credibility

Capitalise on India's proven cost-quality arbitrage—already validated in pharma and auto—to position as a globally competitive sourcing hub for MedTech components and sub-systems

STEP 2

Emerging capabilities—invest to build for the future

Develop new capabilities across the value chain to deliver end-to-end services by expanding into design

Bridge the talent gap in high-value disciplines—regulatory affairs, process validation, and precision manufacturing

Build advanced manufacturing infrastructure—cleanrooms, micro-molding, precision machining, and sterilisation—to move up the value chain

Develop in-house design, prototyping, and Verification and validation (V&V) capabilities to offer full-stack CDMO services

Source: Secondary research; Expert interviews; BCG analysis

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Potential pathways and barriers to capturing the "Make in India" opportunity

AI-GENERATED IMAGE(S)

Call to action: Multiple pathways to capture the “Make in India” opportunity

Non exhaustive

	Incumbent MedTech players	New-to-MedTech Indian conglomerates	MNCs
Players	Meril, Trivitron, Skanray, Agappe, Transasia, Polymed	Zydus, Alkem, Motherson	GE, Siemens, Jabil, Philips, Molnlycke Healthcare, Medtronic, Stryker, Abbott, Transasia, Varex
India for India	Pursue inorganic growth via acquisitions across India, the US, and Europe to add categories, capabilities, and value chain depth	Acquire established MedTech players across India and the EU to build domain expertise	Expand manufacturing in India across product lines to drive cost and supply chain resilience
Export-IP led manufacturing	Advance into complex-category manufacturing from India—serve emerging markets first, then scale to developed markets	Form joint ventures and partnerships with MedTech MNCs and CDMOs to accelerate capability buildout	Leverage India as an export base for emerging markets and low-and-middle-income markets
Contract manufacturing	Build and expand CDMO capabilities in non-compete adjacencies	Leverage transferable manufacturing DNA i.e., precision, quality systems, and scale to build a MedTech CDMO platform	Build and expand CDMO capabilities in non-compete adjacencies

Core strategic priority · Strong opportunity · Selective play · Exploratory capability

Source: Secondary research; Expert interviews; BCG analysis

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However, multiple barriers need to be addressed to realise the full potential

Compliance burden	Multiple NOCs[1], sequential approvals, class ambiguity, and export registrations keep timelines long
Lack of a well-developed components ecosystem	High-value inputs including detectors, tubes, sensors, motors, PCBs[2], speciality materials, and reagents remain import-dependent, limiting local value addition
Inverted duty structure on key raw materials	Multiple key raw materials and components have a higher BCD[3] compared to finished products, making local manufacturing unviable
Regulatory synchronisation with markets (e.g., EU, US FDA)	Limited alignment with standards restricts exports of Indian-made devices, often requiring duplicate approvals
Local market access constraints for "Make in India" players	Public procurement is slow to promote domestic products, and clinician preference for legacy options further delays the adoption of Indian devices
Ease of access to capital at scale	Access to manufacturing capital remains concentrated among large MedTech firms, while MSMEs[4] face significant challenges in securing financing
Absence of notified labs for class C devices	Longer turnaround time for validation of class C devices due to high dependence on CDSCO[5]

1. NOC = No Objection Certificates **2.** PCBs = Printed circuit boards **3.** BCD = Basic Customs Duty **4.** MSMEs = Micro, Small, and Medium Enterprises
5. CDSCO = Central Drugs Standard Control Organisation
Source: Secondary research; Expert interviews; BCG analysis

