



Shaping the Future of Medical Technology

Kerala Medical Device Industry Association

ROAD MAP

2026 – 2031

Positioning Kerala as the Premier Global Hub for MedTech Innovation, Precision Manufacturing and Sustainable Healthcare Technologies.



THE ACADEMIA-INDUSTRY R&D BRIDGE

Connecting research with industrial commercialisation.



POLICY ADVOCACY & KMSCL PROCUREMENT REFORMS

Enabling a level playing field for Kerala's MedTech industry.



THOUGHT LEADERSHIP & GLOBAL VISIBILITY

MedTech Pulse & Digital Portal.



REGULATORY EXCELLENCE & TALENT PIPELINE

CDSCO Compliance and workforce development



Shaping the Future of Medical Technology

Kerala Medical Device Industry Association

A STRONGER INDUSTRY. A HEALTHIER TOMORROW.

The Kerala Medical Device Industry Association (KMDIA) brings together manufacturers, research institutions, policymakers and global partners to build a competitive, innovative and globally connected MedTech ecosystem.

This Road Map (2026 – 2031) sets out a clear pathway to scale Kerala's capabilities, strengthen domestic manufacturing and contribute to India's vision of health security and technological self-reliance.

PEOPLE

Skilled talent, innovative entrepreneurs, healthier communities.

PARTNERSHIPS

Collaboration across industry, academia, government and global markets.

INNOVATION

From research to commercially viable solutions.

A HEALTHIER TOMORROW

Accessible, affordable and high-quality medical technologies.

Together, we can make Kerala a leading MedTech hub, contributing to a healthier India and a healthier world.

FROM
KERALAM
TO A
HEALTHIER
WORLD

STRONGER
MANUFACTURING
ECOSYSTEM

GREATER
INNOVATION
CAPABILITIES

EXPANDED
GLOBAL
OPPORTUNITIES

MEDTECH
FOR A HEALTHIER
KERALAM.
A STRONGER INDIA.
A BRIGHTER TOMORROW.



Kerala Medical Device Industry Association

Presents

The Road Map

2026 - 2031

TABLE OF CONTENTS

SECTION 1

05-10

THE STRATEGIC CASE

- 01 Executive Summary & Macro-Economic Imperative (With State & Central Data)
- 02 Vision, Mission, and Core Strategic Pillars
- 03 Comprehensive SWOT & Environmental Analysis
- 04 Institutional Governance & Ecosystem Architecture (The "Bridge" Framework)

SECTION 2

11-13

THE IMPLEMENTATION ROADMAP

- 05 Phase 1 : Short-Term Operational Plan (0-6 Months)
- 06 Phase 2 : Mid-Term Strategic Plan (1-Year Horizon: Months 7-12)
- 07 Phase 3 : Long-Term Transformation Plan (Years 2-5)

SECTION 3

14-22

THE FUNCTIONAL STRATEGIES

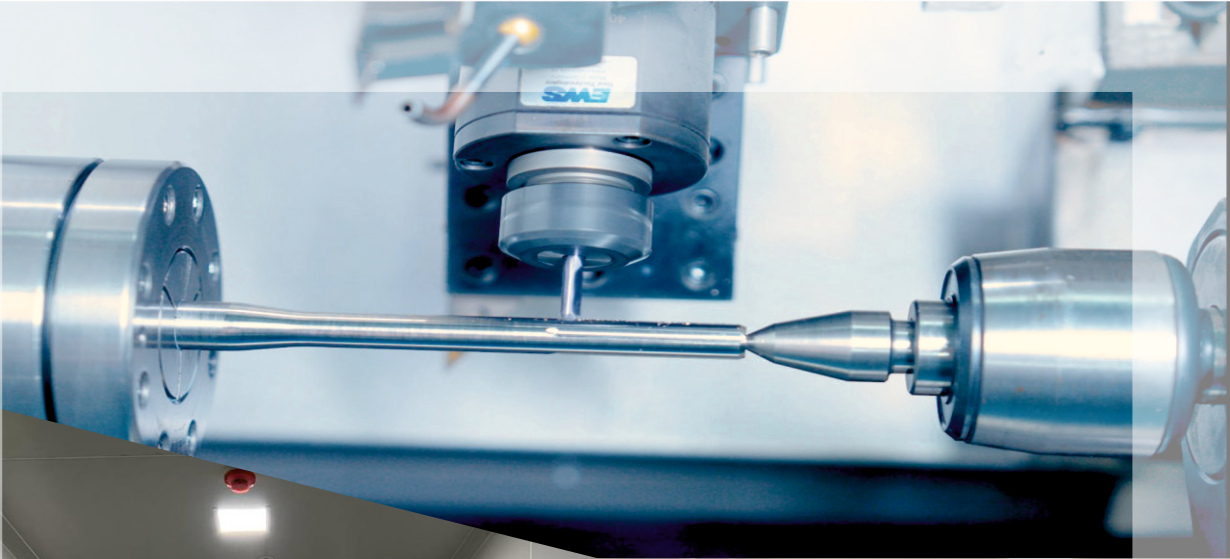
- 08 Detailed Functional Strategy Documents
 - A. Infrastructure: Medical Devices City (MD City) & Plug-and-Play Hubs
 - B. Thought Leadership & Global Visibility: MedTech Pulse & Digital Portal
 - C. Policy Advocacy: KMSCL Procurement Reforms & MOOWR/SEZ Benefits
 - D. The R&D Bridge & Academic Consortium (SCTIMST, IIT, RGCB & NIPER)
 - E. Regulatory Compliance, Quality Infrastructure & Talent

