



Medical Devices in India: Yesterday, Today and Tomorrow

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ABSTRACT

India's medical-device sector has undergone a remarkable transformation—evolving from a fragmented, import-dependent market to a fast-growing innovation ecosystem. As of 2024, the sector is valued at USD 15–18 billion and is projected to reach USD 30–50 billion by 2030. This review analyzes the evolution of the Indian medical-device industry (“Yesterday”), its current landscape (“Today”), and the emerging opportunities and challenges shaping its future (“Tomorrow”). Market data, regulatory milestones, manufacturing cluster insights, and global competitiveness are assessed using available literature and industry reports. A case study of a hypothetical Indian-made handheld cholesterol meter illustrates future technological opportunities, regulatory pathways, and manufacturing challenges.

Keywords: Medical Devices, India, MDR-2017, Point-of-Care Diagnostics, Manufacturing Clusters, Regulatory Affairs, Market Trends.

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INTRODUCTION

The medical-device industry is a critical pillar of India's healthcare system [1]. With rising non-communicable diseases (NCDs), increasing diagnostic needs, and expanding healthcare access across Tier II/III cities, demand for medical devices—especially diagnostics and monitoring tools—has increased significantly [2, 3].

Historically, India relied heavily on imported devices, especially for high-end diagnostics (imaging systems, advanced therapeutic devices). But since the rollout of Medical Device Rules, 2017 [8], and increasing policy support under “Make-in-India,” the sector has experienced rapid shifts in manufacturing, regulation, and innovation [4].

This paper provides an in-depth analysis of the Indian medical-device sector across three phases [7, 9]:

- Yesterday – Pre-2017 evolution
- Today – Current market, regulatory landscape, manufacturing clusters
- Tomorrow – Future opportunities, technological trends, and challenges [5-6].

A case study tailored around *a handheld Indian-made cholesterol meter* is included to show how these macro trends apply to a real product pathway.

Yesterday — Evolution of the Indian Medical-Device Industry

Pre-2000: Import-Driven, Fragmented & Minimally Regulated

Before the 2000s, medical devices in India were not legally distinguished from pharmaceuticals. Oversight was minimal; the CDSCO had limited control over device quality and manufacturing.

Key characteristics:

- Over 80–90% of devices were imported
- Domestic manufacturing limited to low-tech items: syringes, gloves, dressings
- Foreign companies fully dominate high-end imaging, monitoring, and therapeutic devices
- Limited R&D and virtually no major innovation clusters

2000–2015: Early Growth & Gradual Organization

During this phase:

- Growth of private hospitals and diagnostic labs
- First wave of Indian manufacturers adopting ISO 13485
- Entry of some domestic brands in consumables, disposables, and basic diagnostics

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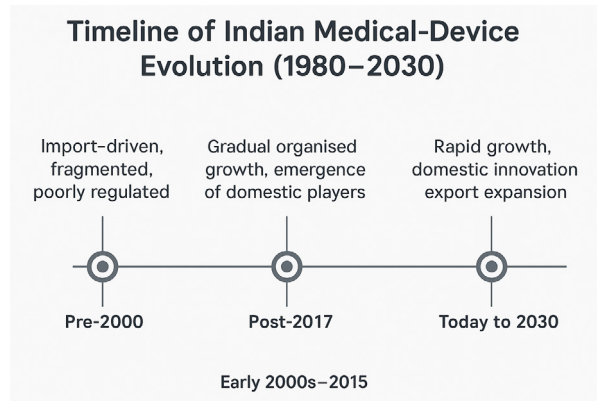


Figure 1: Timeline of Indian Medical-Device Evolution (1980–2030)

- Still import-heavy for medium- and high-tech devices

Post-2017: Inflection Point — Medical Device Rules, 2017 (MDR-2017)

The MDR-2017 framework brought India closer to global standards (IMDRF alignment).