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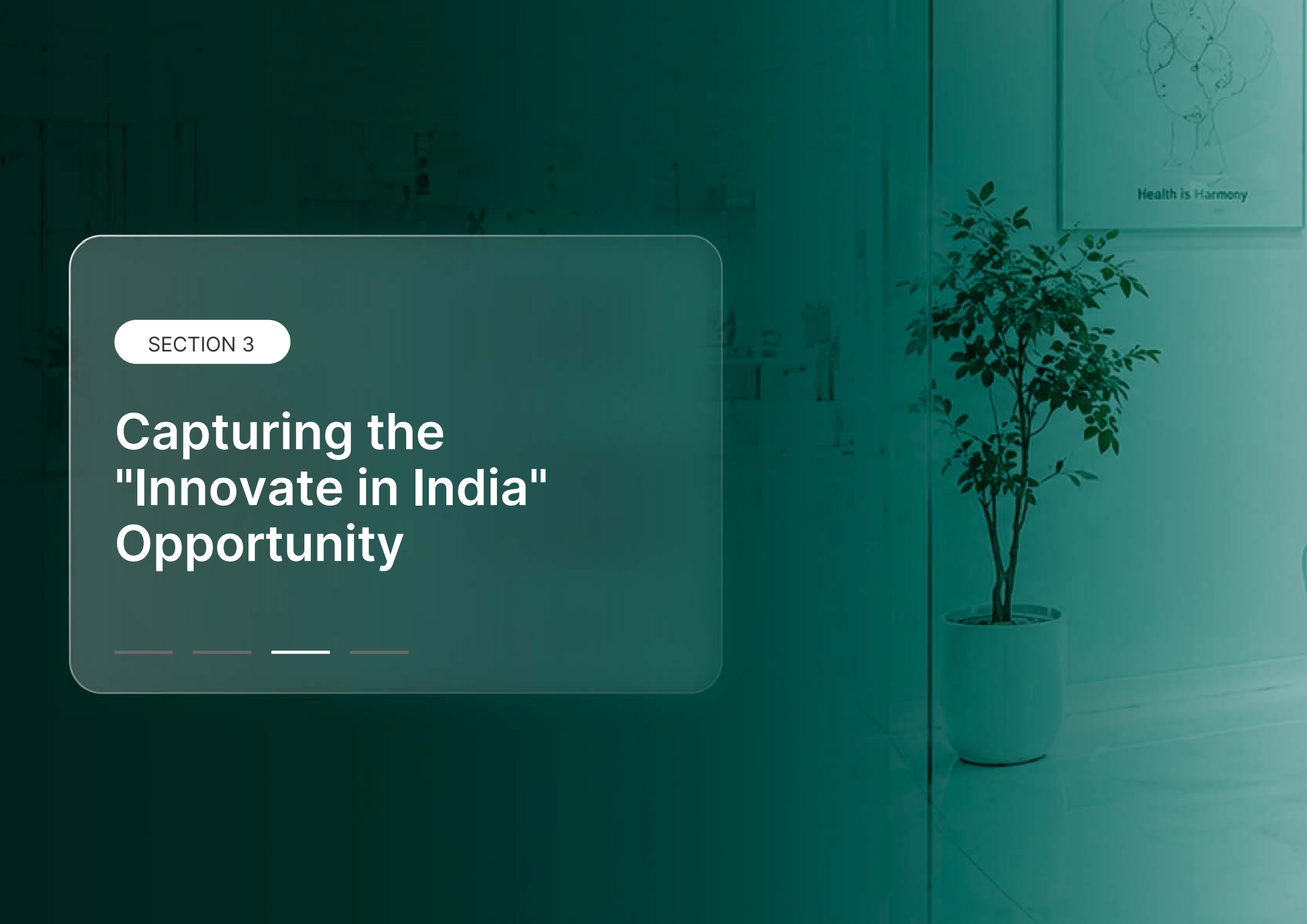
SECTION 3