SECTION 4

23-24

FINANCE, RISK & OUTCOME

- 09 Financial Architecture, Funding Models & PLI Maximization
- 10 Policy Matrix
- 11 Conclusion & Call to Action



1. EXECUTIVE SUMMARY



Macro-Economic Context & Central Government Statistics

India's healthcare and medical technology sectors are experiencing unprecedented expansion as the nation accelerates toward its "Vision 2047" mandate for supply chain sovereignty and national health security:

National Market Trajectory: As per the Central Department of Pharmaceuticals and economic indicators, the Indian medical devices market is valued between \$15.2 Billion to \$16.1 Billion (FY2025-26). This is projected to expand rapidly to \$50 Billion to \$50.1 Billion by 2030 (representing an aggressive CAGR of 15% to 26.9%). Globally, the medical devices market size is expanding by \$227.3 Billion from 2025 to 2030 at a CAGR of 6.3%, while India aims to raise its global market share from 1.6% to ~12%.

Import Dependence Bottleneck: Despite growing domestic capabilities, India still imports 60% to 80% of its medical device

consumption—representing an annual import bill crossing ₹70,000 Crore (\$8.8 Billion). Advanced diagnostic imaging, electro-medical equipment (which alone accounts for nearly 60% of imports), and critical implants account for the majority of this trade deficit.

Export Potential: India's medical device exports crossed \$4 Billion (₹33,000+ Crore) in FY2025, demonstrating strong international appetite for high-quality, cost-effective devices.

Central Policy Support: National frameworks such as the National Medical Devices Policy (NMDP), the Scheme for Promotion of Medical Devices Parks, and MedTech Mitra serve as critical catalysts to reduce import reliance and improve domestic competitiveness.

Government & Industry Market Breakdown by Segment (India MedTech Sector)

According to data compiled from the Ministry of Chemicals & Fertilizers (Department of Pharmaceuticals), CDSCO, and national industry surveys, the Indian Medical Devices market (~\$15.2B-\$16.1B) is segmented across primary categories:

*Note: While Disposables & Consumables currently dominate Keralam's physical output volume, the strategic focus for MD City will be shifting local capacity toward high-margin Electronic Equipment, IVD Kits, Dental and Orthopedic/Bone Implants.

The Kerala Advantage & State Economic Data

Data from the Kerala State Economic Review and industrial surveys reveal that Keralam holds a disproportionately strong foundation in advanced manufacturing:

Production Footprint: Keralam home-grown enterprises produce nearly ₹6,500 Crore to ₹7,350 Crore worth of medical devices annually, contributing around 15% (and up to 25% in specific categories) of India's

total domestic production.

Industrial Base: The state hosts an ecosystem of nearly over 100 active, registered medical device manufacturers, alongside established dominance in medical rubber (gloves, catheters blood bags, tubing), In-Vitro Diagnostics (IVD), Bone implants, wound dressings, dental devices, and active medical electronics.

PREAMBLE & OPERATIONAL SCOPE

Contextual Transition:

While the Executive Summary highlights the macroeconomic potential of India's \$15.2B-\$16.1B medical device sector, translating these numbers into ground-level industrial capacity requires an integrated operational framework. Keralam's current output of ₹6,500 Crore represents an established foundation, but scaling to capture 25%+ of domestic production demands a structural shift from fragmented manufacturing to an ecosystem-led cluster strategy.

Purpose of this Strategic Blueprint:

This document serves as the master policy and operational roadmap for the Kerala Medical Device Industry Association (KMDIA). It defines the strategic bridge connecting manufacturers, research institutions, state/central government bodies, and global capital. The target interventions detailed across the short, medium, and long-term horizons are designed to de-risk capital investment for MSMEs, streamline regulatory pathways, and build high-spec infrastructure (such as MD City) to position Keralam as South Asia's leading MedTech hub by 2031.

2. VISION, MISSION & CORE STRATEGIC PILLARS

Vision

"Making Keralam the MedTech Hub of India, and India the MedTech Hub of the World by 2047?"

Mission

- Unify Industry: Represent more than 100 active manufacturers under a strict "One Corporate Group = One Vote" democratic framework to empower MSMEs and startups.
- Infrastructure via MD City: Establish a dedicated Medical Devices City (MD City / Keralam MedTech Zone) featuring plug-and-play Standard Design Factories (SDF) and shared testing laboratories.
- Thought Leadership: Build MedTech Pulse into South Asia's premier policy publication and curating platform.
- Global Gateway: Present Keralam's manufacturing credentials seamlessly to global investors via the KMDIA international portal, jointly with the government.
- The Strategic Bridge: Serve as the active liaison bridging MSMEs, research titans (SCTIMST, IIT Palakkad, RGCB, NIT Calicut), regulators (CDSCO), and state leadership.

