International Journal of Health Technology and Innovation
An Official Journal of **Kalam Institute of Health Technology** | ISSN - **2583-8547**
EDITORIAL

Medical Devices: Powering India's Health-Tech Future

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Received: 03rd June, 2025; Revised: 26th June , 2025; Accepted: 20th July, 2025; Available Online: 19th August, 2025

International Journal of Health Technology and Innovation (2025)
How to cite this article: Singh SB. Medical Devices: Powering India's Health-Tech Future. International Journal of Health Technology and Innovation. 2025;4(2):1-2.
Doi: 10.60142/ijhti.v4i02.01
Source of support: Nil.
Conflict of interest: None

INTRODUCTION

India's medical devices sector has emerged as a cornerstone of its healthcare economy, growing from $5.4 billion in 2014 to over $11 billion in 2023, with projections to reach $50 billion by 2030. In just three years, exports have doubled to $3.8 billion in FY 2023–24, while reliance on imports for critical products like diagnostic kits, syringes, stents, and implants has declined. Government initiatives, including the Production Linked Incentive (PLI) scheme, regulatory reforms, and robust R&D support, have driven this growth, positioning India as a rising global player. Indian-made devices now serve local hospitals and markets in Latin America, Africa, and Southeast Asia, advancing public health access and economic independence.

Production Linked Incentive (PLI): A Manufacturing Catalyst

The Production Linked Incentive (PLI) Scheme for Medical Devices, launched in 2020 by the Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers, is a cornerstone of India's manufacturing push. With a ₹3,420 crore budget, the scheme offers up to 5% financial incentives for producing advanced devices like:

- CT scanners and MRI machines
- Pacemakers and orthopedic implants
- Diagnostic kits

To date, 26 projects have been approved, with many operational in states such as Himachal Pradesh, Gujarat, Tamil Nadu, and Uttar Pradesh. The PLI scheme has reduced import dependence, strengthened supply chains, and enabled small and medium enterprises (SMEs) to scale up, fostering innovation and job creation in tier-2 and tier-3 cities. This has positioned India to compete in the global medical devices market.

ICMR's Strategic Role: MedTech Mitra & Patent Mitra

The Indian Council of Medical Research (ICMR) plays a pivotal role in nurturing medtech innovation through flagship programs and academic funding via small, intermediate, and advanced center grants. These efforts, combined with clinical trial and testing support, have spurred startup growth. Key initiatives include:

MedTech Mitra

Provides mentorship, clinical validation, and regulatory guidance to early-stage innovators, helping them navigate market entry challenges and develop market-ready products.

Patent Mitra

Offers technical and legal support for patent filing, fostering intellectual property (IP) protection and commercialization.

These programs have enabled startups to launch affordable diagnostic tools and wearable health monitors, strengthening India's medtech ecosystem and supporting grassroots innovation.

REGULATORY BACKBONE: MEDICAL DEVICE RULES (MDR) 2017

The Medical Device Rules (MDR) 2017, enforced by the Central Drugs Standard Control Organization (CDSCO), have streamlined India's regulatory framework. Key features include:

- Risk-based device classification (Class A to D)
- Simplified clinical investigation processes
- Voluntary registration for lower-risk devices

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Continuous updates to MDR align with global standards, enhancing investor confidence and market access. The introduction of Unique Device Identification (UDI) systems and post-market surveillance has improved quality control, ensuring patient safety and product reliability.

Building Talent

NIPERs and Skill Development

The DoP has empowered National Institutes of Pharmaceutical Education and Research (NIPERs) to develop interdisciplinary programs in:

- Medical Devices and BioMEMS
- Microfluidics and implants
- Drug-device interaction and regulatory science

NIPERs also host MedTech testing facilities, file patents, and incubate startups, bridging academia and industry. Collaborations with hospitals and manufacturers have led to practical solutions, such as low-cost ventilators and diagnostic kits tailored to India's healthcare needs.

The Life Sciences Sector Skill Development Council (LSSSDC), supported by DoP, offers industry-aligned skilling programs, including:

- Technician and operator training for device manufacturing and assembly
- Quality assurance, regulatory compliance, and validation roles
- Emerging programs in device servicing, biomedical handling, and digital health instrumentation

These initiatives ensure a skilled workforce, from diploma holders to engineers, through short-term certifications and qualification packs (QPs), enabling professionals to adapt to technologies like AI-driven diagnostics and telemedicine devices.

Boosting Exports

Medical Devices Export Promotion Council (EPC-MD)

Established in 2022 by the DoP, the Medical Devices Export Promotion Council (EPC-MD) drives India's global market expansion through

- Participation in expos like MEDICA (Germany) and Arab Health (UAE)
- Buyer-seller meetings and training on international regulatory compliance
- Market intelligence and promotion of "Brand India MedTech."

Exports rose from $2.9 billion in FY 2021–22 to $3.8 billion in FY 2023–24, with growth in Latin America, Africa, the Middle East, and Southeast Asia. EPC-MD supports SMEs in navigating international regulations, such as CE marking and FDA approvals, enhancing India's global competitiveness.

Funding Innovation

PRIP Scheme

The Promotion of Research in Pharmaceutical & Medical Devices (PRIP) scheme fosters collaborative R&D between academia and industry, supporting prototype development and commercialization. By funding projects in areas like point-of-care diagnostics and minimally invasive devices, PRIP accelerates the transition from research to market-ready solutions, particularly for rural healthcare.

Future-Forward

Strengthening Academia-Industry Collaboration

To sustain innovation, India must deepen academia-industry ties, focusing on:

- Low-cost diagnostics and wearable biosensors
- Smart prosthetics and bioresorbable implants
- AI-integrated devices and personalized medicine

A national repository of MedTech challenges could align industry needs with academic expertise. Collaborative research hubs involving universities, hospitals, and manufacturers could drive breakthroughs tailored to India's diverse healthcare needs.

Attracting Private Investment

Private investment is critical to scaling the sector. Proposed measures include:

- Tax incentives for health-tech investors
- CSR funding for public health R&D
- Public-Private Partnership (PPP) Centers of Excellence
- Global co-development models to attract international capital

These steps can address funding gaps, support early-stage ventures, and accelerate the development of cutting-edge technologies.

Challenges and Opportunities

Despite progress, India imports 80–85% of its medical devices, with imports rising from ₹44,708 crore in FY 2020–21 to ₹69,000 crore in FY 2023–24, a 54% increase. However, exports are growing faster, signaling the success of government initiatives. Key challenges include:

- Limited domestic production of high-end devices
- Supply chain vulnerabilities
- Need for advanced R&D infrastructure

Opportunities lie in leveraging India's cost-effective manufacturing, expanding exports to emerging markets, and developing affordable solutions for rural and semi-urban populations.

CONCLUSION

India's medical devices sector is on a transformative path, driven by initiatives like PLI, PRIP, and EPC-MD, alongside regulatory reforms and academic support. To evolve from a manufacturing hub to an innovation leader, India must foster academia-industry collaboration, attract private investment, and prioritize local design and clinical validation. With rising exports and global demand, India is poised to become a MedTech powerhouse, balancing public health access with economic growth. By addressing import reliance and scaling innovation, India can redefine its role in the global healthcare landscape.