Capturing the "Innovate in India" Opportunity



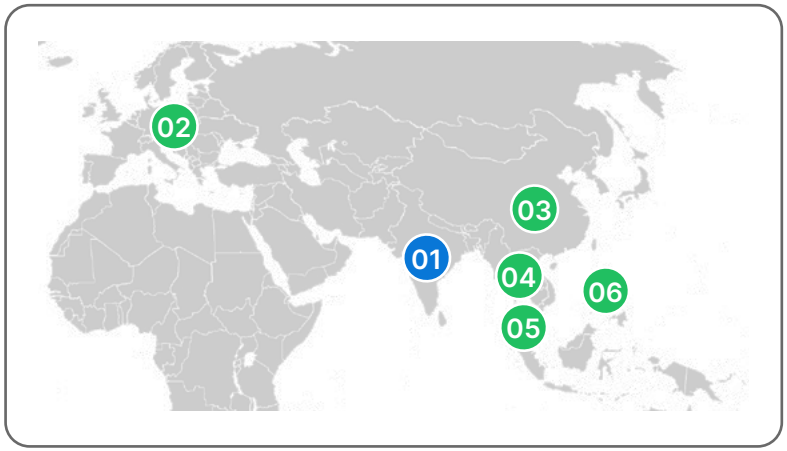

AI-GENERATED IMAGE(S)

MNCs

Indian firms

AI-GENERATED IMAGE(S)

India leads globally in GCC scale across sectors, talent depth, and cost advantage foundational



01 India

Cisco | HSBC | Stripe | J.P. Morgan | Mastercard | Goldman Sachs | Microsoft | American Express | Wells Fargo | Remedly | Barclays | Chime | PayPal | Fiserv

R&D, GTM, solution development, Core Ops, CS, IT, Analytics, F&A, HR, Risk, Audit, prod dev., customer support, tech and app development, infra mgmt., testing, ML, AI, IoT, wireless comms, VR/AR, robotics

02 Poland

HSBC | J.P. Morgan | Standard Chartered | Goldman Sachs | Cisco | Microsoft

Analytics, IT, F&A, HR, Risk, ops, tech support

03 China

HSBC | Barclays | Standard Chartered | Microsoft

Core Ops, CS, IT, HR, F&A, BP, back-office support, ER&D, Automation, AI/ML

04 Malaysia

HSBC | Standard Chartered | American Express | Metlife

F&A, CS, IT, analytics, ops, fraud, collection, Ind-specific

05 Singapore

HSBC | J.P. Morgan | Mastercard | Natwest

IT, F&A, core ops, marketing, ER&D, payment, mobile, ecom

06 Philippines

HSBC | J.P. Morgan | Wells Fargo | PayPal

F&A, HR, CS, ops, analytics, IT, Risk, PM, customer service

Enabled by India's talent and cost advantage

+ **More than 1,100** universities and a STEM[1] talent pool of approximately **2.5 Mn**
+ **One in ten** analytics professionals worldwide are based in India
+ **Approximately 25,000 to 27,000** active tech start-ups, including more than **3,000** in deep tech (for example AI, IoT, and AR/VR)
+ Average cost per FTE in India is **$30,000** in line with competing APAC geographies

Pharma has leapfrogged, with nearly half of top 25 players leveraging India for innovation-led work




	India GCC[1]	Maturity	Type of work	Complexity of work
AstraZeneca, Sanofi, Lilly, Novartis, Novo Nordisk, Roche, Takeda, Bayer, Johnson & Johnson, GSK, Pfizer, Bristol Myers Squibb	✓	Leading	Innovation – IP and engineering-led	Core R&D, new product development, AI and GenAI, platform ownership, and patent-linked work
MSD, Merck, Teva, Biogen, Amgen	✓	Mature	Functional and capability-led	GBS, IT, analytics, regulatory support, and engineering execution
Astellas, Regeneraon	✓	Developing	Commercial	Sales, marketing, service operations, and basic support
Daiichi Sankyo, Vertex, CSL, Boehringer Ingelheim, Abbvie, Gilead	✗	N/A	N/A	Limited to distributor or sales office/minimal presence

True Innovators

Maturity | Leading Mature Developing Nascent N/A

1. GCC = Global Capability Centre
Source: Secondary research; Company reports; Company news; BCG analysis

AI-GENERATED IMAGE(S)

MedTech lags, with majority of MNCs yet to move beyond commercial operations in India