3. COMPREHENSIVE SWOT & ENVIRONMENTAL ANALYSIS

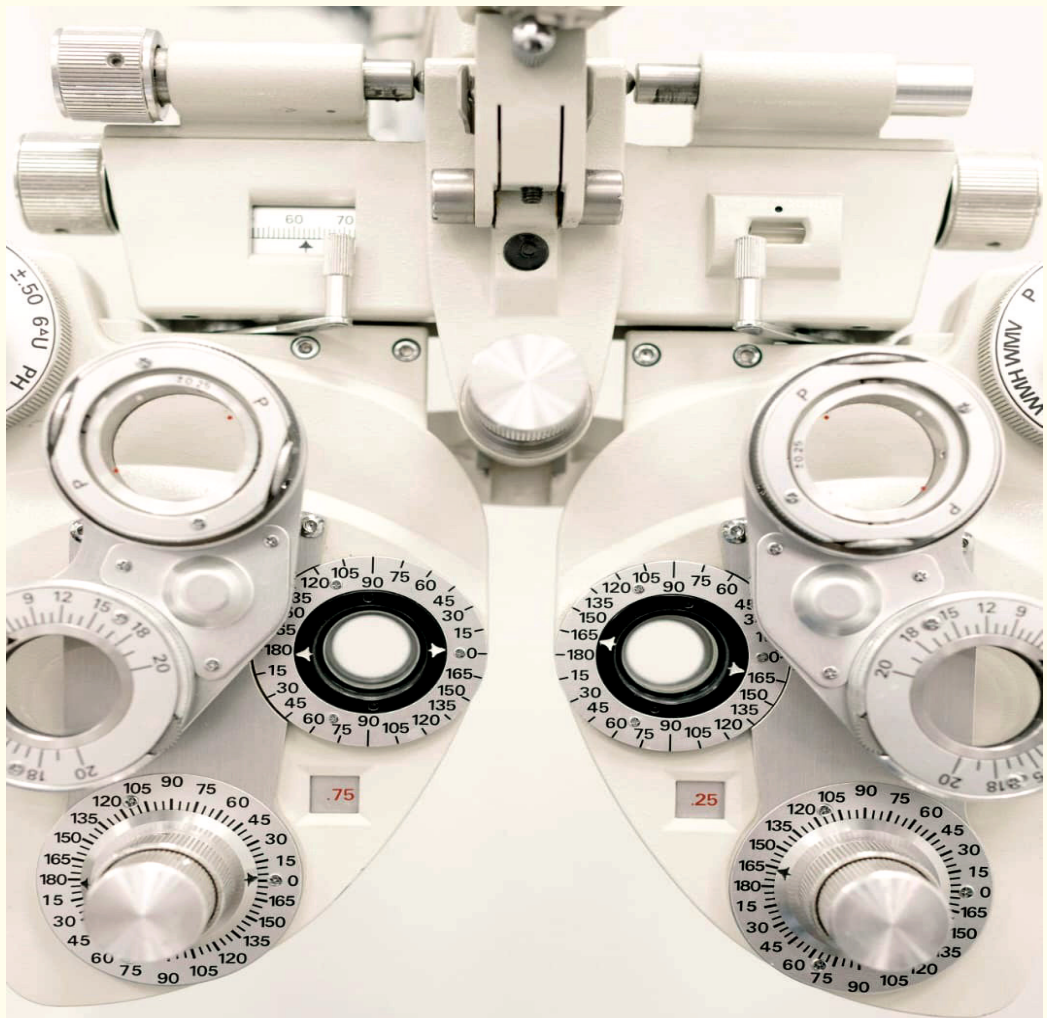
SWOT ANALYSIS MATRIX

STRENGTHS (S) ● Produces 15-20% of India's medical devices (₹6,500 Cr-₹7,350 Cr output). R&D anchors: SCTIMST, RGCB, IIT Palakkad, NIT Calicut. ● High literacy & highly skilled technical workforce. ● Environmental/AQI Moat: Consistently low AQI drastically lowers cleanroom HVAC power consumption, outdoor filter degradation, and electrical OpEx for ISO Class 5-8 cleanrooms. Abundant watershed networks lower water pretreatment costs. ● Talent pool.	WEAKNESSES (W) ● High land acquisition costs (₹3 Lakh per cent vs target ₹30k per cent); high water and power tariffs. ● Fragmented auxiliary supply chain (70% external inputs). ● Restrictive KMSCL turnover and procurement criteria. ● Cumbersome compliance overheads for early-stage Class B/C CDSCO rules.
OPPORTUNITIES (O) ● National PLI schemes (\$400M+ / ₹3,420 Cr pool) & central MedTech park grants. ● MOOWR & EOU/SEZ customs duty deferral frameworks. ● Escalating global demand in IVD, point-of-care, medical rubber, and orthopedic implants. ● Expatriate Dividend: Channeling Non-Resident Keralite (NRK) capital, global mentorship, and returning technical talent from the Gulf and West into high-yield MedTech industrial funds. ● Global ESG Positioning: Leveraging Keralam's green "Clean Tech" baseline to attract ESG-mandated FDI and Joint Ventures.	THREATS (T) ● Aggressive state park subsidies in competing hubs (AMTZ AP, Gujarat, UP, MP, Maharashtra, Karnataka). ● Rapid regulatory shifts in domestic and European markets (CDSCO, EU MDR/IVDR, US FDA).