Key outcomes:

- Device classification into Class A/B/C/D
- Licensing requirements for manufacturers and importers
- Mandatory ISO 13485
- Massive growth in licensed manufacturing units
- Surge in investments, domestic innovation, and export interest

Today — Current Landscape

Market Size & Growth (Data Summary)

Imports vs Domestic Manufacturing

Import Dependency (2023–24):

- Imports \approx 75% of total devices sold in India
- Import value 2023–24 \approx ₹68,885 crore

Domestic Manufacturing Trend

- Domestic share increased from **10 to 30%** in 5 years
- Domestic share, even in some high-end categories, reached 20%
- Major growth in mid-tech, diagnostic, and monitoring devices

Manufacturing Clusters Across India

Regulatory Landscape in 2024–2025

- MDR-2017 fully in force
- All devices notified under regulation
- Increased scrutiny on QMS (ISO 13485) compliance
- Faster licensing timelines due to digitized SUGAM portal
- Greater alignment with IMDRF practices

Current Technology & Market Trends

Tomorrow — Future Prospects & Challenges

Growth Forecasts

- Conservative scenario: USD 30.64 bn by 2033

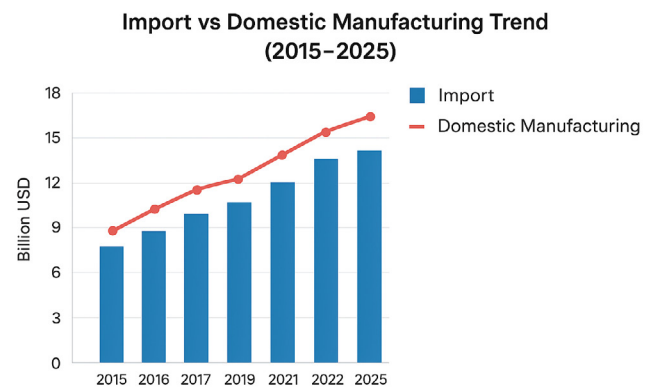


Figure 2: Import vs Domestic Manufacturing Trend (2015–2025)

- Aggressive scenario: USD 50 bn+ by 2030

Future growth drivers

- Aging population
- Chronic diseases
- Expanded insurance coverage
- Tier II/III healthcare penetration
- Medical tourism
- Government policy support
- R&D investment & startup ecosystem

Emerging Opportunities

Point-of-Care Diagnostics (POC)

- Glucose, cholesterol, kidney function, and infectious diseases
- Home-care adoption increasing
- Major opportunity for Indian MSMEs

Wearables & IoT-linked Devices

- Remote monitoring
- Continuous data analytics

Export Expansion

- A large number of export-oriented units in clusters
- “Make for World” vision is gaining traction

Indigenous High-End Device Development

- MRI/CT components, advanced implants, medical software, robotics

Key Challenges Ahead

Case Study: A Hypothetical Indian-made Handheld Cholesterol Meter

Table 1 : Market Size & Growth (Data Summary)

Year/Estimate	Market size (USD)
2023	~15 billion
2024	~18.02 billion
2030 (forecast)	30–50 billion

Sources: IBEF, IMARC Group, Department of Pharmaceuticals reports

Table 2: Medical Device Clusters (CMRSD, 2023)

State	Number of Clusters	Specialization
Tamil Nadu	1	Diagnostics, electronics
Gujarat	4	Implants, disposables
Maharashtra	3	Diagnostic equipment, electronics
Uttar Pradesh	2	Consumables, syringes
Haryana	2	Imaging, disposables
Telangana	2	Startups, R&D
Andhra Pradesh	3	Bulk manufacturing
Karnataka	2	Electronics, software-integrated devices
Others	2	Mixed

Why India Needs This Device

- Cardiovascular diseases = leading cause of mortality
- High cholesterol prevalence: 25–30% urban, 15–20% rural
- Lack of routine lipid monitoring in villages
- Rising demand for affordable, handheld, easy-to-use POC testing

Device Overview**Regulatory Classification**

Under MDR-2017:

- Likely Class B (moderate risk)
- Requires:
 - ISO 13485 QMS (As per Schedule 5 of IMDR)
 - Device Master File (DMF)
 - Plant Master File (PMF)
 - Clinical performance evaluation
 - Stability + shelf-life data
 - CDSCO test and manufacturing license

Manufacturing Ecosystem Fit

Potential cluster: Andhra Pradesh MedTech Zone (Andhra Pradesh, Visakhapatnam)

- Electronics supply chain

**Figure 3:** Case Study: A Hypothetical Indian-made Handheld Cholesterol Meter**Table 3:** Medical Device Clusters in India

