

MEDICAL PLASTICS

DATA SERVICE

A TECHNO-ECONOMIC NEWS MAGAZINE FOR MEDICAL PLASTICS, MEDICAL DEVICES, DIAGNOSTICS AND PHARMA INDUSTRY

www.medicalplasticsindia.com
www.medsourcesia.com

Medical Device Manufacturing Ecosystem in India



Future Scenario

- Industry Report: MedTech in India-Poised for Take-off
- Why India could emerge as a Global MedTech Contract Manufacturing Hub by 2035

Infrastructure & Ecosystem

- AMTZ - Building India's Integrated Medical Device Innovation Ecosystem

Materials

- Innovations In Medical Polymers for Implantable Medical Devices
- Importance of Medical - Grade PVC in Modern Healthcare
- Silicone Tubing: The Silent Enabler of Modern Biopharmaceutical Manufacturing



Components

- Fluid Control Components: Small Parts, Big Impact in Medical Device Design

Global Markets

- Export Of Medical Plastic Components - International Market Exploration



Includes Special Supplement On:

"MPDS Directory of Medical Device Industry Suppliers"

-Raw Materials, Components, Machinery, Services & Manufacturing Solutions.



Ami Polymer

Enabling Healthcare

THE SILENT ENABLER OF MODERN BIOPHARMACEUTICAL MANUFACTURING

Biopharmaceutical Silicone Tubing

From upstream cell culture to final fill-finish, platinum-cured silicone tubing ensures flexible, inert, and contamination-free fluid transfer in the most demanding pharmaceutical environments.

Applications

Upstream Cell Culture
Buffer & Media Transfer
Peristaltic Pump Systems
Chromatography & Filtration
Single-Use Assemblies
Aseptic Fill-Finish

Why Choose Ami Polymer?

Platinum-Cured Purity
Cleanroom Manufactured
Regulatory Ready
Precision Extrusion
Full Traceability



Not only Extruder Manufacturer, but also Extrusion Solution Provider

PS Pipette Extrusion Line



Core Technology

Precision Extrusion System

Utilizes Italy's GEFRA dedicated control system, with precise closed-loop control of screw speed and temperature, ensuring stable 24-hour continuous pipe extrusion.

Multi-stage Cooling and Sizing

Customized combination process of water cooling and air cooling achieves rapid cooling and low-stress forming, ensuring inner wall surface smoothness and dimensional stability of the pipe.

Online Diameter Measurement (with Closed-loop Function)

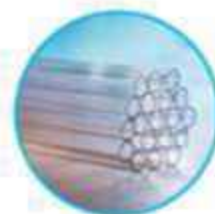
Real-time online monitoring of the pipe diameter, with automatic sorting of non-conforming products.

Flexible Adaptability

Modular structure allows for quick change of extrusion die and sizing die, enabling the production of multiple specifications on a single line.

Process Flow

Feeding → Melt Extrusion → Multi-stage Sizing → Haul-off(Puller) & Cutter → Quality Inspection & Packaging (Optional)



For **precision**, we are committed to every **detail**.....

HIGHRICHJA PRECISION EXTRUSION MACHINERY CO.,LTD

Address: No.1 Industrial Park, Baiteng vil., TaoyuanWest Rd., Shishan Town, Nanhai Dist., Foshan City, Guangdong, China

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Fax: +86-757-86407500

Website: www.chinahjr.com.cn

E-mail: why@chinahrj.com.cn

WhatsApp/Wechat: +0086-13928609286, +0086-13434861212, +0086-13229219297, +0086-13326766657

NEW! Medical Extrusion Capabilities in India

Located in Chennai, Tamil Nadu, this facility offers customers a reliable source of high-quality medical tubing, supported by dedicated quality control and the same rigorous standards applied across Lubrizol's global manufacturing network.

We specialize in delivering precision extruded tubing from a wide range of high-performance materials, including polyamides, nylon, Pebax®, polypropylene, polyethylene, and TPU. Our capabilities support outer diameters from as small as 0.23 mm up to 6.8 mm, (0.009" to 0.27") enabling tight-tolerance solutions tailored to demanding applications across medical devices.

Our Chennai facility supports customers by providing:



Sourcing options outside the U.S. and Europe



Supply-chain diversification



Competitive manufacturing cost advantages



High-precision, high-quality extrusion and component production

Capabilities



Single & Multi-Lumen Precision Extrusion



Braiding



Balloon Tubing



Tri-layer Tubing

Ask about sourcing from our Chennai facility.
Contact our team to start the conversation.



[Lubrizol.com](https://www.lubrizol.com)

FF-M

Electric Medical Injection Molding Machine

160-380T



Core Value Propositions

- Stability and Precision
- High Efficiency and Energy Saving
- Intelligence and Automation
- High cleanliness



Pre-filled flush syringe



Syringe needle cap



Dialysis filter

Yizumi Advanced Processing Technology Pvt. Ltd.

Address: Plot No.1062-1063, GIDC-II, Sanand, Ahmedabad, Gujarat - 382170.

Tel: +91-90999 06175

Email: info.ind@yizumi.com

www.yizumi.com



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krajendr@husky.ca

Premium Silicone Tubing Solutions

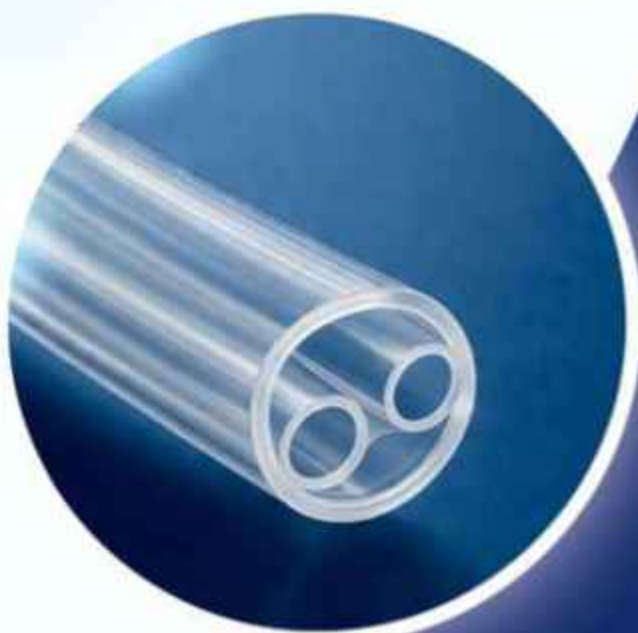
Precision extrusions for diverse medical devices and life science applications

What you can expect:

- World-class extrusions ranging from 0.15 mm ID to 350 mm ID.
- Excellent processability, biocompatibility, and high-temperature resistance.
- Customized solutions leading to high customer satisfaction.
- -60°C to 220°C Temperature Range

Our Medical & Healthcare Range:

- Silicone multi lumen tube for medical application.
- SiliBreath breathing tube.
- SiliCath - Two Way Silicone Foley Balloon Catheter.
- Silicone blister and autoclave gaskets.



Contact us

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Website: www.sevitsil.com

Suresh Enterprises

C1/55, GIDC Phase-II, Dediyaan,
Mehsana - 384002, Gujarat, India.



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STAC MoldTech Private Limited

Corporate Profile



A Leading Medical Plastic Components Manufacturer with State-of-The-Art Tool Room Facility

Manufacturing Facilities & Capabilities Include:

- 19 Injection Moulding Machines (ENGEL, FANUC, JSW, NISSEI and Milacron), ranging from 50T to 200T
- One Vertical Moulding Machine with rotary bed for Insert Moulding
- In-house tool design using CIMATRON for high-precision mould development
- UPS-backed power infrastructure, maintained in temperature-controlled conditions, to ensure seamless operations for high-criticality moulding processes
- Comprehensive fire compliance system safeguarding our entire plant and machinery
- Validated Clean Room Environment

Robust Quality Management System

"StacMold" - An ISO 9001:2015, IATF 16949 certified company with ISO 13485 Under Implementation Has a Robust Quality Management System Offering Consistent Product Quality Through Implementation of Stringent International Standards Related To Risk Management, Process Validation, Documentation and Continuous Improvement.

More Than 4 Decades of Proven Performance Serving Wide Range of Industries Including, Automotive, Medical, Food Packaging, Textiles, Electrical & Electronics, Telecommunications, Pharmaceuticals, Aerospace, Defence, And Cosmetics.

Extensive Experience in Processing a Wide Range of Medical-Grade Thermoplastics and Elastomers, Including PP, PE, ABS, PC, And TPE Materials.

Excellent Customer Support

Design for Manufacturability (DFM) & Tooling development will support our customers to optimize their part design, material selection, and tooling concepts. It will also help us to improve manufacturability, reduce cost, and shorten development timelines.

Please visit our website www.stacmoldtech.in to know more about us !



STAC MoldTech Private Limited

(Formerly SHANKAR TOOLS AND COMPONENTS)

Works: Plot No.8, 2nd Phase, KIADB Industrial Area, Kurliga, Tumkur Dist - 572130, Karnataka, India

Office: No.1013, Nagarabhai BDA Layout, 2nd stage, 9th Block, Bangalore-560 072, Karnataka, India. Ph : +91 94480 55815, +91 8132 222022, Email: shankar@stacmoldtech.in, Web: www.stacmoldtech.in

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Automobile

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- ✓ Resource Planning

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- Batch Release Certificate
- Delivery Challans
- Equipment Calibration Records
- Finished Good Test Reports
- Identification Tags
- Incoming Payments
- Invoices
- IPQC Records
- Machine Preventive Maintenance Records
- Material Inspection Reports
- Material Test Reports
- Material Requisition Slip
- Material Issuance Records
- Material Receipt Note
- Outgoing Payments
- Product Transfer Slip
- Production Register
- Purchase Orders
- Sales Orders
- Stock Register

**BMR
Software**

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Medical Device Solutions:

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At SMC Medical Manufacturing we understand your need for a single source for your full medical device. With over 30 years experience in the medical device market, SMC is an end-to-end provider with capabilities across all aspects of medical device manufacturing. SMC can design, develop prototypes, build tools, manufacture components, assemble and package your finished device while managing the entire supply chain along the way. We've created a seamless process that ensures the highest level of quality while keeping your bottom line and timeline in mind. To see how we can partner with you on your next medical device visit: www.smcltd.com

SMC[®] Ltd.

SMC Medical Manufacturing Pvt. Ltd.
Plot No. 53/54, EPIP Area, Whitefield
Bangalore - 560 066, Karnataka, India
+91 98203 05171 manoj.bhardwaj@smcltd.com

CDSCO LICENSE

CDSCO MANUFACTURING LICENSE – MD5, MD9

DOCUMENTS REQUIRED

Aadhar card, MOA/AOA, Rent Agreement, Device Master Files, Plant Master File, Quality Management System Manual, Fire NOC, Pollution NOC etc.

GOVT FEES

- Class A Non-Sterile Non Measuring - No Fees
- Class A Sterile / Measuring & Class B - ₹5,000 per site, ₹500 per product
- Class C & D - ₹50,000 per site, ₹1,000 per product

CDSCO IMPORT LICENSE – MD15

DOCUMENTS REQUIRED

Free sale certificate, CE Certificate, ISO-13485, Manufacturing License, Power of Attorney, Whole Sale License, Declaration of Conformity etc.

GOVT FEES

- Class A Non-Sterile Non Measuring - No Fees
- Class A Sterile/ Measuring - \$1,000 per site, \$50 per product
- Class B - \$2,000 per site, \$1,000 per product
- Class C & D - \$3,000 per site, \$1,500 per product

DOCUMENTATION

- Device Master Files / Technical Files
- Essential Principles Checklist
- Risk Management File
- SOPs, Formats, Quality Manuals as per ISO 13485
- and more...

PLANT DESIGN

- Civil Design
- Electric Design
- Plumbing Design
- HVAC Design
- and more...

REGULATORY SERVICES

MANUFACTURING LICENSE

IMPORT LICENSE

TEST LICENSE

FACTORY DESIGN

ISO 13485

TECHNICAL FILE

US FDA 510(K)

CE MARKING (MDR, IVDR)

CANADA MDL & MDEL

CLEAN ROOM DESIGN

QMS IMPLEMENTATION

FREE SALE CERTIFICATE





Choose Millad® NX® 8000 clarified polypropylene to improve the quality and production of medical syringes



Millad® NX® 8000 clarifying agent yields ultimate clarity and transparency to PP in injection molded applications and allows clarified PP to become a viable alternative to glass/transparent polymers. In addition, Millad NX 8000 clarified PP enables low-temperature processing in injection molding compared to PP with traditional clarifiers, which in turn yields energy savings, faster cycle time and higher productivity.



Decrease
temperature in
injection molding



Excellent
clarity and
aesthetics



Energy
savings



Complies with
G8 15810,
YY0242
standards



Increase in
productivity



Elimination
of voids

For more information or technical support, please contact Milliken: Call: **+91-20-67307501**, email: **asiachem@milliken.com**, or visit us at **chemical.milliken.com**

Sayujya 2025

सायुज्य 2025

(ISO 17025:2017, OECD GLP, AAALAC, USFDA & ASCA-A2LA Approved Lab)

Globally Ranked Top 10 Lab for Medical Device Testing*

Biocompatibility Testing of Medical Devices (As per ISO 10993-1:2018)

- In-vitro Cytotoxicity Testing (ISO 10993-5)
- Skin Sensitization Testing (ISO 10993-10)
- Irritation or Intracutaneous Reactivity Test (ISO 10993-23)
- Acute Systemic Toxicity Test (ISO 10993-11)
- Material Mediated Pyrogen Test (ISO 10993-11)
- Sub-Acute Systemic Toxicity Test (ISO 10993-11)
- Sub-Chronic Toxicity Test (ISO 10993-11)
- Chronic Toxicity Test (ISO 10993-11)
- Implantation Test (IM/SC/Intraocular/Intra-biliary/Intra-arterial) (ISO 10993-6)
- Genotoxicity Tests (AMES, CHA, MNT) (ISO 10993-3 & ISO 10993-33)
- Hemocompatibility Tests (ISO 10993-4)
- Carcinogenicity Test (ISO 10993-11)
- Reproductive / Developmental Toxicology (ISO 10993-11)
- Degradation Testing (ISO 10993-9, ISO 10993-13, ISO 10993-14 & ISO 10993-15) Toxicokinetic study of Degradation Products (ISO 10993-16)
- In-vitro Skin Irritation Test (ISO 10993-23)
- In-vitro Skin Sensitization Test (ISO 10993-10)
- Mucosal Membrane Irritation Test (Oral, Ocular, Penile, Vaginal & Rectal) (ISO 10993-11)
- Biological Evaluation Plan (BEP) & BER
- Toxicological Risk Assessment (TRA)



1. Biocompatibility Testing of Medical Devices (As per ISO 10993-1:2018)



2. Chemical Characterization (Extractable & Leachable) Testing (ISO 10993-16 & ISO 10993-17)



3. Biological Testing of Raw Material of Plastics, Rubber, Silicon, Polymers, etc.



4. Microbiological Testing Services



5. Packaging Integrity Testing



6. Stability Testing Services & Transport Simulation Testing



7. Mask, PPE, Gloves & Textile Performance Testing



8. Performance Testing of Medical Devices



9. Performance Testing of Rapid In-Vitro Diagnostic Kits



10. Research & Development Services For Devices



11. Clinical Study (CE)



12. Regulatory Dossier Preparation



13. IPR Management Services

With Best Compliments From

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(Managing Director)

Dr.Rina Gokani
(Director & CSO)
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Dr.Manish Rachchh
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*As per two Independent Reports Published by:

- 1) Credible Markets, USA
- 2) MR Accuracy Reports, Canada

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INDO GERMAN TOOL ROOM - AHMEDABAD

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CAPABILITIES IN MEDICAL SECTOR

IGTR delivers high-precision injection molded components that meet the stringent requirements of the medical industry.