4. INSTITUTIONAL GOVERNANCE: THE "BRIDGE" ARCHITECTURE

KMDIA acts as an institutional bridge connecting five distinct pillars of the MedTech ecosystem:

KMDIA EXECUTIVE COUNCIL				
President VP Secretary				
STATE & POLICY (Govt / KMSCL)	R&D & ACADEMIA (SCTIMST, IIT, RGCB)	REGULATION & STANDARDS (CDSCO & BIS)	FINANCIAL INSTITUTIONS (Banks/PLI)	MSMEs & GLOBAL MARKETS



5. PHASE 1: SHORT-TERM OPERATIONAL PLAN (0 - 6 MONTHS)

Months 1-3: Inaugural Activation, Media & Policy Pitch

Inaugural Conclave Execution (September 16, 2026): Execute the landmark inauguration with 300+ delegates, state leadership, and industry leaders.

Launch of MedTech Pulse (Print & E-Edition): Release the 50-page inaugural print edition and digital *MedTech Pulse* as KMDIA's flagship policy curating organ and the launch of Road Map.

Development of the KMDIA Web Portal: Enabling the global-facing portal showcasing Keralam's MedTech credentials, member directory, and interactive investor showcases.

Social Media & Targeted Digital Media Outreach: Formally integrate targeted digital awareness campaigns and social media positioning alongside traditional press and trade journals to establish Association visibility.

Policy Representation Submission: Formally present white papers advocating for:

Subsidized land rates at ₹30,000/cent.

KMSCL Procurement Preference (15% price preference & relaxed turnover rules for local manufacturers).

Months 4-6: Academic Bridge & Regulatory Foundations

Execute Institutional MOUs: Sign formal collaboration pipelines with IIT Palakkad, SCTIMST, RGC, and NIT Calicut to bridge basic research with industrial commercialization.

Regulatory Masterclasses: Conduct association-backed training on CDSCO licensing, ISO 13485:2016, and EU MDR/IVDR.

NIPER MedTech Campus Campaign: Initiate formal petitioning with the Central Ministry of Chemicals and Fertilizers for a specialized NIPER MedTech Centre of Excellence in Kerala.

6. PHASE 2: MID-TERM STRATEGIC PLAN (1-YEAR HORIZON: MONTHS 7-12)

MD City Special Purpose Vehicle (SPV) & Department of Pharmaceuticals Liaison (Months 7-9): KMDIA will lead direct inter-ministerial liaison with the Department of Pharmaceuticals (DoP) and Ministry of Chemicals & Fertilizers to secure Central Park Grants, statutory clearances, and Centre of Excellence sanctions.

Customs & MOOWR Scheme Rollout (Months 8-10)

PLI & Central Grant Helpdesk (Months 9-11)

KMSCL Policy Integration (Months 10-12)

PHASE 2.5: ACCELERATION BRIDGE (MONTHS 13 - 24 / YEAR 2 INTERIM)

While Months 1-12 establish the legal frameworks (SPV, MOUs, KMSCL policy changes), Months 13-24 focus on ground-level civil engineering, technology transfer, and capital deployment:

Months 13-15 (MD City Site Development & Civil Layout): Initiate civil groundwork, utility laying (high-voltage power, dedicated water lines, industrial waste treatment), and construction of Phase-1 Standard Design Factories (SDF) under the MD City SPV.

Months 16-18 (Pilot Tech-Transfer & Clinical Licensing): Facilitate the first formal batch of technology transfers (minimum 5 patents) from SCTIMST and IIT Palakkad to local KMDIA manufacturing units for commercial scale-up.

Months 19-21 (CFC Equipment Procurement & Cleanroom Fit-Outs): Facilitate international tenders for Shared Common Facility Centre (CFC) equipment—including Gamma/EO Sterilization plants, ISO Class 5-8 cleanroom HVAC installations, and 5-axis implant machining tools.

Months 22-24 (Trial Production & ISO 13485 Multi-Site Audits): Facilitate trial runs in completed SDF units and conduct association-wide mock audits to prepare 25+ MSME members for CDSCO Class C/D and EU MDR certification.