Cluster Name	State/Region	Status Category	Color Code (for Map)
AMTZ (Andhra Pradesh MedTech Zone)	Andhra Pradesh	Noteworthy/Major Zone	Green
Delhi-NCR	Haryana, Uttar Pradesh, Delhi	Established Cluster	Green
Mumbai	Maharashtra	Established Cluster	Green
Pune	Maharashtra	Established Cluster	Green
Bengaluru	Karnataka	Established Cluster	Green
Chennai	Tamil Nadu	Established Cluster	Green
Chandigarh	Punjab, Haryana	Emerging Cluster	Yellow
Gujarat	Gujarat	Emerging Cluster	Yellow
Hyderabad	Telangana	Emerging Cluster	Green
Kolkata	West Bengal	Noteworthy Zone	Orange

Table 4: Current Technology & Market Trends

Segment	Growth momentum	Drivers
Point-of-care diagnostics	High	Rise in NCDs, home monitoring
Wearables & IoT	Very High	Preventive care, tele-health
Imaging systems	Medium	Still import-dominated
Implants	Medium	Domestic titanium & polymer capability rising
Disposables	High	Large-scale domestic manufacturing base

Table 5: Market Size

Year / Estimate	Market Size (USD)
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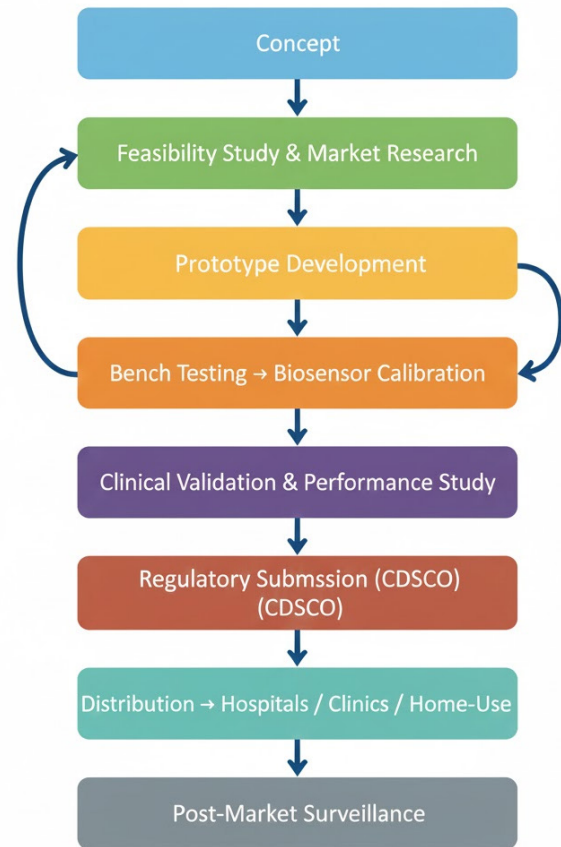
Table 6: Key Challenges for the Medical Device Industry Ahead

Challenge	Explanation
Import dependency (high-end devices)	Local high-tech R&D still limited
Regulatory compliance cost	Startups struggle with certification & testing
Infrastructure gaps	Need full-stack design → prototyping → validation facilities
Skilled workforce	Shortage in biomedical engineering & regulatory affairs
Clinical validation ecosystems	Need more accredited labs, trial centers

Table 6: Biosensor Medical Device Overview

Feature	Description
Principle	Electrochemical biosensor
Measurand	Total cholesterol ± lipid profile
Sample	Capillary blood (finger prick)
Output	mg/dL, stored + Bluetooth sync
Accuracy	±10–15% of lab reference
Portability	<100 g, battery operated
Cost	<₹120 per strip (target)

- Sensor vendors
- Injection molding facilities
- Proximity to shipping/logistics ports
- Regulatory
- Raw material availability

**Figure 4:** Device lifecycle flowchart

CONCLUSION

India's medical-device sector is undergoing a seismic transformation. With strong policy support, expanding manufacturing clusters, digitized regulatory systems, and rising healthcare demand, India is poised to become a global med-tech hub.

However, to fully realize this potential, India must:

- Strengthen R&D ecosystems
- Reduce high-end import dependency
- Support startups with testing/clinical validation infrastructure
- Expand export competitiveness
- Build a skilled medical-technology workforce

Point-of-care devices—such as the handheld cholesterol meter discussed—represent one of the most promising opportunities for the future. They align perfectly with India's needs: affordable, accessible, portable diagnostics for widespread preventive healthcare.

India's med-tech future is bright—if innovation, quality, and regulatory excellence continue to advance.

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