From concept to commercialization, we are your reliable partner in delivering life-enhancing solutions.

PROVIDING SERVICES :

- ✓ Precision machining Job work
- ✓ 4 axis & 5 axis machining
- ✓ Complex accurate mould parts
- ✓ Tool manufacturing using latest technology
- ✓ Tool related innovation for improved product design
- ✓ Conformal cooling using Rapid tooling

PRODUCTION & TOOLING

IGTR offers an array of cutting edge production and job-work services to several organizations not only in Gujarat and India, but across the world. The spectra covers the entire range of manufacturing press moulds, tools die casting dies, jigs & fixtures and gauges. IGTR also under-take manufacturing of standard parts, components and carry out precision job work.

IGTR is equipped with an ultra-modern tool room machines state-of-the-art facilities, all under one roof. The wide range of the latest CNC machines from best of the European make that provides 360 degree solutions to precision machining covering the entire spectrum of tool and die making.

WHY IGTR?

- ✓ Medical-Grade Quality
- ✓ Precision & Consistency
- ✓ Advanced Technology
- ✓ Regulatory Compliance
- ✓ End-to-End Support



ADVANCED MOLDING

State-of-the-art injection molding technology for complex, high-precision medical components.



MEDICAL GRADE MATERIALS

Expertise in engineering thermoplastics and biocompatible materials that meet global standards.



QUALITY ASSURANCE

certified processes with rigorous quality control ensuring safety, reliability and traceability.



CLEAN & CONTROLLED ENVIRONMENT

Controlled manufacturing environment to maintain product integrity and minimize contamination.



DESIGN & ENGINEERING SUPPORT

DFM expertise and rapid prototyping to accelerate product development and innovation.

MEDICAL PRODUCTS WE MANUFACTURE

SYRINGES



IV Dial Flow Regulator



IV CONNECTORS & CANNULAS



Intraocular lens



SAMPLE TUBES & CENTRIFUGE TUBES



CLOSURES & CAPS



SURGICAL INSTRUMENT COMPONENTS



Metal Injection Molds for Laparoscopy Jaws



OTHER PRECISION COMPONENTS & TOOLING (TOOL ROOM CAPABILITIES)



HIGH PRECISION & QUALITY



MEDICAL GRADE MATERIALS



ADVANCED TECHNOLOGY



ON-TIME DELIVERY & RELIABILITY



CUSTOMER FOCUSED SUPPORT

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At IGTR, we are committed to supporting the medical industry with innovative, reliable and compliant solutions that contribute to better patient care and a healthier world.





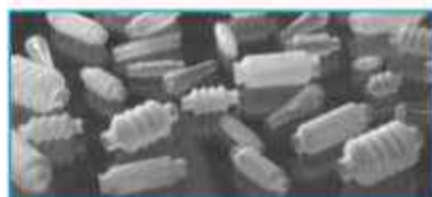
Elastomer Technik



**Your Professional Partner In The
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ET Elastomer Technik GmbH develops high quality Silicone Products in close cooperation with our Customers from all over the world. We offer Complete Product assembly services with on-site clean room & tool shop attached with CAD/CAM systems.

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- DIN EN ISO 13485 Quality management for medical devices
- DIN EN ISO 14001 Environmental management
- Cleanroom EG-GMP-guideline Annex 1 cleanroom class D & ISO14644-1 (class 8)

ET Elastomer Technik GmbH:
Am Stöckleinsbrunnen 10, 97762 Hammelburg, Germany.
Tel: +49 (0) 9732 78865 0 Mail: info@elastomer-technik.com
Website: www.elastomer-technik.com

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We are ISO-9001:2015, ISO-14001:2015 and IATF-16949 certified. Our laboratories are accredited by ISO/IEC-17025 and R&D center is approved by DSIR. Steps forward for certification of ISO-13485 for Medical device Quality Management System.

Our Compounds are also available with special properties like Phthalate Free, Antimicrobial, Antifogging, Radio Opaque, ESD (Electro Static Discharge) properties on demand.

RANGE OF PLASTICIZERS

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RANGE OF COMPOUNDS

PVC | TPE | PP | TPR | EVA | XLPE-PEROXIDE | SEMI-CONDUCTIVE | XLPE-SIOPLAS | ZHFR | EPR | PE | MASTERBATCH-PVC, PE & UNIVERSAL |

COMPOUNDS FOR APPLICATIONS

PVC COMPOUND BASED ON PHTHALATE, PHTHALATE FREE & DINCH | TPE | PP |

Phthalate Free / REACH Compliant Plasticizers available

Our Application Range:

Oxygen masks | Nonwoven surgical masks | Safety Goggles | Catheters | IV sets | Feeding tubes | Blood Transfusion tubes | Endotracheal tubes | Dialysis tubes | Suction tubes | Drip chambers | Blood Bags

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Tube Size Range	1 to 30 mm	1 to 38 mm	5 TO 50 mm
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Tube Puller Motor	0.75 KW	0.75 KW	0.75 KW
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Total Connected Load	12.5 KW	14 KW	20.5 KW



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Our 34th Year of Publication

MEDICAL PLASTICS DATA SERVICE

A TECHNO-ECONOMIC NEWS MAGAZINE FOR MEDICAL PLASTICS, MEDICAL DEVICES, DIAGNOSTICS AND PHARMA INDUSTRY

Medical Plastics Injection Moulded & Extruded Components

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Medical Grade Polymers

Medical Grade Polymers

Medical Grade Polymers

Medical Grade Polymers

Medical Plastics Composites

Medical Plastics Composites

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Medical Plastics Composites

Medical Plastics Packaging

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Dr. HP Testing Solutions Pvt. Ltd. (DRHP) is a pioneering leader in the medical device and pharmaceutical testing industry. We are committed to providing reliable and proven testing services for medical devices and pharmaceutical products, making us a trusted partner for companies across the globe.

We have successfully submitted many chemical characterization reports to USFDA for 510k and got approvals. We strive for excellence in every service, offering accuracy, precision, and reliability at competitive pricing.

Our services span chemical testing, physical testing, analytical testing, and consulting. We are dedicated to adding value through pre- and post-testing support, ensuring our customers meet their regulatory and research needs effectively.

Services

- ISO 10993-1: Biological Evaluation Plan (BEP) and Biological Evaluation Report (BER)
- ISO 10993-7: Ethylene oxide sterilization residuals Analysis
- ISO 10993-13: Identification and quantification of degradation products from polymeric medical devices
- ISO 10993-14: Identification and quantification of degradation products from ceramics
- ISO 10993-15: Identification and quantification of degradation products from metals and alloys
- ISO 10993-17: Toxicological Risk Assessment (TRA) of medical devices, packaging materials and CCS
- ISO 10993-18: Chemical characterization of medical device: (Exaggerated/Exhaustive extraction studies and study designing).
- E&L for Pharma, Packing and Medical devices as per ICH, PQRI, USP <1663> & <1664>, ISO 10993-12 & 18 etc.
- ISO 11979-5: IOLs: Physicochemical tests like Extractables, Leachables, Hydrolytic Stability, Photo Stability and Insoluble Inorganics.
- ISO 11981 & ISO 11986: Soft Contact Lenses: Physicochemical tests
- 21 CFR 177.1500 Chemical Testing of Nylon Resins and Polymers
- EN 1186 Migration Study
- ISO 18562-2: Emission of Particulate Matter from Gas Pathways

- ISO 18562-3: VOCs from Gas Pathways
- ISO 18562-4: Condensate Leachables from Gas Pathways
- ASTM D7823-18: Residual Phthalate Testing
- Raw material and finished products testing
- Ink Migration and Glassware Delamination Studies.
- Toys testing for nitrosamines and phthalates as per EN 14350:2020, EN-71-12, EN-73-14
- REACH Study as per regulation (EC) No.1907 etc.
- BS EN 455-3 and ASTM D5712: Aqueous Extractable Protein Test
- ASTM D6499: Antigenic Protein tests.
- ASTM D7558: Extractable Chemical Dialkylidithiocarbamate, Thiuram, and Mercaptobenzothiazole Accelerators Test.

- TOC, THC as per ISO 19227:2018; BS EN 1484:1997
- Particulate Matter as per USP <788> and EP 2.9.19, ISO 19227:2018
- Syringe Tests as per ISO 7886-1
- Nitrosamines and NDSRIs Method development and Validation
- USP <661> Plastic Packaging Systems and Their Materials of Construction
- Unknown peak identification and characterization
- Forced degradation Study
- Residual solvents analysis
- Heavy metal analysis
- Elemental analysis as per ICHQ3D & USP<233>



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Table of Contents

Vol. 34 No. 3 May-June 2026

25



COVER STORY

Innovations In Medical Polymers for Implantable Medical Devices

The use of specialized polymers with metal-like performance is changing the landscape of medical implants, offering a wider range of options for manufacturers and healthcare professionals. These new materials can improve the surgery outcomes and quality of life.

27



INNOVATION

Building India's Integrated Medical Device Innovation Ecosystem

- **Divya Patil**, Materials Scientist, COO-Indian Society for Assembly Technologies - AMTZ

Innovation begins long before manufacturing. Recognizing this, AMTZ has established a comprehensive support framework that assists innovators throughout their product development journey. The ecosystem includes specialized support cells for technology transfer, product realization, market intelligence, trade facilitation, certification services, and health technology assessment.

30

QOSINA

COVER STORY

Fluid Control Components: Small Parts, Big Impact in Medical Device Design

- **Qosina**

For manufacturers developing infusion systems, diagnostics equipment, drug delivery devices and other fluid-handling applications, selecting the right fluid control components is essential to achieving consistent performance and regulatory compliance.

While often overlooked, fluid control components are fundamental to medical device performance.

31

DIRECTORY

"MPDS Directory of Medical Device Industry Suppliers"

1. Medical Disposables, Implants, Hygiene Products, Allied Medical Device.
2. Components, Raw Materials, Packaging Materials & Consumables.
3. Manufacturing Machineries, Equipment's & Accessories.
4. Services: Testing, Quality Certifications, Consulting, Contract Manufacturing, Training, Others.

51

INDUSTRY REPORT

MedTech in India-Poised for Take-off

The MedTech ecosystem is evolving toward the delivery of world class, patient safe, internationally benchmarked medical technology from India to the world. The sector is witnessing momentum: modern factories, advanced R&D labs, expanding exports, and Indian enterprises steadily moving up the value chain.



53



MEDICAL COMPONENTS

Silicone Tubing: The Silent Enabler of Modern Biopharmaceutical Manufacturing.

- **Mr. Priyabrata Pattnaik** Chief Executive Officer (CEO), Ami Polymer Pvt Ltd

Biopharmaceutical silicone tubing is far more than a passive conduit. It is a precisely engineered, chemically sophisticated, and rigorously validated component that directly impacts product quality, patient safety, and manufacturing reliability.

Table of Contents

Vol. 34 No. 3 May-June 2026



55

MATERIALS

Importance of Medical - Grade PVC in Modern Healthcare

- **Mr. R C Gupta**, Vice-President, KLJ Polymers & Chemicals

Medical-grade PVC remains one of the most important materials used in the healthcare industry. Its combination of flexibility, durability, transparency, chemical resistance, sterilization compatibility, and cost-effectiveness makes it suitable for a broad range of medical applications.



57

GLOBAL MARKETS : MEDICAL DEVICES

EXPORT OF MEDICAL PLASTIC COMPONENTS - INTERNATIONAL MARKET EXPLORATION

Mr. Amit Dave, M. Pharm, MBA Former CEO – Brazil operations/ Vice President Export - Zydus Cadila Claris Lifesciences

The strengths in favour of this opportunity are a growing market and "Advantage India" for high quality and low cost. The challenges would be to find the right buyer with price and volume, followed by robust supply chain management

59

AiMeD & REGULATORY UPDATES

- AiMeD hails appointment of 22 drug inspectors for medical devices, calls for stronger regulatory capacity
- ICMR launches Innovator-Industry platform, transfers 41 public health technologies for development

60

INDUSTRY NEWS

Panel asks DoP to monitor progress of medical devices parks



23

DID YOU KNOW?

About why India could emerge as a Global MedTech Contract Manufacturing Hub by 2035

India's MedTech contract development and manufacturing organization (CDMO) opportunity could scale to \$6-7 billion by 2035 as global original equipment manufacturers (OEMs) look for alternative production bases.

HIGHLIGHTS

Applications, Book Review, Company Profiles, Country Profiles, Design, Discovery, Eminent Institutions, Eminent Personalities, Events, Global Opportunities and Trends, Health Update, Import-Export News, Industry News, Manufacturing, Markets, Materials, Product Profiles, Products & Processes, Regulatory Affairs, Sterilization, Quality, Technology **All related to Medical Plastics/Devices and Equipments Industry and Trade.**

Flashback

MEDICAL PLASTICS DATA SERVICE

Select Article Index

March-August 2023

PRESS RELEASE

- Qosina Introduces New Genderless AseptiQuik® W Series Connectors for Large-Volume, High Flow Production Environments. (May-June 2023)

DID YOU KNOW?