	India GCC[1]	Maturity	Type of work	Complexity of work
Siemens, Philips, Medtronic, BD, GE, Stryker, Boston Scientific	✓	Leading	Innovation – IP and engineering-led	Core R&D, new product development, AI and GenAI, platform ownership, and patent-linked work
Resmed, Olympus, Abbott, Alcon, Danaher, Terumd	✓	Mature	Functional/ capability-led	GBS, IT, analytics, regulatory support, and engineering execution
Solventum, Zimmer Biomet, Baxter, Inuitive Surgucal, Smith & Nephew, Medline, Johnson & Johnson, Braun	✓	Developing	Commercial	Sales, marketing, service operations, and basic support
Mindray, Edwards, Sonova, Steris	✗	N/A	N/A	Limited to distributor or sales office/minimal presence

True Innovators

Maturity | Leading Mature Developing Nascent N/A

1. GCC = Global Capability Centre

Source: Secondary research; Company reports; Company news; BCG analysis

AI-GENERATED IMAGE(S)

Challenges related to talent quality and IP protection have emerged for companies currently not present in India

Lack of skilled talent

+ Limited talent with domain expertise in areas such as advanced imaging, diagnostics, and device design, etc.
+ Academic and research institutions' curricula focus mainly on testing and validation rather than full-cycle product development

India's positioning

+ India is still perceived primarily as a cost-arbitrage centre, not a destination for core R&D
+ Concerns related to IP protection and risk of reverse engineering reduce the willingness to locate proprietary innovation activities
+ R&D budgets are preferentially allocated to established innovation ecosystems (US, EU) with proven track records

Source: India: An Evaluation of Capability Centers 2024 (SSON Research and Analytics); Expert calls, Secondary research; BCG analysis

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Scaling MNC-led innovation from India could multiply healthcare jobs severalfold within the next decade

40,000+

Professionals employed

Across MedTech GCCs, drawing from 1.5 Mn engineering graduates per year

Where we are today

500,000+

New jobs by 2030

As import dependency decreases and local innovation scales

What “Innovate in India” can unlock

Source: BCG analysis; IBEF; Invest India; IMARC; Secondary research

AI-GENERATED IMAGE(S)

MNCs

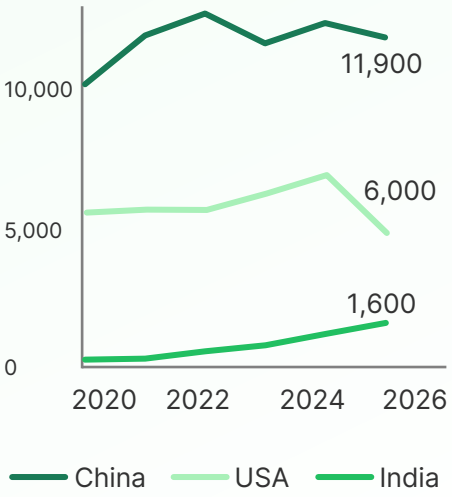
Indian firms

AI-GENERATED IMAGE(S)

Indian MedTech sector is currently underinvested in cutting edge innovation

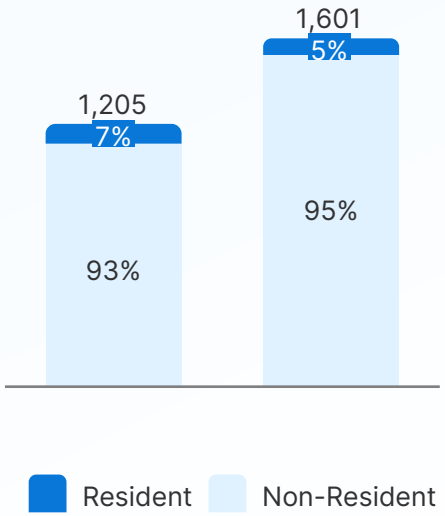
Only 3% of MedTech patents are filed from India...