7. PHASE 3: LONG-TERM TRANSFORMATION PLAN (YEARS 2 - 5)

Year 3 - MD City Shared Common Facility Centre (CFC):

Commission Phase 1 MD City Shared Infrastructure: ISO Class 5-8 Cleanrooms, Gamma/EO Sterilization units, and accredited QC labs.

Achieve a 50% YoY increase in KMDIA members securing Central PLI incentives.

Year 4 - NIPER Approval & Tech Commercialization:

Secure official Central Government approval and seed capital for the NIPER MedTech Centre of Excellence in Kerala.

Successfully commercialize maximum number of patents via the SCTIMST-IIT-KMDIA academic bridge.

Year 5 - Global Expo Roadshows & Auxiliary Ecosystem:

Conduct international trade delegations to Europe, Middle East, and Southeast Asia.

Establish local component vendor clusters within MD City to cut raw material import reliance.

Elevate Kerala's share of national medical device production beyond 20%.

Full MD City Operationalization & Vision 2047 Anchor:

MD City reaches 100% tenant capacity as a self-sustaining ecosystem of startups, MSMEs, and global OEMs.

Graduate the first cohort of specialized regulatory bio-engineers from the proposed NIPER Kerala.

Formally position Kerala as the primary anchor state driving India's 2047 MedTech dominance.

8 DETAILED FUNCTIONAL STRATEGY DOCUMENTS

A. Medical Devices City (MD City): Infrastructure Architecture & Operational Specifications

Modeled on successful developer-enabler models like Technopark and Infopark (and benchmarking international successes like AMTZ Visakhapatnam), MD City will provide plug-and-play manufacturing infrastructure:

PLUG-AND-PLAY / INDUSTRIAL SPACE	SHARED COMMON FACILITY (CFC)
● Standard Design Factories (SDF) ● Customizable Manufacturing Modules ● EOU/SEZ Processing Enclaves ● Customs Bonded Warehouses (MOOWR)	● ISO Class 5-8 Cleanrooms ● Rapid Prototyping & 3D Printing ● Gamma & EO Sterilization Units ● Accredited Testing & QC Labs (EMC/EMI, Biomaterials)

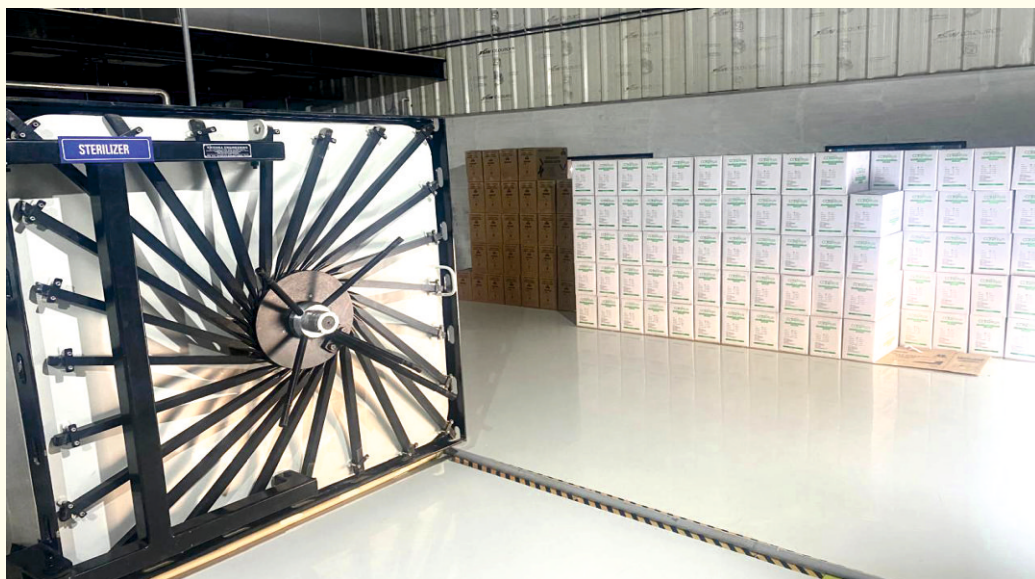
8.A.1 Technical Specifications & HVAC Standards for Standard Design Factories (SDF)

To ensure seamless onboarding for high-precision device manufacturers and cleanroom operators, all SDF modules within MD City will adhere to rigid structural and environmental engineering standards:

Floor-Load Capacity & Structural Grid: Ground-floor heavy machinery zones engineered for a structural loading capacity of 2.5 tonnes/sqm, specifically rated for high-tonnage plastic injection molding machines, 5-axis CNC metal cutters, and automated packaging lines. Upper levels designed for 1.2 tonnes/sqm.

HVAC & Cleanroom Classifications: Integrated central HVAC utility

ducts supporting modular conversion to ISO Class 5 for bio-implant assembly, ISO Class for sterile packaging, and ISO Class 8 for general medical electronics assembly. Air Handling Units (AHUs) will feature terminal HEPA filtration (99.97% efficiency at 0.3 microns) with 20-30 air changes per hour (ACH) and positive pressure differential controls (10-15 Pa).