- About Defects In Intraocular Lens (IOL). (May-June 2023)

COVER STORY

- Medical Devices in India: Overcoming the Challenges and Capitalizing on Opportunities Mr. Chandrasekhar Padamkumar President, Kerala Medical Technology Consultant, Director, Kerala Life Science Park and Former Managing Director, Penpol Pvt. Ltd., Trivandrum. The Indian medical device industry can be said to have formally taken shape in the nineteen eighties after the Government of Kerala set up SCTIMST in 1976 and the Institute developed first the Blood Bag and a host of medical devices soon after, including the blood oxygenator, cardiomy reservoir, tubing for the extracorporeal circuit in heart-lung machines and the artificial heart valve...
- Chemical characterization of Polymeric Medical Devices: Unveiling the Identity and Risks Dr. Renjith S., Scientist B, Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum Polymeric medical devices play an inevitable role in day-to-day medical care. We can observe materials of polymeric origin in a wide range of medical devices viz. injection syringes, blood bags, intra-ocular lenses, vascular grafts, hernia patches, facial implants, catheters, personal protective equipment (PPE), and many more. Material selection is one of the first and foremost steps in the development of medical devices...
- Lubrizol enables Make in India Through High-Quality Components and Raw Material Mr. Rajib Bhattacharjee, Business Director Life Science Health for South Asia & Middle East region, Lubrizol Life Science The company is focused on the healthcare market and not only participates in the medical devices segment with the polymers, design and manufacturing capabilities but has a strong presence in the pharmaceutical, nutraceuticals market & oral care markets...
- The Sustainable Polymers of the Future..... Available Today When healthcare professionals use plastic-based materials in patient care, they expect them to provide safety and proven performance. That means they must deliver the high clarity, durability, strength....(July-August 2023)



Did You Know?

About why India could emerge as a Global MedTech Contract Manufacturing Hub by 2035

India could emerge as a \$7 billion contract manufacturing hub for global medical device companies by 2035, as multinational firms diversify supply chains beyond China and India deepens its domestic manufacturing ecosystem, according to a report by Boston Consulting Group (BCG), the Association of Indian Medical Device Industry (AiMeD), and the Kalam Institute of Health Technology (KIHT).

Report on 'Poised for Take-off: MedTech in India', Highlights:

- India's overall MedTech opportunity could expand more than fourfold to \$83-89 billion by 2035 from around \$20 billion currently, driven by rising domestic demand, exports, and contract manufacturing.
- Domestic manufacturing share in MedTech demand has already risen sharply from about 20 per cent in 2022 to nearly 45 per cent in 2025, reflecting accelerated import substitution across categories such as consumables, diagnostics, and hospital equipment
- India's MedTech contract development and manufacturing organisation (CDMO) opportunity could scale to \$6-7 billion by 2035 as global original equipment manufacturers (OEMs) look for alternative production bases.
- Ongoing free trade agreements with markets such as the UK, New Zealand, and Oman could improve export access.
- India currently accounts for only about \$4 billion of global MedTech exports despite a global market estimated at \$670-680 billion in 2025.
- Consumables continue to dominate exports, though higher-value segments such as implants, devices, and diagnostics are emerging as faster-growing areas.
- Global MedTech outsourcing is increasingly shifting towards components, sub-assemblies, and value-added manufacturing services, opening opportunities for Indian firms in areas such as imaging systems, disposables, implants, and diagnostics.

However, the report cautioned that India still faces structural bottlenecks, including import dependence for critical components and raw materials, fragmented testing infrastructure, regulatory complexity, and low R&D intensity. Indian MedTech firms spend only 2-4 per cent of revenue on research and development compared with 15-20 per cent in China, it said.

In a Nutshell....



It is a profound and necessary truth that the deep things in science are not found because they are useful; they are found because it was possible to find them."

- J. Robert Oppenheimer

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From the Editor's Desk



The major theme for this issue of magazine is on, "Medical Device Manufacturing Ecosystem in India".

As per a recent Joint Report by Boston Consulting Group (BCG), The Association of Indian Medical Device Industry (AiMed), and The Kalam Institute of Health Technology (KIHT) titled "MedTech in India-Poised for Take-off", "The MedTech ecosystem is evolving toward the delivery of world class, patient safe, internationally benchmarked medical technology from India to the world.

The sector is witnessing momentum: modern factories, advanced R&D labs, expanding exports, and Indian enterprises steadily moving up the value chain. 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".

The report (highlights covered in this issue) also further mentions that "India could emerge as a \$7 billion contract manufacturing hub for global medical device companies by 2035, as multinational firms diversify supply chains beyond China and India deepens its domestic manufacturing ecosystem".

However, the report cautioned that India still faces structural bottlenecks, including import dependence for critical components and raw materials, fragmented testing infrastructure, regulatory complexity, and low R&D intensity.

We still have to go a long way to match the global competitiveness. Global competitiveness is increasingly associated with capabilities beyond assembly, including components, materials, testing, validation, clinical evidence, and regulatory excellence. Another focus area highlighted is about components and raw materials supply ecosystem.

This bimonthly magazine, "MEDICAL PLASTICS DATA SERVICE" being published since last 34 years, has a mission to integrate the raw materials, components, machinery and services ecosystem with the Indian Medical Device Industry. This issue includes a "Special Supplement titled," MPDS Directory of Medical Device Industry Suppliers" with detailed profiles of about 40 suppliers for the benefit of Indian Medical Device Industry.

Relevant to the theme is an introductory article on "AMTZ: Building India's Integrated Medical Device Ecosystem" by Ms Divya Patil, Material Scientist, COO-Indian Society for Assembly Technologies - AMTZ. As explained by Ms Divya Patil, the AMTZ ecosystem includes support cells for technology transfer, product realization, market intelligence, trade facilitation, certification services and health technology assessment. One of the most distinctive features of AMTZ is its network of specialized scientific facilities designed specifically for the medical device industry.

One more development to support medical device industry innovation ecosystem is the launching of innovator-industry platform by ICMR dedicated to biomedical innovation aimed at translating indigenous biomedical research into accessible, real-world healthcare solutions through strong industry partnerships.

While the cover story in the magazine highlights "Innovations in Medical Polymers for Implantable Medical Devices" there are more technical articles introducing Medical Polymers and components. It also includes our regular columns about Industry & Regulatory News as well as Global Markets.

D.L. Pandya

Innovations In Medical Polymers for Implantable Medical Devices

Implantable applications and the types of plastic materials

The use of specialized polymers with metal-like performance is changing the landscape of medical implants, offering a wider range of options for manufacturers and healthcare professionals.

Orthopaedic

Joint replacements: For hips, knees, shoulder, etc (UHMWPE, ketones, bio durable) Fracture fixation: Plates, screws, nails, pins (metal and bio durable) Implantable applications and the types of plastic materials

Cardiac

Pacemakers: Regulates hearts rhythm (metal for the casing, TPU or silicone for the leads) Cardiac defibrillators: Treats irregular heart rhythms (metal for the casing, TPU or silicone for the leads)

Hearing

Cochlear Implants: provide for a sense of sound to people with severe hearing loss (silicone, metals)

Bodily Augmentation

Breast implants: Used for breast augmentation (shell is made of silicone, gel is made of silicone)

Neurostimulation

Neurostimulators: Used to treat chronic pain or neurological conditions (metal for the casing, TPU or silicone for the leads)

Drug Delivery

Implantable Infusion Pumps: Deliver medications continuously or intermittently over extended periods (metals for the casing and silicone, PLA or PLGA for the catheter and other components)

Material Innovations for Medical Implants.

From artificial muscles and sensory textiles to a cornea from the printer – current research & developments show just how versatile modern polymer materials are in medical applications today.

Some of the developments show smart materials that make medical innovations possible.

Modern medicine can hardly do without plastics. What sounds like an everyday material to many is actually a key to the future of healthcare: malleable, adaptable, hygienic and increasingly sustainable.



New Muscle Power From the 3D Printer

Researchers at Empa and ETH Zurich have developed a process with which artificial muscles, so-called dielectric elastic actuators, can be produced from silicone-based materials using 3D printing. These actuators are soft, elastic and yet powerful. Similar to real muscle fibers, they contract under electrical tension and relax again.

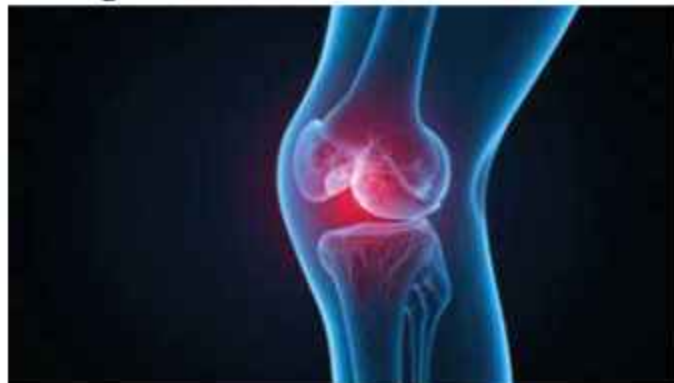
Artificial Cornea in Practical Use



The artificial cornea "Endo Art", developed in Israel and approved in Europe since 2021, is used in special cases, e.g. in patients for whom human transplants have failed.

It is made of hydrophilic acrylate, which does not trigger a rejection reaction. Although the implant does not achieve the visual acuity of donor tissue, the clear cornea and reduced swelling significantly improve quality of life.

Cartilage From the 3D Printer



Researchers at TU Wien are working on a method for producing replacement tissue from biodegradable plastic. A special 3D printing process is used to produce porous microspheres that are colonized with cells.

These "mini-scaffolds" grow together to form uniform cartilage tissue and are ideal for use in regenerative medicine. The plastic structure gradually degrades itself so that only the living tissue remains. A solution with great potential, for example for joint surgery or personalized therapy approaches.

Latest Innovations In Knee Implant Materials



Cover Story

The cutting-edge materials transforming knee replacements, from advanced polyethylene blends that reduce wear to bioactive coatings promoting faster bone growth. These new materials can improve the surgery outcomes and quality of life.

Key Takeaways

Recent advancements in knee implant materials, such as Highly Cross-Linked Polyethylene (HXLPE) and oxidized zirconium, significantly enhance durability and reduce the need for revision surgeries, addressing key concerns of patient dissatisfaction post-surgery.

Bioactive coatings, including hydroxyapatite and antibacterial coatings, and the development of patient-specific and hypoallergenic implants are pivotal innovations aimed at improving implant integration, reducing infections, and catering to patients with metal allergies. Emerging technologies like 3D printing, smart implants, and nanomaterials are revolutionizing knee arthroplasty by enabling patient-specific solutions, real-time monitoring, and enhanced biocompatibility, promising improved clinical outcomes and personalized patient care.

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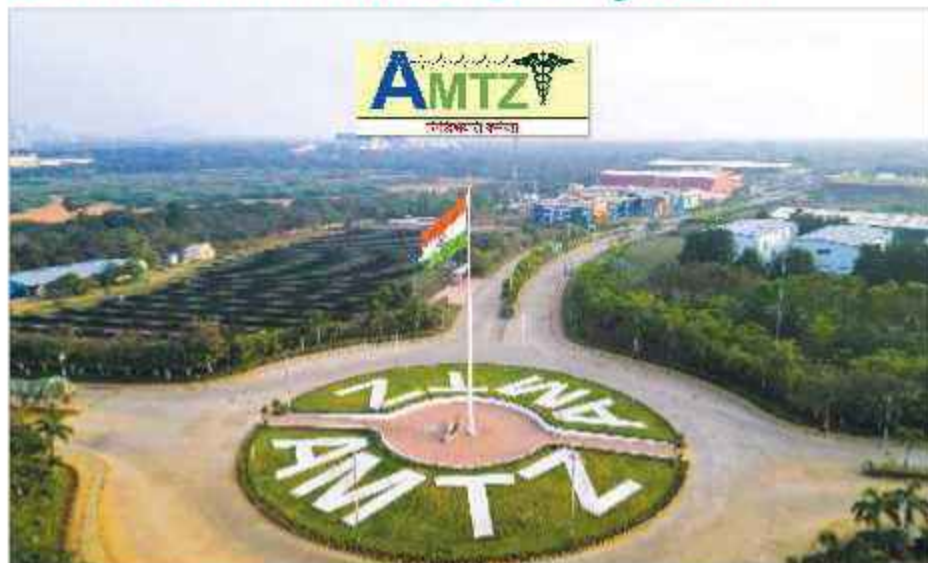
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AMTZ: Building India's Integrated Medical Device Innovation Ecosystem



Divya Patil, Materials Scientist
COO-Indian Society for Assembly Technologies
- AMTZ

Transforming Healthcare Manufacturing Through Shared Infrastructure, Scientific Excellence, and Industry Collaboration

The medical device industry has emerged as one of the most strategic sectors for national healthcare security, technological advancement, and economic growth. As countries across the world seek to strengthen their healthcare supply chains and reduce dependence on imports, India has embarked on an ambitious journey to establish itself as a global hub for medical technology innovation and manufacturing.

At the heart of this transformation stands the Andhra Pradesh MedTech Zone (AMTZ), India's premier medical technology manufacturing cluster and one of the largest integrated MedTech ecosystems in the world. Conceived with a simple yet powerful vision—to reduce the cost and complexity of medical device manufacturing—AMTZ has evolved into a comprehensive innovation ecosystem that supports every stage of the medical device lifecycle, from concept and design to manufacturing, testing, validation, and commercialization.

Today, AMTZ represents far more than an industrial park. It is a collaborative platform where scientists, clinicians, entrepreneurs, manufacturers, regulators, and investors converge to accelerate healthcare innovation and strengthen India's position in the global medical technology landscape.

A New Paradigm for Medical Device Manufacturing

Traditionally, establishing a medical device manufacturing facility requires significant investments in specialized testing laboratories, sterilization facilities, quality control infrastructure, regulatory compliance systems, and manufacturing support services. These capital-intensive requirements often create barriers for startups, innovators, and even established companies seeking to enter the healthcare sector.

AMTZ was established to address this challenge through a shared infrastructure model. Rather than each company independently investing in expensive facilities, manufacturers can access world-class common scientific facilities and manufacturing infrastructure housed within the ecosystem.

This approach dramatically reduces capital expenditure, shortens product development timelines, and enables companies to focus on innovation and commercialization rather than infrastructure creation.

The result is an ecosystem that promotes faster innovation, lower manufacturing costs, improved quality standards, and enhanced competitiveness for Indian medical device manufacturers.

The Foundation: Advisory and Innovation Support

Innovation begins long before manufacturing. Recognizing this, AMTZ has established a comprehensive support framework that assists innovators throughout their product development journey.

The ecosystem includes specialized support cells for technology transfer, product realization, market intelligence, trade facilitation, certification services, and health technology assessment. These services help innovators navigate complex regulatory pathways, identify market opportunities, establish commercialization strategies, and align product development efforts with healthcare needs.