MedTech patents by priority country[1]



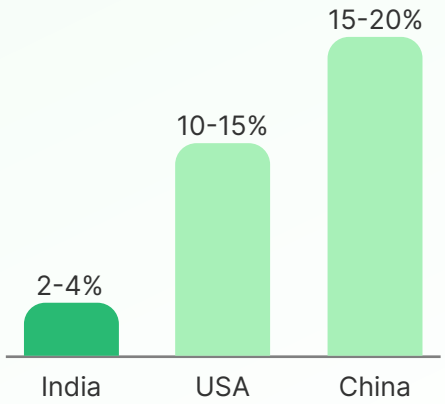
... and <10% of these patents are filed by Indian entities

MedTech patents filed by Indian vs Foreign entities in India



R&D intensity of Indian firms 20-25% vs. peers

R&D spend as a % of Revenue



Low share of Indian companies in innovative product approvals

Food and Drug Administration

Less than 1% share (47 out of 50,000 or more) of Indian firms in FDA approvals (2010-2025)[2]

100% of the approved products were "substantially equivalent" to existing products – 510(k)

1. Derwent innovation IP statistics; Expert interviews; Secondary research; BCG analysis **2.** FDA filing data

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However, green shoots of innovation are starting to emerge as capital, policy, and ecosystem capabilities begin to align

Quantum of public and private funding is converging

+ ₹750 Cr ANRF fund, ₹5-25 Cr per project; co-funded by Gates Foundation
+ PRIP Scheme: ₹5,000 Cr for idea-to-market stage R&D by MSMEs and startups
+ RDI fund of ₹1L Cr; ₹2,000 Cr committed to TDB and BIRAC each; MedTech as a focus area
+ PE/VC investment scaled more than 6x (~$180 Mn to ~$1.25 Bn) from 2019 to 2024

Policy is shifting from “Make in India” to “Innovate in India

+ Joint ventures via technology transfers are encouraged to commit more than 5% of revenue to R&D in India
+ IMDRF affiliate membership helps align regulatory standards, accelerate approvals, and enable export competitiveness

Ecosystem capabilities are deepening...

+ AMTZ - India's largest cluster with 183 firms
  - Leadership in radiology and regenerative medicine (bio 3D printing and artificial organs)
  - India's first dedicated MedTech investment platform (MedArtha)
  - WHO collaboration centre and WTO center for trade promotion

...with early results already visible

+ Over 150 MedTech startups incubated across four accelerators[1]; ~17% expected to reach commercialisation
+ Emergence of complex indigenised products:
  - Helium-free MRI machine by Voxelgrids
  - Soft tissue surgical robot by SS Innovations

1. Representative number derived from 4 incubators – including academic projects and incubated startups
Source: Secondary research

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This is evident in several success stories emerging across segments

Biotek

+ Ahmedabad based firm founded in 2002; provider of arthroscopy products
+ Focus on knee and shoulder arthroscopy implants, differentiated by in-house design and advanced materials (titanium, PEEK, bio-composites)
+ Approximately 15% of revenue is reinvested into surgeon education programmes across India, LATAM, and Africa, reinforcing brand equity and stickiness
+ EU MDR certification across entire sports medicine portfolio (approximately 1,500 SKUs) was achieved in 2023
+ Approximately 120 Cr revenue in FY25, with exports to more than 35 countries; the EU is the largest export market

Shalya

+ Founded in 2002 (Navi Mumbai), Xcellance (Shalya) is a provider of end-to-end operating room (OR) solutions
+ Broad product portfolio across electrosurgery, endoscopy, OT lights, tables, pendants, and OR integration systems
+ 15 patents across the US, EU, China, India; in-house R&D with multi-disciplinary engineering capabilities
+ Global footprint with exports to 60+ countries and 3,000+ hospital customers
+ More than ₹100 Cr revenue in FY25; approximately 25% growth over previous year

Surgiwear

+ UP-based firm founded in 1990; manufacturers hydrocephalus shunts, orthopedic implants, and surgical drapes
+ DSIR-recognised in-house R&D unit with 3D printing and CNC capabilities
+ 31 patents in India and 8 internationally; certifications: WHO-GMP and ISO 13485:2016
+ Exports to more than 40 countries across Africa, South Asia and South America via 58 international distributors
+ ₹224 Cr revenue in FY25—highest among peers in India; approximately 22% year-on-year revenue growth over FY23–25