Emerging MedTech infrastructure

Economic Impact of Low Ambient AQI on HVAC Operations: ISO Class 7 cleanrooms consume 15 to 50 times more energy than commercial buildings, with HVAC driving 50%-75% of total electrical usage. In polluted industrial hubs, heavy PM 2.5/PM 10 loads cause rapid outdoor filter degradation and force blowers to draw exponentially higher power. Kerala's pristine AQI functions as a state-wide natural pre-filter, extending HEPA filter lifecycles, lowering motor pressure drop, and slashing daily electrical OpEx across facility lifecycles.

Utility Infrastructure: Dedicated industrial power feeder lines backed by 100% redundant dual-diesel generators, high-purity water systems (Purified Water / Water for Injection grade piping), and centralized

compressed air lines (7 bar, oil-free, dry air).

8.A.2 Land Lease Structures & Financial Frameworks

Subsidized Long-Term Leases: Land parcels structured under 30-to-90-year long-term lease agreements via the public-private Special Purpose Vehicle (SPV). Land pricing pegged at the target policy benchmark of ₹30,000 per cent for core manufacturing plots to dramatically lower upfront capital expenditure for local MSMEs.

Rationale for ₹30,000/cent Land Subsidy: Current industrial land rates exceeding ₹3,00,000/cent severely restrict MSMEs and drive MNCs to competing states. Treating subsidized land allocation as a strategic "loss-leader" neutralizes real estate barriers, allowing capital redirection into cleanrooms and R&D. The initial state outlay is rapidly recouped via SGST surcharges, corporate tax velocity, high-value employment creation, and ancillary supply chain development.

Plug-and-Play Lease Model: Standard Design Factory (SDF) built-up spaces made available on flexible monthly rental terms (per sq. ft.) with initial 3-year lock-in options, allowing startups to achieve operational status within 90 days of licensing.

8.A.3 Customs Deferral & MOOWR Framework

Operating under the Manufacture and Other Operations in Warehouse Regulations (MOOWR) scheme, manufacturers can import raw electronics, medical plastics, titanium alloys, and capital machinery with zero upfront Basic Customs Duty and IGST. Taxes are deferred until finished products enter the domestic tariff area (DTA), or waived entirely upon export out of India.

B. Thought Leadership, Global Visibility & NRK Diaspora Network

8.B.1 MedTech Pulse (Policy & Industry Organ)

Inaugural Issue: A 50-page print and digital publication featuring

detailed industry analysis, CDSCO/EU MDR regulatory roadmaps, state industrial policy features, and leadership spotlights.

Targeted Physical Distribution List:

Central & State Regulators (300 copies): CDSCO officials, State Drug Control Authorities, NITI Aayog Health vertical, and Ministry of Chemicals & Fertilizers policy heads.

Hospital & Procurement Leadership : Purchase directors, Chief Medical Officers (CMOs), and biomedical engineering heads across major public (KMSCL, AIIMS, Regional Cancer Centres) and private hospital chains nationwide.

Trade Commissioners & Global Embassies : Commercial wings of foreign embassies in New Delhi, Indian trade missions abroad, and global MedTech trade associations.

Industry & Academic Institutions : CEOs of licensed manufacturers, university libraries, research directors (SCTIMST, IITs, RGCB), and venture capital partners.

Ongoing Role: Evolves into South Asia's premier bi-monthly policy curating journal, shaping regulatory dialogue between manufacturers and government bodies.

8.B.2 KMDIA Global Web Portal & Advisory Council

Digital Investor Gateway: Displays Keralam's MedTech capabilities to foreign buyers, venture capitalists, and MNCs seeking contract manufacturing or joint venture partnerships. Features an interactive member directory, digital trade stalls, regulatory step-by-step guidebooks, and an online matchmaking portal for technology licensing.

KMDIA Global MedTech Advisory Council (NRK Diaspora Network

Integration): Formally establishes the KMDIA Global Advisory Council, tapping into Non-Resident Keralite (NRK) clinical, regulatory, and corporate experts across key international regions (US, UK, Europe, Middle East, Singapore, Japan, Australia) to provide Association members with direct mentorship, global clinical connections, export market access pathways, and private co-investment avenues.