International collaborations further strengthen this support framework. Partnerships with global organizations and regulatory bodies ensure that products developed within the ecosystem are aligned with international quality and compliance standards, facilitating both domestic adoption and global market access.

This integrated advisory structure transforms promising ideas into commercially viable healthcare solutions.

Common Scientific Facilities: The Engine of Innovation

One of the most distinctive features of AMTZ is its extensive network of specialized scientific facilities designed specifically for the medical device industry.

BIOME – Centre for Biomaterial Testing

Modern medical devices increasingly rely on advanced materials that interact directly with the human body. BIOME provides critical testing capabilities for biomaterials, enabling manufacturers to assess safety, performance, and biocompatibility requirements essential for regulatory approval.

ELECTRA – Centre for EMI and EMC Testing

Medical electronics must function reliably in increasingly complex electromagnetic environments. ELECTRA ensures that medical devices comply with stringent electromagnetic interference (EMI) and electromagnetic compatibility (EMC) requirements, helping manufacturers meet international regulatory standards.



DECIBLE – Centre for Acoustics and Wireless Testing

As connected healthcare technologies continue to expand, wireless communication performance has become a critical aspect of medical device functionality. DECIBLE supports testing and validation of acoustic systems, wireless technologies, and communication platforms used in modern healthcare solutions.

COBALTA – Centre for Gamma Irradiation

Sterilization remains a cornerstone of patient safety. COBALTA provides gamma irradiation capabilities essential for the sterilization of medical devices, ensuring compliance with international safety requirements while supporting large-scale manufacturing operations.

ORGEN – Advanced Cell Culture and Biological Testing Facility

Biological testing plays a vital role in medical device validation. ORGEN provides advanced cell culture capabilities and biological assessment infrastructure that supports research, development, and regulatory evaluation of healthcare technologies.

Collectively, these facilities create a scientific foundation that enables manufacturers to develop world-class products within India while maintaining global quality standards.

Manufacturing Excellence Under One Roof

Beyond scientific testing, AMTZ offers specialized manufacturing infrastructure that supports a diverse range of healthcare technologies.

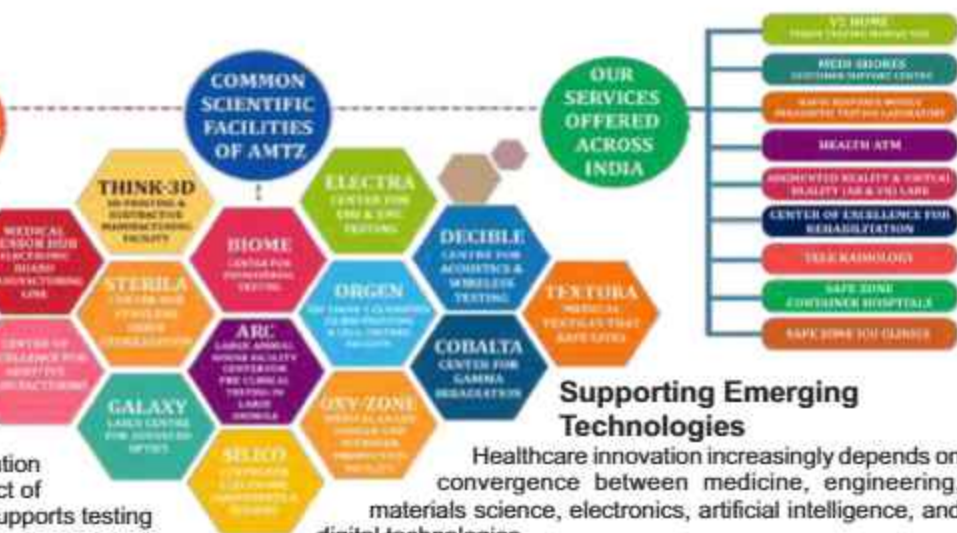
Centre of Excellence for Additive Manufacturing

Additive manufacturing is reshaping healthcare through patient-specific implants, surgical guides, anatomical models, and customized medical devices. THINK-3D serves as a dedicated center for 3D printing and additive manufacturing, enabling rapid prototyping and advanced production capabilities.

The facility supports emerging technologies such as metal additive manufacturing, polymer printing, and customized medical device fabrication, helping bridge the gap between design and clinical application. This dedicated center supports research, development, and commercialization of next-generation additive manufacturing technologies for healthcare applications.

STERILA – Centre for Ethylene Oxide Sterilization

Many medical devices require specialized sterilization methods that preserve functionality while ensuring safety. STERILA provides ethylene oxide sterilization capabilities essential for a broad spectrum of healthcare products.



Supporting Emerging Technologies

Healthcare innovation increasingly depends on convergence between medicine, engineering, materials science, electronics, artificial intelligence, and digital technologies.

AMTZ has strategically established specialized centers that support these emerging fields.

GALAXY – Laser Centre for Advanced Optics

Advanced optics and laser technologies are transforming diagnostics, surgery, imaging, and therapeutic interventions. GALAXY supports innovation in optical technologies that are increasingly critical to modern healthcare.

TEXTURA – Medical Textiles That Save Lives

Medical textiles play an indispensable role in wound care, infection prevention, surgical applications, implantable products, and protective healthcare equipment. TEXTURA focuses on the development and manufacturing support of advanced medical textile technologies that improve patient outcomes while expanding domestic manufacturing capabilities.

These specialized centers ensure that AMTZ remains aligned with the evolving needs of the healthcare technology industry.

Beyond Manufacturing: Building Complete Healthcare Solutions

The AMTZ ecosystem extends beyond manufacturing and scientific facilities to encompass healthcare service innovations that directly impact patient care.

These initiatives demonstrate how technology can be translated into practical healthcare delivery solutions.

Key initiatives include:

- Mobile diagnostic laboratories
- Tele-radiology services
- Rehabilitation support centers
- Customer support platforms
- AR and VR healthcare training laboratories
- Mobile vision testing units
- Healthcare ATM solutions
- Container-based hospitals

These programs address healthcare accessibility challenges while creating opportunities for deployment and validation of innovative technologies developed within the ecosystem.

By integrating healthcare delivery with manufacturing and innovation, AMTZ creates a unique feedback loop that accelerates product improvement and adoption.

Accelerating India's Healthcare Self-Reliance

The importance of indigenous medical device manufacturing has become increasingly evident in recent years. Global disruptions have highlighted vulnerabilities in healthcare supply chains and underscored the need for domestic production capabilities.

AMTZ directly contributes to India's vision of healthcare self-reliance by enabling local manufacturing, supporting innovation, reducing import dependence, and creating a globally competitive MedTech industry.

The ecosystem has helped numerous companies establish manufacturing operations, develop innovative healthcare products, and access advanced scientific infrastructure that would otherwise require substantial capital investments.

This model not only strengthens domestic manufacturing but also positions India as a preferred destination for global healthcare technology partnerships and investments.

The Road Ahead

The future of healthcare will be defined by personalization, digital connectivity, advanced materials, artificial intelligence, and precision manufacturing. AMTZ is strategically positioned at the intersection of these transformative trends.

As the ecosystem continues to expand, its role is evolving from infrastructure provider to innovation catalyst. New centers, advanced technologies, collaborative research initiatives, and global partnerships are expected to further strengthen its impact on healthcare innovation.

The vision extends beyond manufacturing. It encompasses creating a complete healthcare innovation ecosystem where ideas are nurtured, technologies are validated, products are manufactured, and healthcare solutions reach patients faster and more efficiently.

A National Asset for Global Healthcare

The success of modern healthcare depends on collaboration. No single organization can independently deliver the infrastructure, expertise, scientific capabilities, regulatory knowledge, and manufacturing capacity required to bring complex medical technologies to market.

AMTZ demonstrates the power of an integrated ecosystem approach. By combining common scientific facilities, advanced manufacturing infrastructure, regulatory support, innovation services, and healthcare delivery platforms within a single collaborative environment, it has created a model that is both nationally significant and globally relevant.

As India advances toward becoming a leading global medical device manufacturing destination, AMTZ stands as a symbol of what can be achieved when innovation, infrastructure, and collaboration come together with a common purpose.

It is not merely a manufacturing cluster—it is a platform that is redefining the future of healthcare innovation in India and beyond.

This version is formatted as a professional magazine cover story suitable for healthcare, MedTech, innovation, investment, or government publications.

FAST FACTS

Eventually, brain implants will become as common as heart implants. I have no doubt about that.

- Miguel Nicolelis

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Fluid Control Components: QOSINA Small Parts, Big Impact in Medical Device Design

In medical devices, performance and patient safety often depend on components that rarely get the spotlight. Valves, stopcocks, check valves and injection sites play a critical role in managing fluid flow, maintaining sterility and ensuring reliable device operation.

For manufacturers developing infusion systems, diagnostics equipment, drug delivery devices and other fluid-handling applications, selecting the right fluid control components is essential to achieving consistent performance and regulatory compliance.

Why Fluid Control Matters

Every fluid-path component contributes to the overall safety and effectiveness of a device. Properly specified valves and access points help:

- Maintain consistent flow and pressure
- Prevent leaks and fluid loss
- Enable safe injection, sampling and flushing
- Reduce contamination risks

Poor component selection can lead to pressure fluctuations, sterility concerns and device failures, creating both clinical and commercial risks.

Quality and Compliance Considerations

Medical device manufacturers should evaluate fluid control components based on both material performance and regulatory requirements. Key considerations include:

- ISO 10993 biocompatibility compliance
- USP <88> biological reactivity testing
- REACH and RoHS compliance
- Cleanroom manufacturing processes

Material choice is equally important. Polycarbonate offers strength and transparency, polypropylene provides chemical resistance, and silicone is widely used for sealing and flexible valve applications.

Selecting the Right Component

Fluid-path requirements vary by application, making it important to match components to specific performance needs:

- High-pressure or low-pressure operation
- One-way, bi-directional or multi-port flow control
- Luer lock, barbed or custom connection options
- User-friendly features that reduce handling errors

Careful selection helps improve reliability while simplifying assembly and clinical use.

Examples of Fluid Control Solutions

Several component types commonly used in medical devices include:

- Flow control switches for precise shutoff in high-pressure systems
- Stopcocks for compact fluid-direction management
- Dual check valves that allow injection and aspiration through separate ports
- High-flow check valves for low-resistance fluid transfer
- Needleless injection sites that support safe, closed-system access while reducing needle-stick risks

These components are widely used across infusion therapy, diagnostics, laboratory instrumentation and other fluid management applications.

Designing for Reliability

Successful integration goes beyond component selection. Engineers should also evaluate:

- Flow dynamics and pressure drop
- Fluid and material compatibility
- Sterilization method compatibility
- Assembly ergonomics and labeling requirements

As India's medical device industry continues to grow, attention to these details can help manufacturers improve product reliability, streamline regulatory approval and enhance patient safety.

Conclusion

While often overlooked, fluid control components are fundamental to medical device performance. Selecting high-quality, compliant components designed for specific application requirements can help manufacturers build safer, more reliable products and support long-term success in increasingly demanding healthcare environments.



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01. Medical Disposables, Implants, Hygiene Products, Allied Medical Device..



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5	Leelavathy Medical Devices Company	www.lmed.co.in		8939480062 9884399735	sales@lmed.co.in
6	Life - O - Line Technologist	www.lifeonline.com		9898162576	lifeonline2011@yahoo.com
7	Morrisons Lifecare Pvt. Ltd.	www.morrisonslifecare.com	Mr. Jaysinh	044-826155047	email@morrisonslifecare.com
8	S.Nath & Company	http://www.snathco.com/	Mr. S N Srivastava	9825360531	snathco@hotmail.com

02. Components, Raw Materials, Packaging Materials & Consumables..



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2	Beacon Plastics	www.beaconplastics.com	Mr. Keyur Patel	7201969437	beaconplastics@hotmail.com
3	Carclo Technical Plastics Pvt. Ltd.	www.carclo-plc.com	Mr. Premchand Pandurangan	9663300373	prem.chand@carclo-plc.com
4	Celanese chemical	www.celanese.com	Mr. Rajesh Shinde	8879177176	rajesh.shinde@celanese.com
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7	ET Elastomer Technik India Pvt. Ltd.	www.elastomer-technik.com	Mr. Hardik Patwa	9727763274	admin@elastomer-technik.in
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9	I-Kare Polyallloys Pvt. Ltd.	www.i-kare.in	Mr. Pritesh K. Vyas	9377000389	care@i-kare.in
10	Jain Rubbers Pvt. Ltd.	www.jainrubbers.com	Mr. Rajiv Jain	9840049313	jainrubbers@gmail.com
10	JRD Polymer Pvt. Ltd.	www.jrdpolymer.com			amol@jrdpolymer.com jrdoffice@gmail.com jrdcorporation@gmail.com
12	KLJ Polymers and Chemicals Ltd.	www.kljindia.com	Mr. Amol Doshi	9323184471 996332111	
			Mr. Ashok Singha Mr. R. C. Gupta	9958323399 9601257024	ashoks@kljindia.com rcgupta@kljindia.com
13	Lakshmi Electrical Control Systems Ltd	www.lecsindia.com	Mr.Boobalan R	7305814196	boobalan.r@lecsindia.com
14	Lubrizol Life Science	www.Lubrizol.com/Health	Mr. Rajnish Singh	9818689669	rajnish.singh@lubrizol.com
15	Milliken Chemical and Textile (India) Co. Pvt. Ltd.	www.milliken.com	Mr. R Balaji Narasimhan	9833462611	balaji.narasimhan@milliken.com
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21	SMC Medical Manufacturing Pvt. Ltd.	www.smcltd.com	Mr. B. Balakrishna Menon Mr. Manoj Bhardwaj	8197318343 9820305171		balakrishna.menon@smcltd.com manoj.bhardwaj@smcltd.com
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23	Surgi Pack (India) Pvt.Ltd.	www.surgipackindia.com	Mr. Birju Tanna	9819970333		birju.t@surgipackindia.com sales@surgipackindia.com
24	TekniPlex Healthcare	www.Tekni-Plex.com/healthcare	Mr. Dinesh Rai	7428919120 9999258151		dinesh.Rai@tekni-plex.com

03. Manufacturing Machineries, Equipments & Accessories..



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3	Eewa Engineering Co. Pvt. Ltd	www.eewaengineering.com		9879538559 9825038559		contact@eewaengineering.com
4	FANUC INDIA Private Limited	www.fanucindia.com	Mr. Manish Sharma	9686511997		manish.sharma@fanucindia.com
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6	HighRichJa Precision Extrusion Machinery Co., Ltd.	www.chinahhj.com.cn		+ 8675786407501		why@chinahrj.com.cn
7	Husky Injection Molding Systems (India) Pvt. Ltd.	www.husky.com	Mr. Biplob Das	7845909562		bdas@husky.ca
8	Khishboo Scientific		Mr. Praveen Bachawat	9820230835		praveen@khushbooscientific.com
9	Shiabaura Machine	www.shibauramachine.co.in	Mr. Abhijitkumar M	9150021901		abhujitkumar.m@shibauramachine.co.in
10	Twist Engineering Works	www.twistplasticmachinery.com		9825028418 9898028418		twistew@gmail.com
11	Yizumi Precision Machinery India Pvt Ltd	www.yizumi.com	Ms. Kinnari Kalavadia	9099906175		kinnari@yizumi.com

04. Services: Testing, Quality Certifications, Consulting, Contract Manufacturing, Training, Others..



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2	Apro Project Consultancy		Mr. Alpesh Ghoghari	9723458881		alpeshghoghari11@gmail.com
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8	Medicall	www.medicall.in				
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10	Pharmadocx (rapid facto)	www.rapidfacto.com	Mr. Neil Dahiya		8708856807	neil@pharmadocx.com
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FANUC FANUC India Pvt. Ltd.