Source: Secondary research; Company reports; Company news; BCG analysis

Innovation momentum is building — gaps in clinical validation, regulatory pathways, procurement, and academia must be addressed to unlock value

Clinical validation gap
Clinical validation facilities are fragmented and hard to access, especially for novel and complex product development

Lack of separate regulatory pathways and support for innovation—ambiguity in classification and approval pathways for devices without predicate, including SaMD and AI-enabled devices

Procurement barriers favour incumbents using rigid technical qualification, limiting market entry for new products

Academic research cycles in MedTech are prolonged, with limited industry collaboration, slowing validation and commercialisation of innovations

Access to capital
Limited access to capital for R&D, clinical validation, and prototyping

Source: Secondary research; Company reports; Company news; BCG analysis

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SECTION 4

Delivering Impact

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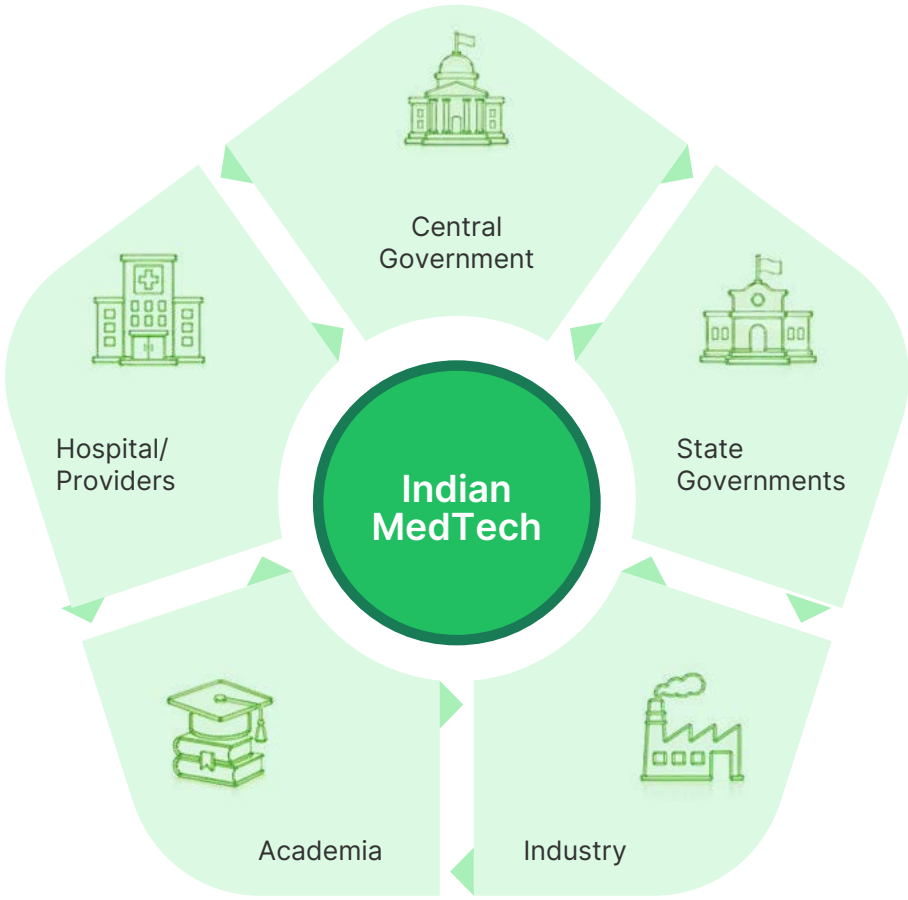
Progress depends on coordinated action across stakeholders