C. Policy Advocacy & Dedicated Taskforces

8.C.1 KMSCL Procurement Policy Amendment Matrix

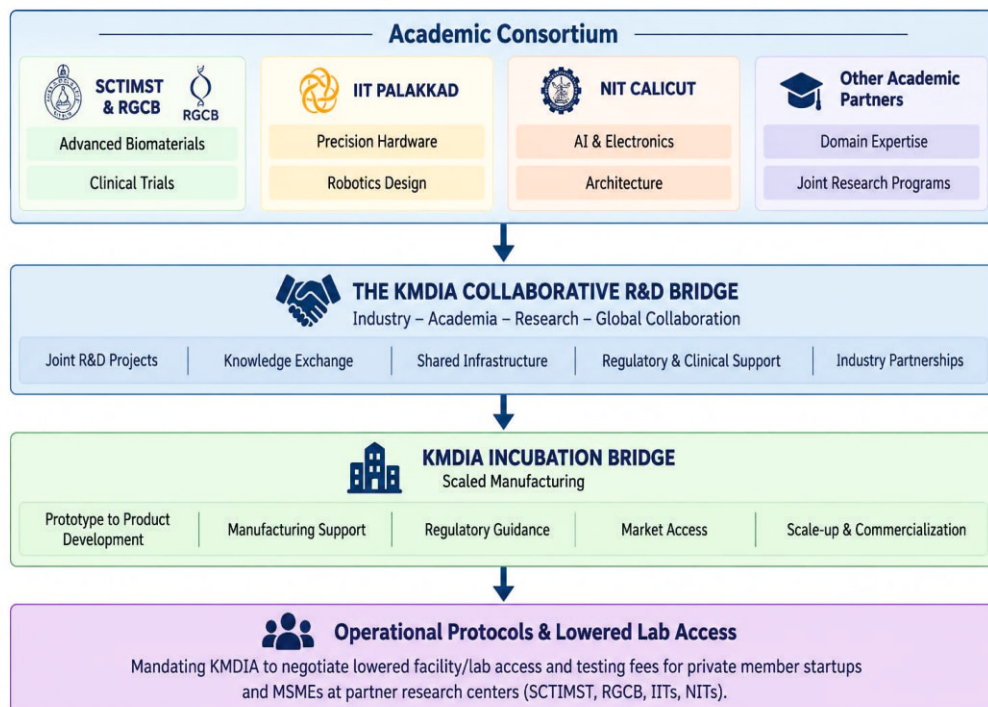
KMDIA serves as a policy bridge to reform state procurement frameworks through the Kerala Medical Services Corporation Limited (KMSCL):

8.C.2 State-Level Incentive Advocacy Taskforce

Structured as a dedicated taskforce within KMDIA to actively lobby state departments and statutory bodies for member incentives:

- Subsidized power, land, and water pricing inside MD City.
- SGST reimbursement / exemptions for state-manufactured medical devices.
- Capex interest subvention on commercial bank loans.
- Regulatory expense support & subsidies for CDSCO / ISO 13485 / CE / USFDA certifications.
- Opening specialized research centers (RCC, MCC, state medical colleges) to industry-collaborative clinical trials and sample-banking policies.
- Collaborating with State Government to present policy issues of the industry before the Central Government.

D. The R&D Bridge, Academic Consortium & Operational Programs



8.D.1 Operational Protocols & Lowered Lab Access

Mandating KMDIA to negotiate lowered facility/lab access and testing fees for private member startups and MSMEs at partner research centers (SCTIMST, RGCB, IITs, NITs).

8.D.2 KMDIA MedTech Cohort-Based Accelerator

Introduced as a structured, cohort-based association program designed to assist 10–15 promising startups or early-stage product companies annually with:

Lab-to-Market Translation: Design for Manufacturability (DFM) and prototyping support.

Regulatory Navigation: Structured mentorship for ISO 13485, CDSCO, CE mark, and US FDA pathways.

Investor Readiness: Connecting founders with venture capital and institutional investor networks.

8.D.3 Core Product Segments & Strategic Focus Areas

To ensure a balanced industrial footprint and maximize economic return across Kerala's manufacturing landscape, KMDIA will provide structured R&D, infrastructure, and regulatory support across four primary medical device product categories:

Consumables & Medical Rubber Disposables:

Product Scope: Examination and surgical gloves, blood collection bags, infusion sets, catheters, precision tubing, and latex/nitrile accessories.

Strategic Role: Capitalizes on Kerala's natural rubber resources and existing production dominance, which currently forms a core pillar of the state's ₹6,500 Crore output.

R&D & Infrastructure Support: SCTIMST bio-compatibility testing, automated dip-molding process optimization, and low-cost ISO Class 8 cleanroom access.

Active Medical Electronics & Diagnostic Equipment:

Product Scope: Patient monitoring systems, ECG machines, digital X-ray detectors, ultrasound probes, point-of-care diagnostic devices, and wearable sensors.

Strategic Role: Addresses the largest national import drain (where 80%+ of equipment is currently imported) by leveraging Kerala's strong hardware and software engineering talent pool.

R&D & Infrastructure Support: Hardware design and embedded system

prototyping with IIT Palakkad (i-MEC program for cyber-physical systems) and NIT Calicut, alongside electromagnetic compatibility (EMC/EMI) testing facilities within MD City.

In-Vitro Diagnostics (IVD) & Molecular Reagents:

Product Scope: Rapid diagnostic test kits, biochemistry reagents, microfluidic chips, immunodiagnostic analyzers, and molecular testing assays.

Strategic Role: Expands Kerala's established IVD base to capture growing national demand for decentralized, point-of-care diagnostic solutions.

R&D & Infrastructure Support: Assays and diagnostic reagent development in collaboration with Rajiv Gandhi Centre for Biotechnology (BRIC-RGCB/BioNEST Class 10K cleanrooms), supported by climate-controlled ISO Class 7 production suites.