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Gem Orion is an Indo Japanese Joint Venture company located at Coimbatore, Tamil Nadu. Orion Machinery, our Japanese Parent company is a Leading manufacturer of Precision Chillers, Air dryers, Vacuum pumps, milk extraction systems in Japan and have 9 factories worldwide including Gem Orion facility in India. Gem Equipments Pvt Ltd, our Indian Parent company is a Pioneer in Compressed Air Dryers (including desiccant dryers for medical application) and Cooling Towers. Gem Orion manufactures various chillers in India under technological collaboration with Orion Machinery Japan.

1. Precision Inverter Chiller
2. Standard ON / OFF chiller

Gem Orion is having after sales across the country aiming at faster response to customer service requests. Gem Orion undertakes AMC for the chillers with & without spares. Gem Orion chillers are widely used in Medical machinery cooling like LINAC, MRI machine, X Ray, CT etc. Also, Gem Orion having a larger share in Precision Injection moulding components for various medical and critical industrial applications

Orion Japan is having products for Clean room – Precision Air Product (PAP) to maintain a smaller space within $\pm 0.1^{\circ}\text{C}$ from set point and with $\pm 1\%$ RH control. These products are available in India through Gem Orion.

Apart, Gem Orion can supply Japan made chillers in India with after sales support. Gem Orion is having a strong presence in Industrial products, Food packaging industry, Laser cutting industry, Automotive components industry as well

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Glowtronics Pvt. Ltd., Mysore is a globally recognized manufacturer of high-precision medical devices, components,

and sub-assemblies, established in 1986 in Karnataka, India. Over nearly four decades, the company has evolved into a trusted OEM and ODM partner for leading medical device companies worldwide, serving markets across the USA, Europe, Australia, and Asia.

The company specializes in manufacturing components for minimally invasive medical applications, including laparoscopy, endoscopy, urology, gynecology, gastroenterology, and oncology. Its product portfolio includes hypotubes, guidewires, PTFE tubes, biopsy devices, electrodes, micromotors, and precision-engineered assemblies. In addition to medical products, Glowtronics also supports aerospace and defence applications through advanced engineering capabilities.

Glowtronics operates as a full-service manufacturing partner, offering design, engineering, prototyping, and end-to-end production support. Its capabilities include laser cutting, laser welding, precision grinding, cleanroom assembly, and micro-engineering processes, ensuring high accuracy and reliability for critical applications.

The company adheres to stringent global quality standards, being ISO 9001:2015 and ISO 13485:2016 certified, CDSCO MD5 & MD9 Licensed, along with regulatory compliance for international markets such as US FDA and European MDR. Its manufacturing facilities include advanced Class 7 and Class 8 cleanrooms, ensuring contamination-free production of sensitive medical devices.

A key strength of Glowtronics lies in its strong R&D foundation and customer-centric approach, enabling value engineering and innovative product development. As a professionally managed, family-run enterprise, the company emphasizes long-term partnerships, ethical business practices, and consistent quality. With a reputation for reliability and innovation, Glowtronics continues to expand its global footprint as a preferred partner in high-precision manufacturing.

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HUSKY® Husky Technologies

Husky Technologies is a leading global technology provider enabling the delivery of essential needs to the global community through the pursuit of relentless innovation, industry-leading expertise, and real-time responsive service. The company delivers the industry's most comprehensive range of complete, engineered systems that integrate injection molding machines, molds, hot runner technology, mold controllers, automation, auxiliaries, and connected monitoring.

Customers use Husky equipment and services to produce a wide range of products across the beverage and food packaging, home care, beauty and personal care, automotive, consumer electronics, and medical markets, producing medical disposables, pharmaceutical packaging, and diagnostic components. Its integrated approach helps manufacturers improve productivity, ensure consistent quality, reduce material usage, and lower total cost of ownership.

With deep application expertise, advanced technology platforms, and a focus on long term customer partnerships, Husky Technologies enables manufacturers to operate efficiently while meeting high standards for quality, performance, and sustainability.

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IKARE I Kare Compounds Pvt. Ltd.

I Kare Compounds Pvt. Ltd. is a fast-growing manufacturer of high-quality PVC compounds, established in 2020 and based in Gujarat, India. The company specializes in developing customized solutions for medical, rigid, and flexible PVC applications, supported by modern manufacturing facilities and a strong commitment to quality, consistency, and customer satisfaction.

The company has built a strong presence in the medical PVC compound segment, offering formulations for applications such as IV tubing, catheters, oxygen masks, and other disposable medical devices. Its compounds are designed to meet stringent international standards, including USP and ISO requirements, ensuring safety, reliability, and performance in critical healthcare applications.

A key strength of I Kare is its focus on DEHP-free PVC compounds, addressing growing global demand for safer and environmentally responsible materials. These compounds are developed with enhanced biocompatibility and are supported by relevant testing and compliance reports, making them suitable for sensitive medical applications where patient safety is paramount.

In addition to medical grades, the company offers a wide range of rigid PVC compounds used in Urometer bottles, leur lock. These compounds are engineered for superior mechanical strength, dimensional stability, and long-term durability, catering to infrastructure and industrial sectors.

Driven by innovation and technical expertise, I Kare Compounds Pvt. Ltd. emphasizes custom formulation, consistent quality, and strong technical support. With an ISO 9001:2015-oriented approach and a vision to become a trusted global supplier, the company continues to expand its footprint across medical and industrial markets while delivering reliable, application-specific PVC solutions.

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Jain Rubbers Pvt. Ltd.

A rubber products manufacturing company in the field for over 30 years, we produce more than 200 types of different Rubber Products in Natural, Polyisoprene, Butyl, Bromobutyl, Silicon, Nitrile, Polychloroprene and other Synthetic Rubbers and produce 250 million Rubber components for Medical and Pharmaceutical Industry alone. With capabilities to cater to custom demands of the rubber industry, our most popular products are Rubber Bulbs/Injection Sites for infusion and transfusions sets, Pharmaceutical Rubber Closures, Rubber Gaskets for Disposable Syringes, Rubber Plugs for Blood Collection Vaccutainers, Rubber Sleeves/Covers for Blood Collection Needles, Rubber Float Discs, Rubber Plugs for Y-Connection.

Jain Rubbers Pvt. Ltd. is the latest iteration of rubber technology and industry know-how passed down through 3 generations over 6 decades. Incorporated in 1991, we are located in the industrial estate at Gummidipoondi in the state of Tamilnadu, India. With over 60 years of experience in the rubber industry, Jain Rubbers continues to thrive under the visionary leadership of our Managing Director, Sri. Sudarshan Kumar Jain. An unwavering dedication to our customer-centric business approach rooted in high technical expertise continues to stand the test of time.

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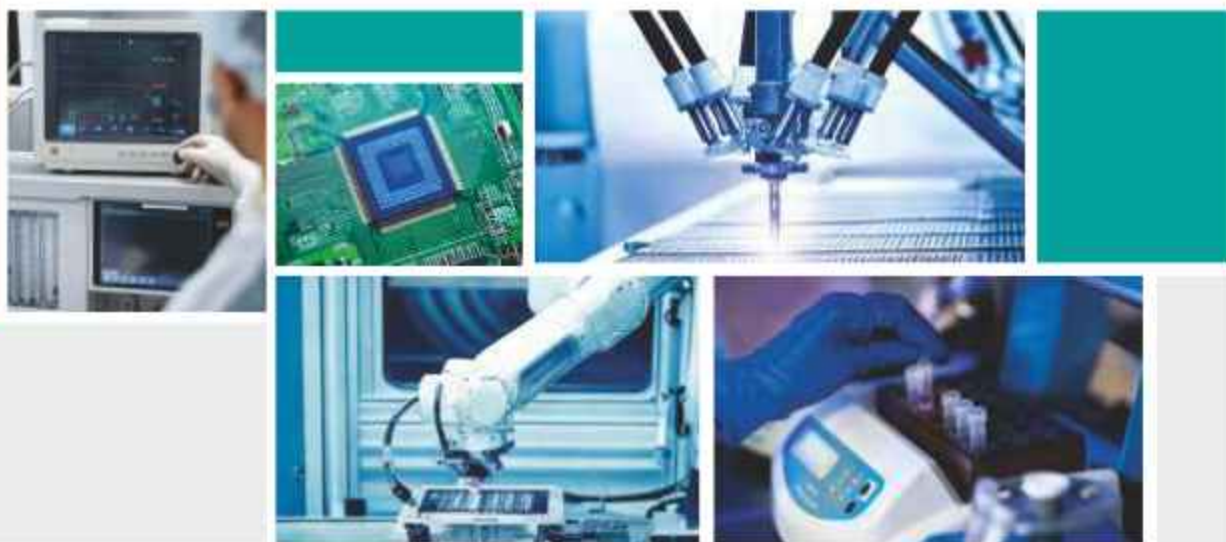
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India's medical devices sector is undergoing a rapid shift driven by booming domestic demand, strong government incentives, and growing global interest in India as a reliable, scalable manufacturing destination.

- India's medical devices market estimated at **US\$11 billion in 2022**, projected to reach **US\$50 billion by 2030**, with a CAGR of 8%.
- Government support: 100% FDI allowed, earlier PLI schemes, dedicated clusters/parks
- Global supply-chain shifts (reshoring, diversification) drive demand for "India base + export" manufacturing.

Sources: India Brand Equity Foundation, Invest India

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Jimit Medico Surgicals Pvt. Ltd.

JIMIT is a Front-line manufacturers and exporters of world class Disposable Surgical Products / Medical Devices based at Ahmedabad, India since 1989. We have our own sophisticated manufacturing unit having MDR Manufacturing License to manufacture Disposable Surgical Products / Medical Devices of high quality. We are an ISO 13485 certified company driven by professionals having experience of more than 3 decades in medical field.

We have our own manufacturing unit since 1989 having in-house E.T.O. Sterilization facility with capacity to sterilize 88,000 pcs. Infusion sets a day. E.T.O. sterilization is the latest and safest method of sterilization accepted and recommended globally. For Quality Control, we have the most sophisticated Laboratories including Micro-Biological Testing Laboratories In-House.

Our Quality Control Dept. consists of: Physico-Chemical Laboratory, Sterility Testing Laboratory, Media Preparation Section, Pyrogen Testing Laboratory and Toxicity Testing Laboratory under one roof. Our products have to undergo most stringent testing process from all laboratories, ensuring zero defect products.

We are glad to say that our 80% goods is being exported regularly.

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JRD Polymers

JRD Polymer, a part of the well-established Doshi Group of Companies, carries forward a legacy of trust and excellence dating back to 1945. With over 25 years of industry experience, the company specializes in the distribution of high-quality chemicals and plastics, serving a wide range of customer needs.

Led by promoters Rajesh Doshi and Amol Doshi, JRD Polymer is driven by strong leadership, market insight, and a commitment to continuous growth. The company focuses on building long-term relationships by offering reliable products, tailored solutions, and responsive service.

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KLJ Polymers and Chemicals Ltd.

Founded in 1967, KLJ is not only **Largest Manufacturer and the Market Leader in Plasticizers & Polymer Compounds in South Asia**, but also an outright leader in the Secondary Plasticizer-Chlorinated Paraffin segment as the **largest Manufacture across the Globe**. Their Ultra Modren Manufacturing facilities in Silvassa, Bharuch, Agra & Kutch in India, Rayong in Thailand and Masaieed in Qatar are equipped with State of the Art Technology and Equipment, producing a wide range of products to meet their Customer's Requirements. Group has a combined **Manufacturing Capacity of 1.4 Million tpa**.

In 2022, Group has started an integrated manufacturing plant

May-June 2026

with installed capacity of 300,000 tpa of plasticisers and 100,000 tpa of Phthalic Anhydride in Bharuch, India.

In 2019, a state of the Art **Chlor Alkali** complex in Qatar was established with a total investment in excess of USD 125 Million. It is a joint venture project with Qatar Industrial Manufacturing Co. (QIMC)

In 2016, group has diversified into manufacturing of **Benzyl Derivatives** in Bharuch, India.

Group has also made strong in roads into the **Distribution of Petrochemicals** and is proud to be **No. 1 Chemical Distribution Company in India**.

Identifying infrastructure as a significant factor in the development of the national economy, the Group has also expanded into **Real Estate Development**.

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Lakshmi Electrical Control Systems Ltd.

Lakshmi Electrical Control Systems Limited (LECS), based in Arasur, Coimbatore, Tamil Nadu, is a sister company of Lakshmi Machine Works (LMW) and is listed on the BSE stock exchange. With a 45-year legacy in tool room and plastic injection moulding, LECS provides engineering plastic components and related assemblies, supported by an in-house tool room for precision moulds and tooling. LECS is certified to IATF and ISO 13485 standards. In addition to its manufacturing capabilities in plastics and tooling, LECS designs and manufactures customized control panels and electrical assemblies. The company's product portfolio includes engineered plastic parts, control panels, smart energy meters and electric vehicle (EV) chargers, enabling customers across sectors such as medical, automotive, electrical & electronics, manufacturing, utilities and infrastructure to implement reliable power distribution and automation. With integrated design-to-production capabilities and a focus on quality and consistency, LECS supports both standard and customer-specific requirements, delivering dependable solutions through robust processes, precision engineering and continuous improvement.