1 Atmanirbhar value chain	Drive component and raw material level "Atmanirbharta" Test and validate infrastructure Market access to enable 'Make in India' and 'Innovate in India'
2 Policy and regulatory enablement	Simplify NOCs Synchronise India standards with global (where relevant) Notified bodies for class C devices Enable increased exports Active progress tracking of initiatives
3 Attracting global firms to India	Outreach to attract top MedTech OEM and CDMOs to India Address IP-related concerns and perceptions
4 Strengthen foundational enablers	Attract and develop quality talent at scale Enable ease of access to capital



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Theme 1 | Building an Atmanirbhar value chain – potential initiatives

1 Drive component and raw material Atmanirbharta

+ Incentivisation of global tier-1 suppliers to establish operations in India
+ Inverted duty structures on critical inputs (e.g., flat panel detectors, medical-grade plastics) through zero – or low-duty corridors
+ Inclusion of raw material and intermediate suppliers within existing schemes

Global Learnings

China: Tax incentives and subsidised land for foreign suppliers

US: Miscellaneous tariff bill provides duty relief on selected unavailable materials

2 Testing and validation infrastructure

+ Hub-and-spoke networks linking MedTech parks, apex institutes and incubators
  - Pricing transparency and open access across the testing ecosystem
+ Shared facilities in sterilisation, calibration, and cleanrooms
+ Accredited testing hubs aligned with global regulatory pathways (e.g., FDA/MDR[1])

Global Learnings

China: Suzhou BioBAY provides end-to-end, co-located services

US: Accredited labs linked to FDA ASCA[2] program

3 Market access to enable 'Make in India' and 'Innovate in India'

+ Potential to explore a 50% domestic value addition threshold in public procurement across key segments (akin to Positive indigenization list in defense)
+ Potential to align tender norms with functional outcomes rather than specifications based on legacy products
+ Pilot programmes with leading hospitals and opinion leaders, supported by published performance data, could be explored

Global Learnings

China: Mandates over 70% domestic procurement in public hospitals

UK: NHAP[3] provides dedicated adoption support for approved products over two years

1. FDA/MDR = Food and Drug Administration/Medical Device Regulation **2.** ASCA = Accreditation Scheme for Conformity Assessment **3.** NHAP = National Health Action Plan
Source: BCG proprietary knowledge, Industry experts, Secondary reports and publications

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Theme 2 | Policy and regulatory enablement – potential initiatives (I)

4 Simplify NOCs

+ A single-window digital portal could streamline approvals
+ Potential to rationalise and parallelise approvals processes
+ Potential to incentivise ISO 13485 adoption among MSMEs
+ Pre-approved plug-and-play infrastructure in MedTech parks could be expanded
+ Defined stage-wise timelines with real-time tracking for applicants

Global Learnings

Singapore: Single portal and risk-based approvals

Ireland: Notified bodies for compliance and parks with pre-clearances

5 Synchronise India Standards with global (where relevant)

+ Potential to pursue MRAs[1] with ASEAN/EU and align with IMDRF[2] risk classification and terminology
+ Potential to consider acceptance of FDA/CE clinical data, supported by defined local bridging studies
+ Transition towards an end-to-end digital approval platform with defined SLAs[3] could be considered
+ Fast-track pathways for breakthrough and locally developed devices could be explored
+ Clear guidance for SaMD[4] and AI-enabled devices could be developed

Global Learnings

China: Aligned with global standards, accepts overseas clinical data

Japan: Sakigake fast-track for innovators

6 Notified bodies for class C devices

+ Potential options India can consider:
  - Use of accredited assessment bodies for inspection of class C devices to streamline workflow
  - While CDSCO[5] continues to oversee regulatory approval

Global Learnings

EU: Class III devices require notified body review and mandatory expert panel consultation

1. MRA = Mutual recognition agreement; **2.** IMDRF = International Medical Device Regulators Forum; **3.** SLAS = Service level agreements; **4.** SaMD = Software as a medical device; **5.** CDSCO = Central Drugs Standard Control Organisation
Source: BCG proprietary knowledge; Industry experts; Secondary reports and publications