High-Precision Implants & Bio-Materials (Including Bone & Orthopedics):

Product Scope: Orthopedic bone implants, joint replacements, trauma plates, titanium/PEEK spinal fixation systems, dental implants, vascular stents, and intraocular lenses (IOLs).

Strategic Role: High-value, low-footprint manufacturing designed to maximize revenue yield per square meter of industrial land while addressing critical national import dependencies.

R&D & Infrastructure Support: Advanced biomaterials development with SCTIMST (IIPC cell), 5-axis CNC titanium machining, electron beam melting (EBM) 3D metal printing, surface passivation (Hydroxyapatite coatings), and dedicated CDSCO Class C & D compliance advisory.

E. Regulatory Compliance, Quality Infrastructure & Talent

8.E.1 Compliance Advisory Pathway

KMDIA's Regulatory Cell: Proposes to provides step-by-step advisory services, taking member enterprises from foundational CDSCO manufacturing licensing (Form MD-5/MD-9) up to international accreditations including ISO 13485:2016, EU MDR/IVDR, and US FDA 510(k) clearances.



8.E.2 Human Capital & Specialized Training Pipeline

Harnessing Keralam's high literacy and engineering graduate pool to establish structured certification bootcamps. In collaboration with NIPER and academic partners, KMDIA will train specialized bio-engineers, cleanroom quality assurance managers, ISO internal auditors, and regulatory submission experts to supply the growing workforce needs of MD City tenants. Re-integrating returning Gulf and Western diaspora talent into local MSMEs raises operational maturity immediately.

9. FINANCIAL ARCHITECTURE & PLI MAXIMIZATION

INSTITUTIONAL & BANKING	STATE & CENTRAL GRANTS	CENTRAL PLI & MOOWR SCHEMES
Preferred Banking Ties Project & Export Credit	State Park SPV Grants Central Cluster Grants	\$400M+ (₹3,420 Cr) PLI Pool Customs Duty Deferral

Banking & Project Finance: Strategic partnerships with major commercial banks to provide dedicated credit lines, working capital, and export credit facilities for MedTech MSMEs.

Financial Catalyst Cell & PLI Pooling: To overcome the high ₹180 Crore individual investment threshold for Central PLI schemes, KMDIA will facilitate MSME consortiums and Joint Ventures, while offering dedicated documentation support to capture 4%-5% incremental sales disbursements.

NRK Diaspora Venture Funds: Collaborating with NORKA and state bodies to launch specialized NRK investment funds and SPVs, channeling expatriate capital into high-yield industrial MedTech assets.

10. THE POLICY MATRIX

Key Operational Milestones (Monitoring Matrix)

[M01] Launch of MedTech Pulse, KMDIA Web Portal & Targeted Digital Media Campaigns.

[M03] Submission of KMSCL & Land Subsidies White Paper.

[M06] Execution of MOUs with SCTIMST, IIT, RGCB & NIT Calicut.

[M12] Formation of MD City SPV, DoP Central Grant Liaison & MOOWR Framework Rollout.

[Y03] Commissioning of Shared Common Facility Centre (Cleanrooms/QC) & Launch of KMDIA Accelerator Cohorts.

[Y05] Kerala Captures 25%+ Share of India's MedTech Output.

11. CONCLUSION & CALL TO ACTION

The 2031 Vision

The transformation of Kerala into a global MedTech powerhouse is not merely an industrial objective; it is a strategic economic imperative. By synthesizing Kerala's high-precision manufacturing capabilities, world-class bio-research institutes (SCTIMST, RGCB, IIT, NIT), cleanroom-friendly natural environment (low AQI), and global diaspora capital, this roadmap provides a clear, executable path to scale the state's medical device production from ₹6,500 Crore to over ₹25,000 Crore by 2031.

Collective Commitment

Achieving this vision requires synchronized execution across four primary stakeholders:

- The Government of Kerala KMTL & KINFRA/KSIDC: By collaborating with Govt. for land allocation for MD City at the competitive ₹30,000/cent policy rate and notifying local purchase preferences in KMSCL tenders.
- Academic & Research Titans: By actively licensing clinical patents to domestic MSMEs under fair commercialization terms.
- Central Ministry of Chemicals & Pharmaceuticals: By sanctioning the proposed NIPER MedTech Centre of Excellence and extending PLI benefits to Kerala's MSME clusters.
- KMDIA Member Enterprises: By committing to strict ISO 13485 / EU MDR quality standards, investing in R&D, and driving unified industry growth under a single democratic framework.

Through the execution of this Master Strategic Roadmap, KMDIA stands ready to bridge policy, technology, and industry - making Kerala the premier MedTech hub of India, and India a trusted MedTech provider to the world.



Shaping the Future of Medical Technology

Kerala Medical Device Industry Association

9/595A, Kadayiruppu P.O., Pattimattam, Ernakulam, Kerala - 682311

www.kmdia.org