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Lubrizol Corporation

The **Lubrizol Corporation** is a global specialty chemicals and advanced materials company, and a wholly owned subsidiary of **Berkshire Hathaway**. Founded in 1928 and headquartered in **Cleveland, Ohio**, Lubrizol operates more than **100 manufacturing, sales, and technical facilities worldwide**, serving markets that span healthcare, mobility, infrastructure, and consumer applications.

Lubrizol is a global leader in **medical grade thermoplastic polyurethane (TPU) technologies**, anchored by its well established brands **PELLETHANE®**, **TECOTHANE®**, **ISOPLAST®**, **CARBOTHANE™**, and **TECOFLEX®**. These are widely used in **minimally invasive medical devices**, including neurovascular and cardiovascular catheters, balloon tubing,

Implantable components, and electrostimulation devices, where biocompatibility, flexibility, and durability are critical. Beyond material supply, Lubrizol has expanded into **contract manufacturing and design for manufacturing services**, offering end to end capabilities that support customers from **concept to commercialization**. Its medical operations adhere to stringent regulatory requirements, including **ISO 13485**, enabling customers to meet global quality and compliance standards.

A key milestone is Lubrizol's **new state of the art medical manufacturing facility in Chennai, Tamil Nadu**. Scheduled to become operational in **mid 2026**, the facility will increase Lubrizol's **medical tubing capacity in India by five fold**, producing high precision tubing for **cardiovascular, neurovascular applications**, and others including balloon catheters and minimally invasive devices. In addition to Chennai, Lubrizol maintains **corporate offices, R&D, and manufacturing operations across Maharashtra, Gujarat, and Tamil Nadu**, reinforcing India's role as a global center for engineered polymers and medical device innovation.

Through its continued invest in medical grade TPU technologies, integrated manufacturing capabilities, and localized innovation, Lubrizol is strengthening its position as a **trusted global partner to the medical device industry**. With India emerging as a key manufacturing and engineering hub, Lubrizol's expanding footprint supports both regional healthcare needs and global medtech supply chains, reinforcing its long term commitment to quality, compliance, and patient centric innovation.

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MDR Laboratories Private Limited is an **OECD GLP-certified, & ISO/IEC 17025** accredited testing facility, specializing in high-quality, cost-effective biocompatibility testing as per ISO 10993 and safety assessment of medical devices. We are accredited in accordance with **A2LA R256** Specific Requirements, ISO/IEC 17025:2017, and 21 CFR Part 58 for biocompatibility and chemical characterization.

We are a trusted, independent, mid-sized laboratory with strong expertise in biological evaluation, advanced analytical chemistry, and regulatory toxicology. We support medical device manufacturers in over 60 countries, and our reports are widely accepted by global regulatory authorities and EU Notified Bodies. As a pioneer in the field, MDR Laboratories was among the first laboratories in India to establish comprehensive testing capabilities for a wide range of medical devices and related products.

We have extensive experience across multiple device categories, including:

- Urological devices
- Cardiovascular devices
- Orthopaedic devices
- Ocular and ophthalmic devices
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- Surgical devices
- Surface-contact devices
- Respiratory devices
- Gastrointestinal devices
- Haematological devices and IV sets

- Neurological devices
- Personal care products
- Raw materials and ingredients

Our key strengths include:

- One of the first laboratories in India to establish a dedicated Regulatory Toxicology Department, supporting manufacturers with biological evaluation, risk assessment, and test strategies aligned with international guidelines
- A pioneer in introducing chemical characterization and extractables & leachables (E&L) studies as per ISO 10993-18 since year 2016.
- A dedicated scientific team with proven expertise in developing and validating specialized test methods for ophthalmic products, including intraocular lenses (ISO 11979), contact lenses (ISO 9394), and related devices.
- An independent Quality Assurance (QA) unit that ensures full compliance with OECD GLP and ISO/IEC 17025 standards through rigorous auditing of all studies
- Conducting free webinars and seminars for medical device manufacturers on recent ISO standard updates and their practical impact on product compliance and regulatory requirements.

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Milliken Chemical and Textile (India)

Milliken is a global, diversified manufacturer rooted in a legacy of innovation. Originating in textiles, the company has expanded its capabilities to deliver advanced solutions across textiles, chemicals, flooring, and healthcare—guided by curiosity driven expertise and world class manufacturing.

At the heart of Milliken is deep materials science knowledge, transformed into a robust portfolio serving 15 industries. Supported by centuries of manufacturing excellence, we pair insight and bold problem solving with a clear sense of purpose to drive meaningful, lasting impact.

Through our portfolio, Milliken applies materials science to enhance the products people rely on every day. Our innovations can strengthen, adapt, modify, or sustain key product attributes—helping customers stand out and succeed in competitive markets. With more than 11,000 product innovations across industries such as building and construction, consumer goods, government and defense, and paints and coatings, Milliken works behind the scenes to shape everyday experiences.

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Pharmadocx FDA Consultant

Pharmadocx Consultants assists in setting up new plants and obtaining manufacturing licenses in India for medical devices, ayurvedic products, cosmetics, nutraceuticals, and pharmaceuticals.

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QOSINA

Qosina is a global supplier and trusted one-stop source for more than 5,000 single-use, off-the-shelf components serving medical device and pharmaceutical manufacturers worldwide. For more than 45 years, we have helped engineers accelerate product development by providing immediate access to high-quality components and the expertise needed to move efficiently from concept to production.

Our consultative, end-to-end approach simplifies the development process. Engineers can rapidly prototype and iterate using free samples, downloadable CAD files, low minimum order quantities and fast access to an extensive in-stock product portfolio. This enables teams to evaluate, test and refine designs without the delays, expense or risk associated with custom tooling during early development stages.

As projects advance toward commercialization, Qosina supports customers with scalable supply solutions including tiered pricing, blanket orders and dependable inventory management. Our global distribution network ensures consistent availability and reliable delivery, helping manufacturers maintain momentum from development through full-scale production.

Every product is backed by detailed specifications and comprehensive documentation, giving engineers the confidence they need when selecting components for critical applications. Guided by our in-house product development team, we continually expand and refine our portfolio to address evolving needs across the medical device and biopharmaceutical industries.

By combining a broad component offering, technical expertise and responsive service, Qosina serves as a single, trusted partner that simplifies sourcing, reduces development time and helps bring life-changing healthcare innovations to market faster.

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S. Nath & Co.

Established in 1980, S. Nath & Co. is a premier Indian manufacturer and exporter specializing in high-volume medical disposables and surgical consumables. The company is ISO 9001:2015 and ISO 13485:2016 certified with safety regulations. Their commitment to "Perfection, Commitment, and Customer Satisfaction" has made them a trusted partner for over four decades for providing medical devices on a global level. The company operates a state-of-the-art facility equipped with ultra-modern machinery for the assembly of plastic components and medical tubing. To ensure the highest level of patient safety, all manufacturing and packaging processes are conducted in Class 10,000 cleanrooms. The facility features in-house Ethylene Oxide (ETO) sterilization and testing laboratories that meet stringent international standards.

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SEVITSIL stands as a global leader in advanced silicone materials, delivering tailored solutions for medical original equipment manufacturers (OEMs) worldwide. At the core of our approach is a strong commitment to collaboration, engineering excellence, and co-development. We believe that the best innovations come from truly understanding our customers, which is why we actively listen, engage, and partner closely to meet their unique needs. Our goal is to provide high-quality, reliable solutions that address the increasingly complex challenges of today's healthcare environment.

With deep expertise in regulatory requirements and quality assurance standards, SEVITSIL ensures that every product meets stringent global compliance expectations. This, combined with our advanced material science capabilities, allows us to develop critical components and applications that contribute to life-saving medical technologies. We are not only focused on solving present-day challenges but are also dedicated to driving future innovation in the medical field.

Our core capabilities include precision molding, advanced extrusion, and integrated catheter system solutions. We specialize in material differentiation through custom compounding techniques, enabling us to create silicone formulations tailored to specific performance requirements. Additionally, our continuous advancements in surface modification technologies enhance product functionality, durability, and patient safety.

At SEVITSIL, we view every partnership as an opportunity to innovate and grow together. By leveraging our collective ingenuity, technical expertise, and customer-centric approach, we empower our partners to transform ideas into impactful medical solutions. Join us as we push the boundaries of silicone technology and bring the next generation of healthcare innovations to life.

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Shibaura Machine

Shibaura Machine India is a leading manufacturer of advanced Injection Moulding Machines and automation solutions, catering to the evolving needs of the medical devices and healthcare manufacturing industry. Part of the globally renowned Shibaura Machine Co., Ltd. group, the company combines Japanese precision engineering with India-based manufacturing excellence to deliver reliable, energy-efficient, and high-performance manufacturing solutions. The company offers a wide range of hydraulic, hybrid, and all-electric Injection Moulding Machines designed for applications requiring high precision, repeatability, cleanliness, and process stability. Its all-electric machine series is particularly suitable for manufacturing medical and healthcare components where consistent quality and contamination-free production are critical. Shibaura Machine India supports the production of products such as syringes, diagnostic consumables, pharmaceutical packaging, laboratory ware, caps & closures, and other precision-moulded medical components. Through its advanced Technical Centre in Chennai, the company provides application engineering support, mould trials, process optimisation, and customer training to help manufacturers improve productivity and maintain stringent quality standards. Focused on innovation and sustainable manufacturing, the company also integrates automation and IoT-enabled monitoring solutions to support smart factory initiatives, enabling better process control, traceability, and operational efficiency. With strong manufacturing infrastructure, growing global presence, and customer-centric engineering capabilities, Shibaura Machine India continues to strengthen its role as a trusted technology partner for the medical and healthcare manufacturing ecosystem.

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Shriram PolyTech is one of the largest organized players for PVC compounds in India and has a world class manufacturing facility that started in 1964. It is certified by DNV for ISO 9001, ISO 14001, OHSAS 18001, 13485 & Biocompatibility certification for medical grades.

Evolving along with its consumers and their needs over time, what started 60 years ago with footwear and wire & cable segments, has steadily graduated to value added segments like Flame Retardant, Flame Retardant Low Smoke & Heat Resistant Cable Compounds, Automotive, Food & Medical, Colors, and now, Specialty Compounds.

Shriram PolyTech strives to continually innovate and develop new ideas that can enable better dispensing of medical facilities. This involves manufacturing critical medical compounds that affect people's lives directly, at critical hours.

Our healthcare grades adhere to various Indian Standards as well as biological tests prescribed under USP Class VI. Shriram PolyTech ensures that all ingredients used in the compounds are manufactured meeting the GMP norms prescribed by FDA. These compounds are manufactured in a state-of-the-art fully automated and dedicated compounding line with class 100,000 facilities conforming to GMP requirements.

Phthalate free non-toxic compounds are available to meet the critical toxicological and microbiological resistance requirements specified by our customers. Customized medical compounds are available for kink-free, phthalate-free, radiation free applications.

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TekniPlex Healthcare, one of two divisions of TekniPlex, utilizes advanced materials science expertise and technologies to develop and deliver critical solutions for medical and diagnostic devices, drug delivery systems and sterile barrier healthcare packaging applications. With a global reach, the division's deep understanding of the greater pharmaceutical and medical landscape helps it produce exemplary barrier properties for drugs and precision medical devices for interventional and therapeutic procedures. Headquartered in Wayne, Pennsylvania, TekniPlex operates a global network of manufacturing and innovation centres, including facilities and commercial operations serving the Indian medical technology market.

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Oragadam, Chennai, with planned completion by 2026. This upcoming facility will support comprehensive product qualification and global regulatory compliance aligned with USFDA, CE, and Health Canada requirements. It will offer advanced services including Transportation Simulation & packaging Testing Chemical Testing Microbiology Testing, Electrical Safety Testing Implantable Device Testing, In-vitro Studies, and Personal Protective Equipment (PPE) Testing.

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Shri Himanshu Baid

Managing Director, Poly Medcure Ltd., Faridabad

Thanks for sharing the online version of the publication. I always find it very informative and learn a lot of new things from the Advertisements and the articles. Wishing you very best of health and success. I look forward to receiving from time to time all future editions.



Dr. JK Sharma

MD & CEO, AMTZ & Advisor, Health & Med. Tech.,
Govt. of A.P., Visakhapatnam

Congratulations and looking forward to the 50th year of publication Thank you



Jitesh Shah

Director, Suru International Pvt. Ltd., Mumbai

Congratulation sir and I wish you many more successes!



Dr. S. S. Murugan

PhD, Safety Toxicologist,
Managing Director, GLR Laboratories Pvt Ltd., Chennai

Congratulations! We are happy to know that Medical Plastics Data Service magazine is entering into the 29th year of Publication. It is our pleasure to extend our support in future also. Also, thanking you for your continuous support.



Anil Jauhari

(ex-CEO, NABCB), New Delhi

Congratulations for such a feat of sustaining the magazine into 29th year. I would be happy to support in whatever way you may wish. I keep posting educational pieces on Linked in etc and you are free to reproduce any of them should it interest you.



Rajnikant Shah

Director Marketing - MRK Healthcare Pvt. Ltd. and
Nulife Global Medical Devices Pvt.Ltd., Mumbai

Arrangement of dais and compare and order of event was excellent. Food and beverages were well arranged. The volunteers were very courteous and active. Whole atmosphere was like a international conference



Kishore Khanna

Managing Director, Romsons Group of Industries, & Joint
Co-ordinator, Medical Consumables Products Segment,
Association Of Indian Medical Devices Ind. Agra, India.

The exhibition and presentations of the papers were very useful for SME industry.



Brian Reilly

Marketing & Sales Director, Nusil Silicone Tech., USA.

There was a good blend of vendor booths, technical presentations, academic and professionals from healthcare device industry.

Rajiv Nath

Managing Director, Hindustan Syringes & Medical Devices
Ltd & Forum Coordinator, Association of Indian Medical
Device Industry (AIMeD)



We appreciate Medical Plastic Data Service endeavor in creating awareness about Medical Device Industry in India

and the insights and quality literature articles as well as your wonderful initiative for holding the technical conferences and technology show exhibitions for the benefit of Medical Device Industry.

Congratulations to Medical Plastic Data Service for completing 32 years of its publication journey.

We wish to offer our gratitude to Mr. D L Pandya and Team @ MPDS for their sincere and selfless efforts in creating awareness by their publications and technical and technology show exhibitions for enabling the manufacturing growth of Indian Medical Device Sector over last 3 decades.