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Theme 2 | Policy and regulatory enablement – potential initiatives (II)

7 Enable increased exports

+ Potential to review preferential rules of origin in key FTAs (ASEAN/EU/GCC) for the MedTech industry to support low-tariff access
+ Explore options for low-cost export credit via platforms such as EXIM[1], ECGC[2] to support capacity and de-risk large orders
+ A national MedTech export digital platform with verified suppliers, alongside certification support, could help connect Indian firms with buyers

Global Learnings

Pan-Euro-Mediterranean convention: 25 countries share identical rules of origin

USA EXIM: Seven-year dedicated export credit window

8 Active progress tracking of initiatives

+ A unified tracker with defined deliverables and ownership across government, regulators, states and industry
+ Outcome-focused KPIs, including approval TAT, licenses issued, NOC reduction milestones
+ Quarterly central reviews and state-level check-ins with clear escalation paths
+ A public dashboard with state-level comparisons and mechanisms for timely bottleneck resolution

Global Learnings

Best practices: Outcome-focused KPIs, cross-agency dependencies and defined accountability cadence

1. EXIM = Export-Import Bank; **2.** ECGC = Export Credit Guarantee Corporation
Source: BCG proprietary knowledge, Industry experts, Secondary reports and publications

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Theme 3 | Attracting firms to India – potential initiatives

9 Outreach to attract top MedTech OEM[1] and CDMOs[2] to India

(A) Focused engagement with priority players not currently present in India

+ Identify priority OEMs and CDMOs for targeted engagement
+ A high-level coordination mechanism could be considered
+ Encourage proactive engagement to articulate "India advantage"

(B) Tailored value proposition to support an attractive business case

+ Customised packages (e.g., PLI[3], state incentives, land, utilities, customs facilitation, regulatory fast-track) could be aligned to each firm's needs (e.g., manufacturing, R&D or export hub)
+ Potential to explore linking incentives (e.g., PLI/tax breaks) to the level of domestic value addition, with a focus on component-level manufacturing

Global Learnings

Ireland: Bundled 12.5% corporate tax, R&D tax credits, and capital grants delivered through a single-window agency model

Malaysia: Tax incentives (e.g., five-year tax holidays), duty exemptions, and dedicated SEZs[4] with ready infrastructure to support large-scale MedTech manufacturing

1. OEM = Original Equipment Manufacturer; **2.** CDMO = Contract Development and Manufacturing Organization; **3.** PLI = Production-Linked Incentive; **4.** SEZ = Special Economic Zones
Source: BCG proprietary knowledge; Industry experts; Secondary reports and publications

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Theme 4 | Strengthening foundational enablers – potential initiatives

10 Attract and develop quality talent at scale

+ Targeted incentives could help attract Indian-origin MedTech professionals from the US and the EU
+ National MedTech programmes at NIPER[1] and AMTZ[2] could be developed, focusing on areas such as imaging, implants and diagnostics
+ Industry-relevant curricula could be co-designed with MNCs, covering design, quality and compliance
+ Multidisciplinary fellowships, apprenticeships and clinician-engineer development programmes could be developed

Global Learnings

China: Thousands talent programme, offering stipend of approximately $160,000 per year and lab funding; estimated 7,000+ recruits since 2008

11 Enable ease of capital access

+ A revised PLI scheme with lower entry thresholds could support broader MSME participation
+ Potential to evaluate priority sector lending and reduced risk weights for MedTech equipment financing, especially for Tier 2 and beyond areas
+ A dedicated innovation fund for clinical evidence could focus on multi-centre trials and pre-clinical studies
+ Outcome-linked financing mechanisms, with fund disbursement tied to trial success milestones, could be explored

Global Learnings

China: Value-chain-linked incentives, not solely output-based

Israel: Yozma model with government co-investment in venture funds

1. NIPER = National Institute of Pharmaceutical Education and Research; **2.** AMTZ = Andhra Pradesh MedTech Zone Limited
Source: BCG proprietary knowledge; Industry experts; Secondary reports and publications

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