Dr. Sanjay Behari

Director, Sree Chitra Tirunal Institute for Medical Sciences
& Technology, Thiruvananthapuram



- A wonderful initiative
- I learnt a lot and am honoured and privileged
- Outstanding participants who have spent a lifetime making biomedical products.
- Excellent amalgamation between academia and industry

Dr. Roy Joseph

Scientist G
Biomedical Technology Wing, (SCTIMST) Trivandrum



I have seen Medical Plastics Data Service since its inception. The magazine has evolved over the years, and I find it a good source of information for raw materials, Medical Devices, processing and shaping machinery and relevant articles on medical devices.

Dr. Renjith S

Scientist C
Biomedical Technology Wing, (SCTIMST) Thiruvananthapuram



Magazine plays crucial role in connecting the R&D people with industry benefiting in understanding recent trends in the polymer industry and other related aspects. The conferences are wonderful opportunities to interact with industry and share our knowledge and understanding with them. I hope to be part of your future endeavors as well.

Dr. Richa Dayaramani

Scientist - Grade F, Centre of Excellence in Medical
Devices NIPER - Ahmedabad



Please accept my sincere greetings for the efforts to organise the conference. It was a great event to attend.

Tim Galekop

TIGAMED, Global Consultancy Infection Prevention, Belgium



For me this was the first time that I, in India, spoke on a conference dealing with Medical Plastics. It was for me extremely useful to network and meet interesting people.

MedTech in India-Poised for Take-off

(A Joint Report by Boston Consulting Group (BCG), The Association of Indian Medical Device Industry (AiMed), and The Kalam Institute of Health Technology (KIHT))

Highlights

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

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.

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+ PEVC and corporate deals in 2025; India's first dedicated MedTech fund (MedArtha) launched by AMTZ in March 2026
- + **Favourable cost and trade position:** labour 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

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 PEVC 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 Voxel grids (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 favouring 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

Industry Report

- + 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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Silicone Tubing: The Silent Enabler of Modern Biopharmaceutical Manufacturing

Dr. Priyabrata Pattnaik

Chief Executive Officer (CEO)
Ami Polymer Pvt. Ltd.

Silicone tubing is a critical yet often underappreciated component of modern biopharmaceutical manufacturing. From upstream cell culture to downstream purification and final fill-finish operations, silicone tubing enables sterile, flexible, and chemically inert fluid transfer in highly regulated environments. Unlike commodity elastomer tubing, biopharmaceutical-grade silicone tubing is engineered through tightly controlled chemistry, precision extrusion, pharmaceutical-grade curing, and rigorous quality control to meet global regulatory expectations. This article explains how such tubing is made, focusing on material chemistry, manufacturing engineering, quality systems, and real-world applications.

1. Silicone Chemistry: The Foundation of Performance

Biopharmaceutical silicone tubing is typically based on polysiloxane chemistry, most commonly polydimethylsiloxane (PDMS). The backbone consists of repeating $-Si-O-$ units, which impart exceptional thermal stability, flexibility, and chemical inertness compared to carbon-based polymers.

Key Chemical Components

- **Base polymer (PDMS):** Determines elasticity, transparency, and temperature resistance
- **Reinforcing fillers:** High-purity fumed silica is added to improve tensile strength, tear resistance, and dimensional stability
- **Curing system:** Typically platinum-catalyzed (addition cure) rather than peroxide cure for biopharmaceutical use
- **Processing aids:** Controlled at ppm levels to improve extrusion without compromising extractables profile

Platinum-Cured vs Peroxide-Cured Silicone

Biopharmaceutical tubing almost exclusively uses platinum-cured silicone. Platinum catalysts enable addition curing without generating by-products, unlike peroxide curing which can leave residuals and increase extractables.

Advantages of platinum curing:

- Ultra-low extractables and leachables
- Odorless and tasteless
- Superior optical clarity
- Better lot-to-lot consistency

This chemistry is essential for compliance with regulatory standards such as those defined by USP and regulatory agencies like the FDA.

2. Engineering the Manufacturing Process

Industrial silicone rubber extruder machine used for molding liquid silicone rubber into various shapes

The transformation of silicone compound into biopharmaceutical tubing is a highly engineered process, typically conducted in ISO Class 7 or Class 8 cleanroom environments.

Step 1: Compounding

High-purity silicone base polymer is mixed with reinforcing silica and platinum catalyst in closed, contamination-controlled systems. The compound must exhibit:

- Uniform dispersion of filler
- Precise rheological behavior
- Zero foreign particulate contamination

Each batch is traceable by raw material lot numbers.

Step 2: Extrusion

The compounded silicone is fed into a precision extruder and pushed through a die and mandrel assembly that defines inner diameter (ID) and wall thickness.

Key engineering controls include:

- Extrusion pressure and speed
- Die concentricity
- Temperature uniformity

Tolerances are extremely tight—often ± 0.05 mm or better for critical bioprocess tubing.

Step 3: Curing (Vulcanization)

Extruded tubing passes through a continuous hot-air or infrared curing oven. Platinum-cured systems crosslink rapidly and uniformly, locking in mechanical and chemical properties.

Step 4: Post-Curing

Some applications require post-curing at elevated temperatures to further reduce volatile residues and stabilize mechanical properties, especially for long-term or high-purity applications.

Step 5: Cutting, Coiling, and Packaging

Tubing is cut to length or coiled, cleaned if required, and packaged in cleanroom conditions using double-bagging systems compatible with gamma or autoclave sterilization.

3. Quality Control and Regulatory Compliance

USP Class testing is one of the most common methods of testing to determine bio-compatibility of materials. There are six classes, VI being the most rigorous. Class VI testing is aimed to certify that there are no harmful reactions or long-term bodily effects caused by chemicals that leach out of plastic materials. USP Class Testing standards are determined by the United States Pharmacopeia and National Formulary (USP-NF), the organization responsible for the quality and safety of medical devices and foods. Class testing is frequently conducted on plastic materials that come in contact with injectable drugs and

other fluids found in various steps of the drug manufacturing process. USP Class VI Testing Methods

USP Class VI testing is conducted by producing an extract of the product with different extraction fluids, such as polyethylene glycol and vegetable oil, and injecting it in specimen (rabbits and mice) in vivo (alive), to observe the biological response to the extract. Testing is commonly done as per USP <88>, which requires three types of testing: systemic injection, intracutaneous, and implantation.

Quality control is not an inspection step—it is embedded across the lifecycle of biopharmaceutical silicone tubing.

Raw Material Controls

- Certificate of Analysis (CoA) for every polymer and filler lot
- Supplier qualification and audits
- Incoming material identity and purity checks

In-Process Controls

- Continuous OD/ID measurement using laser gauges
- Visual inspection under controlled lighting
- Statistical process control (SPC) for dimensional consistency

Finished Product Testing

Typical qualification tests include:

- Physical: Tensile strength, elongation, hardness (Shore A)
- Chemical: Extractables profiling under worst-case solvents
- Biological: Cytotoxicity, sensitization, irritation
- Thermal: Autoclave resistance and heat aging

Most biopharmaceutical silicone tubing complies with:

- USP <88> Class VI
- USP <87> Biological Reactivity
- ISO 10993 standards
- BPOG extractables guidance

Full traceability, batch records, and change control documentation are mandatory for regulated customers.

4. Performance Requirements in Biopharmaceutical Use

Silicone tubing is selected not because it is inexpensive, but because it performs reliably under demanding bioprocess conditions.

Key Performance Attributes

- Biological inertness: No interaction with proteins, enzymes, or cells
- Thermal stability: -60 °C to +200 °C operating range
- Flexibility: Maintains kink resistance in peristaltic pumping
- Sterilization compatibility: Autoclave, gamma, and EtO resistant
- Transparency: Enables visual flow monitoring and bubble detection

5. Applications across the Biopharmaceutical Value Chain

Upstream Processing

- Media and buffer transfer
- Cell culture feeding and sampling
- Peristaltic pump loops

Downstream Processing

- Chromatography buffer delivery
- Filtration and diafiltration systems
- Sterile fluid connections

Fill-Finish and Final Drug Product

- Aseptic filling lines
- Single-use manifolds
- Drug substance transfer

Silicone tubing also plays a foundational role in single-use bioprocessing, where flexibility, sterility assurance, and rapid

changeover are essential.

6. Future Trends and Innovation

The future of biopharmaceutical silicone tubing is shaped by lower extractables through advanced filler chemistry, hybrid tubing combining silicone with fluoropolymer liners, digital batch traceability & serialization, and increased regional manufacturing for supply chain resilience. As biologics, cell therapies, and mRNA platforms continue to expand, silicone tubing will remain a mission-critical enabling technology.

7. Conclusion

Biopharmaceutical silicone tubing is far more than a passive conduit. It is a precisely engineered, chemically sophisticated, and rigorously validated component that directly impacts product quality, patient safety, and manufacturing reliability. From platinum-catalyzed chemistry and cleanroom extrusion to exhaustive quality control and regulatory compliance, every step in its manufacture reflects the uncompromising standards of the biopharmaceutical industry. Understanding how this tubing is made helps manufacturers, engineers, and quality professionals make better decisions in designing robust and compliant bioprocess systems.

As biologics, cell therapies, and mRNA platforms scale globally, the industry's success increasingly depends on "invisible technologies"—components that rarely make headlines but silently determine robustness, compliance, and speed to market. The next time a process deviation, contamination event, or scale-up challenge appears, it's worth asking: did we treat tubing as a commodity—or as a critical system component? Because in biopharma, the smallest components often carry the largest consequences. Silicone tubing is one of them.



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Importance of Medical - Grade PVC in Modern Healthcare

Mr. R. C. Gupta

Vice-President
KLJ Polymers & Chemicals

Introduction

Medical-grade PVC plays a critical role in modern healthcare systems due to its versatility, reliability, and cost-effectiveness. Hospitals, clinics, laboratories, and pharmaceutical companies depend on PVC-based products for patient care and medical procedures. The material can be manufactured in both flexible and rigid forms, making it suitable for a wide range of applications. Its ability to meet stringent regulatory and safety requirements has made it one of the most trusted polymers in the medical industry.

Key Characteristics of Medical-Grade PVC

Medical PVC compounds are manufactured under strict quality control procedures to ensure patient safety. They are designed to comply with various international standards and regulations governing medical devices and healthcare products. These compounds undergo extensive testing for biocompatibility, toxicity, chemical resistance and sterilization compatibility before being approved for medical use. Compliance with regulatory requirements helps ensure consistent product performance and patient protection.

- **Biocompatibility** – Safe for contact with blood, tissues, and pharmaceutical products.
- **Flexibility** – Can be made soft and flexible using plasticizers.
- **Transparency** – Allows visual monitoring of fluids and blood flow.
- **Sterilization Compatibility** – One of the most important advantages of medical-grade PVC is its compatibility with multiple sterilization methods. Medical devices and packaging materials must be sterilized before use to prevent infections and contamination. PVC products can withstand sterilization using ethylene oxide (EO), gamma radiation and Steam Sterilization.
- **Chemical Resistance** – Resistant to many chemicals, disinfectants, and drugs.
- **Durability** – High mechanical strength and long service life.
- **Cost Efficiency** – Economical compared to several engineering polymers.
- **Ease of Processing** – Suitable for extrusion, injection molding, calendaring, and blow molding.

Environmental and Economic Benefits

PVC offers significant economic advantages compared to many alternative materials. Its durability, ease of processing, and relatively low manufacturing cost help reduce healthcare expenses while maintaining product quality. The long service life of PVC products minimizes replacement frequency and support efficient resource utilization.

Many PVC products can also be recycled through specialized recycling programs. Continuous development in recycling technologies are helping improve the environmental

sustainability of PVC in healthcare applications.

Types of PVC Used in Medical Applications

1. Flexible PVC

Produced by adding plasticizers to provide softness and flexibility.

Typical Uses

- Blood bags
- IV tubing
- Catheters
- Oxygen masks
- Dialysis tubing

2. Rigid PVC

Manufactured without plasticizers, offering higher strength and dimensional stability.

Typical Uses

- Pharmaceutical blister packaging
- Medical device housings
- Containers and trays
- Diagnostic equipment components

Major Applications of PVC in the Medical Segment

1. Blood Bags and Blood Storage Systems
2. Blood collection – AVF Set
3. Feeding Bag Set
4. Urine collection bag
5. Detox Set
6. Intravenous (IV) infusion Set
7. Catheters and Medical Tubing
8. Oxygen Masks and Respiratory Equipment
9. Oxygen set
11. Wound Drainage Set
12. Pharmaceutical Packaging
13. Disposable Medical Devices
14. Hospital Infrastructure Applications
15. Hemodialysis Blood Tubing Set
17. Diagnostic and Laboratory applications

Advantages in Patient care

PVC –based medical devices contribute significantly to patient comfort and treatment effectiveness. Flexible PVC tubing and masks provide comfort during prolonged use, while transparent materials allow healthcare professionals to monitor fluid flow and detect any abnormalities quickly.

Challenges and Concerns

1. Plasticizer Concerns

Traditional flexible PVC often uses phthalate plasticizers such as DEHP, which have raised health and environmental concerns.

Industry Response

Manufacturers increasingly use:

- Non-phthalate plasticizers
- DEHP-free PVC formulations
- Alternative bio-based additives

2. Environmental Concerns

PVC disposal and incineration may generate environmental issues if not properly managed.

Current Trends

- Recycling initiatives
- Sustainable formulations
- Improved waste management systems
- Development of eco-friendly additives

3. Regulatory Compliance

Medical PVC products must comply with strict standards such as:

- ISO 10993 (biocompatibility)
- USP Class VI
- FDA regulations
- EU MDR requirements

Emerging Trends in Medical PVC

1. DEHP-Free Medical PVC

Growing demand for safer formulations in neonatal and critical-care applications.

2. Smell Free Medical PVC

Suitable for medical devices requiring a clean and patient-friendly environment.

3. Antimicrobial PVC

Development of PVC compounds with antimicrobial properties for infection prevention.

4. Sustainable Medical Plastics

Focus on recyclable and lower-carbon-footprint PVC materials.

5. Advanced Multi-Layer Structures

Improved pharmaceutical packaging using PVC laminates and barrier coatings.

6. Gamma compatible Non Phthalate PVC compound

Excellent transparency, flexibility, mechanical properties, and resistance to discoloration after gamma sterilization.

Future Outlook of PVC in Healthcare

The demand for medical-grade PVC is expected to continue growing due to increasing healthcare requirements, advancements in medical technology, and expanding access to healthcare services worldwide. Ongoing research and development efforts are focused on improving PVC formulations, enhancing sustainability, and developing safer plasticizer systems for specialized medical applications.

As healthcare systems continue to evolve, PVC is expected to remain a key material for manufacturing high-quality, cost-effective, and reliable medical devices and packaging solutions.

Conclusion

Medical-grade PVC remains one of the most important materials used in the healthcare industry. Its combination of flexibility, durability, transparency, chemical resistance, sterilization compatibility, and cost-effectiveness makes it suitable for a broad range of medical applications. From blood bags and IV tubing to pharmaceutical packaging and diagnostic equipment, PVC continues to support safe and efficient healthcare delivery. Its proven performance, regulatory compliance, and adaptability ensure its continued importance in the medical sector for years to come.

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- Humanitarian Device Exemption (HDE)
- US Agent | MDSAP

Europe

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- (EU) 2017/746
- EN ISO 13485
- Authorized Representative
- Product Registration

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For Further Details

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Export Of Medical Plastic Components - International Market Exploration

Mr. Amit Dave

M. Pharm, MBA

Former CEO – Brazil operations/ Vice President Export - Zydus Cadila Claris Lifesciences

In line with the central theme for this issue of the Magazine, this section on export dynamics has also changed its pitch accordingly. We have taken a detour here and are writing some information for the export of plastic components, hoping that the readers will enjoy this information.

MARKET DYNAMICS

As the well-informed readers know, the world's plastic moulded medical products components are estimated at about 28 bn USD and will reach about 41 bn USD in 2035, with a growth rate of 4.5% pa (GR equal to that for the medical devices sector). Besides India, some major countries involved in the manufacturing of medical devices (which will be the target countries for exports of such products) are the USA, Germany and some EU countries, China and Singapore, besides some other Asian countries.

Some experts estimate that North America will be the main market even in future, in line with today's market dominance. The factors like a robust health setup and quality treatment, besides higher insurance coverage, will help in maintaining the dominance of the USA even in the future. Higher prevalence of chronic diseases, as well as an ageing population, will also be important contributors. Stricter quality norms by the FDA may drive quality, precision and higher costs in this market, however. From a growth perspective, the growth of the Asia Pacific region is expected to be the highest, again in line with the current trends for the finished devices market. Population growth, better health awareness, and a rise in government healthcare spending, besides increased life expectancy (like that in the USA), along with more health insurance coverage, will drive and maintain this high growth momentum for the Asia Pacific region. The markets of South America, the Middle East & Africa also share some of these growth-propelling factors. Cost sensitivity is an important factor in these markets, it needs to be noted.

PRODUCT DYNAMICS

As the learned readers are aware, plastic injection moulding involves moulding medical-grade plastic pellets and inoculating the molten material into a high-quality mould, applying pressure. Once brought to the normal temperature, finer designing may be performed if a product demands so. This process allows high volumes, dependable quality and a fair degree of flexibility. Thermoplastics dominate the market, and this trend may not

change soon. The disposables, meaning the single-use devices, dominate the market, and the same trend will continue. The current market share of disposables is more than 50%. However, the growth rate may be much higher for implantable devices. Some experts predict that the bioabsorbable plastics segment will have higher growth and a faster CAGR in the near future. Research in new materials for this segment may accelerate, seeing their future potential. Though home healthcare and hospital healthcare are both important, the hospital segment right now dominates the demand. Despite the growth of the home healthcare segment, this dominance of hospital usage may not change in the near future.

OVERSEAS MARKET EXPLORATION

Based on expert opinions, some strategic pre-activities are emerging for exploring this crucial avenue.

Conferences, seminars and exhibitions

The business of component supply is a B2B business. Understanding this particular nature (B2B) of this business may clarify many points about the market exploration and market development activities. Assuming quality, reliability and cost competitiveness favouring India, contacting a buyer will be very effective through trade conferences, seminars and exhibitions of international stature. Targeting the right company and right people in such companies and organising meetings with them in advance will be very effective, in the opinion and experience of the writer. Use of the chamber of commerce, local embassies and business development platforms (like a commercial consul, CC) of the Government in an outside country facilitates such meetings, besides giving credibility.

An overseas partner

Though somewhat tricky, a reference given by an overseas partner to a prospective new buyer for an Indian exporter is highly effective. Reliability is generally considered very high in such cases of referrals. A buyer in one country telling a new possible buyer in another country is seen very positively by a new party. A caveat here is that this is not as easy and simple as written here. The effectiveness, however, surpasses these difficulties if managed properly.

A competitor's information

Again, easier said than done. However, some informal data on an overseas competitor's supplies to some clients can give good



leads for an entry with a price advantage offer with the same quality.

REGULATORY ASPECTS

In most of the cases, the internal requirements and norms of a buyer company will govern quality standards rather than the importing country's regulatory laws. This aspect may be checked once the discussion and negotiation reach a crucial or penultimate stage.

IN SUMMARY..

The strengths in favour of this opportunity are a growing market and "Advantage India" for high quality and low cost. The challenges would be to find the right buyer with price and volume, followed by robust supply chain management. Opportunities are new product development and India's international reach. The major threats would be an unstable international environment affecting the currency rates, raw material prices and, of course, competition from other countries like China and Italy.

READING SUGGESTIONS

It is highly recommended to see the following links leading to some useful reports on the subject. Some of the information stated in this small summary is from these reports, but this summary may not substitute for the reading of these detailed reports, as mentioned here.

<https://www.nlr.org/blog/indias-medical-plastic-exports/>

<https://www.towardspackaging.com/insights/plastic-injection-molding-for-medical-devices-market-sizing>

<https://www.imarcgroup.com/india-medical-plastics-market>



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AiMeD Hails Appointment Of 22 Drug Inspectors For Medical Devices, Calls For Stronger Regulatory Capacity

The Association of Indian Medical Device Industry (AiMeD) has welcomed the Union Health Ministry's notification appointing 22 drug inspectors to take up responsibilities in the medical devices sector, but cautioned that India needs far greater regulatory capacity to match global best practices.

"These officers were recruited seven years ago but remained confined to headquarters file evaluations. Their science and engineering skills have been underutilized for too long. This notification is a start, yet India needs 10x-100x this capacity," said Rajiv Nath, Forum Coordinator, AiMeD.

Nath stressed that medical devices must be regulated separately from drugs under a distinct framework, requiring regulators with engineering backgrounds. "Posting these officers to zonal offices will ensure manufacturers and field regulators gain from their expertise on the ground. We cannot ensure patient safety if complex devices continue to be overseen by inspectors with only pharmacy training," he added.

The ministry's notification, issued on June 3 under Section 21 of the Drugs and Cosmetics Act, 1940, designates the 22 inspectors for duties under the Medical Devices Rules (MDR), 2017. It comes alongside efforts to fill 43 additional posts of Drugs

Inspector (Medical Devices) in the Central Drugs Standard Control Organisation (CDSCO).

The newly appointed officers will be deployed across India to strengthen oversight of the medical devices sector. Their role will include inspecting manufacturing and sales facilities to ensure they meet prescribed quality and safety standards, verifying that companies comply with Medical Devices Rules governing the production, import and sale of medical devices, and taking enforcement action against products found to be defective or non compliant.

The move follows repeated calls from the Parliamentary Standing Committee on Health and Family Welfare to address manpower shortages in the regulatory system. The panel has noted that only 24 personnel are currently in place against a sanctioned strength of 249 in the medical devices vertical, warning that such gaps could undermine regulatory efficiency and patient safety.

<https://www.pharmaclick.co.in/news/aimed-hails-appointment-of-22-drug-inspectors-for-medical-devices-calls-for-stronger-regulatory-capacity> (Published by Laxmi Yadav, Mumbai / Thursday, June 11, 2026)

ICMR Launches Innovator-Industry Platform, Transfers 41 Public Health Technologies For Development

New Delhi, May 25 (PTI) Several institutes under the Indian Council of Medical Research (ICMR) and innovators on Monday transferred 41 public health technologies to industry partners for further development, manufacturing, and commercialisation.

The technologies included advanced diagnostics, vaccines, medical devices and biomedical solutions addressing critical public health priorities.

Among the technologies transferred were glycoconjugate and recombinant vaccines for typhoid and paratyphoid, as well as diagnostic technologies for diseases such as Japanese encephalitis, tuberculosis, and mpox, a health ministry statement said.

The transfer was made at 'Medical Innovations Patent Mitra: Innovators-to-Industry (I2I) Connect' — India's largest biomedical and technology transfer facilitation event held by ICMR at the Manekshaw Centre.

The event marked the establishment of one of the country's first structured platforms dedicated to biomedical innovation, showcasing and technology transfer under the ICMR initiative, the statement said.

The venture is aimed at translating indigenous biomedical research into accessible, real-world healthcare solutions through strong industry partnerships, it said.

The event was inaugurated by Union Ayush Minister Prataprao Ganpatrao Jadhav.

"This initiative marks a decisive step in connecting Indian science with industry, ensuring that innovations developed in our laboratories translate into technologies that strengthen public health and advance Viksit Bharat," Jadhav said, according to the

statement.

The minister of state said India is moving from being a consumer of health technologies to becoming a global source of affordable and innovative healthcare solutions, powered by institutions like ICMR and strong industry partnerships.

Dr Gobardhan Das, Member, NITI Aayog, said, India has the scientific capability and innovation ecosystem to emerge as a global leader in health technologies.

"Medical Innovation Patent Mitra will play a crucial role in protecting intellectual property, enabling technology transfer and accelerating the journey of indigenous innovations from laboratories to society," he said.

<https://theprint.in/india/icmr-launches-innovator-industry-platform-transfers-41-public-health-technologies-for-development/2941371/> (25 May, 2026 10:51 pm IST)

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Panel Asks DoP To Monitor Progress Of Medical Devices Parks

The Parliamentary Panel on Chemicals and Fertilisers has recommended to the Department of Pharmaceuticals (DoP) to consistently monitor the progress of the medical devices parks in coordination with the state agencies, to expedite commencement of production by the units in the park.

The Department-related Parliamentary Standing Committee on Chemicals and Fertilisers, while considering the Demand for Grants of the DoP for the financial year 2026-27, observed that while 193 medical devices manufacturers have been allotted land in the approved Medical Devices Parks with a projected investment of Rs. 4,735.41 crore and estimated employment generation of about 27,148, only four units in Tamil Nadu park have commenced production so far, while the parks in Uttar Pradesh and Madhya Pradesh are yet to begin production despite land allotments.

"In this regard, the Committee recommend that the department consistently monitor the progress of the Parks in coordination with the State Implementing Agencies concerned and take necessary steps to expedite commencement of production by the remaining allotted units," said the panel headed by Member of Parliament Kirti Azad Jha.

Under the Scheme for Promotion of Medical Device Parks, which falls under the Scheme for Strengthening of Medical Devices Industry (SMDI) announced by the Department earlier, proposals from 16 states were received, out of which 4 states - Uttar Pradesh, Tamil Nadu, Madhya Pradesh and Himachal Pradesh - were conveyed final approval for creation of common infrastructure facilities in the proposed Medical Device Parks. However, Himachal Pradesh withdrew from the Scheme in 2024.

As reported earlier, the Panel in the same report, recommended

the DoP to take measures including promotion of stronger collaboration among the industry, academic institutions and research organisations to accelerate indigenous development of advanced medical devices.

It observed that currently 30 per cent of domestic content exists in medical device manufacturing indicating that a substantial proportion of components continue to be imported.

"In this context, the Committee are of the view that concrete and sustained efforts are required to decrease imported content in indigenous manufacturing of medical devices," said the panel.

"Therefore, the Committee recommend the Department to promote stronger collaboration among pharmaceutical industry, academic institutions and research organizations to accelerate indigenous development and manufacturing of advanced medical devices and thereby reducing significant import-export gap in the medical devices sector," it added.

<https://www.pharmabiz.com/NewsDetails.aspx?aid=185497&sid=1>

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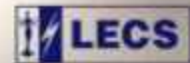
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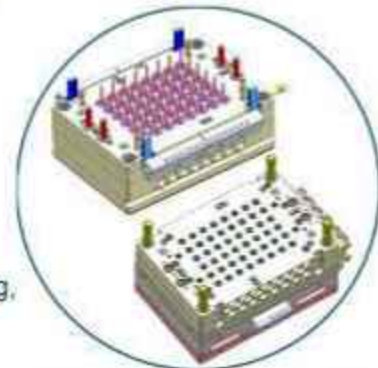
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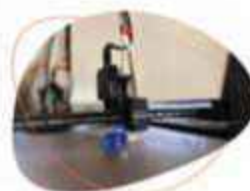
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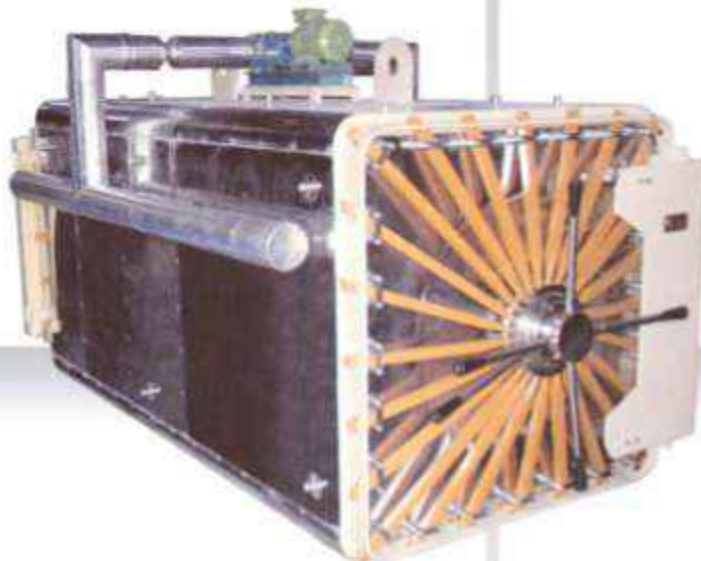


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An ISO 9001-2008 Certified Company



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- Plants equipped with **Sophisticated Analytical Instruments** to measure oxygen, Moisture, CO2 in PPM & percentage level.
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- Can Provide **Duracell & Porta-Cryo** to the customers requiring bulk quantity of liquid materials.

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20%	80% Carbon Dioxide	Non-Flammable
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- I. V. Set With Flow Regulator
- Codan Set

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- ECG Paper & ECG Accessories
- Patient ID Belt
- Oxygen Flow Meter
- Cautery Pencil

UROLOGY & NEPHROLOGY

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- Urine Bag With Urometer
- Hemodialysis Catheter Kit
- Neilan Catheter
- Blood Tubing Set
- AV Fistula Needle
- DJ Stent - All Type

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- Ryles Tube
- Stomach Tube
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- Levins Tube
- Solum Sump Tube

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- Close Wound Suction Set
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- Umbilical Cord Clamp



AN ISO 9001:2015
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ISO 13485:2016



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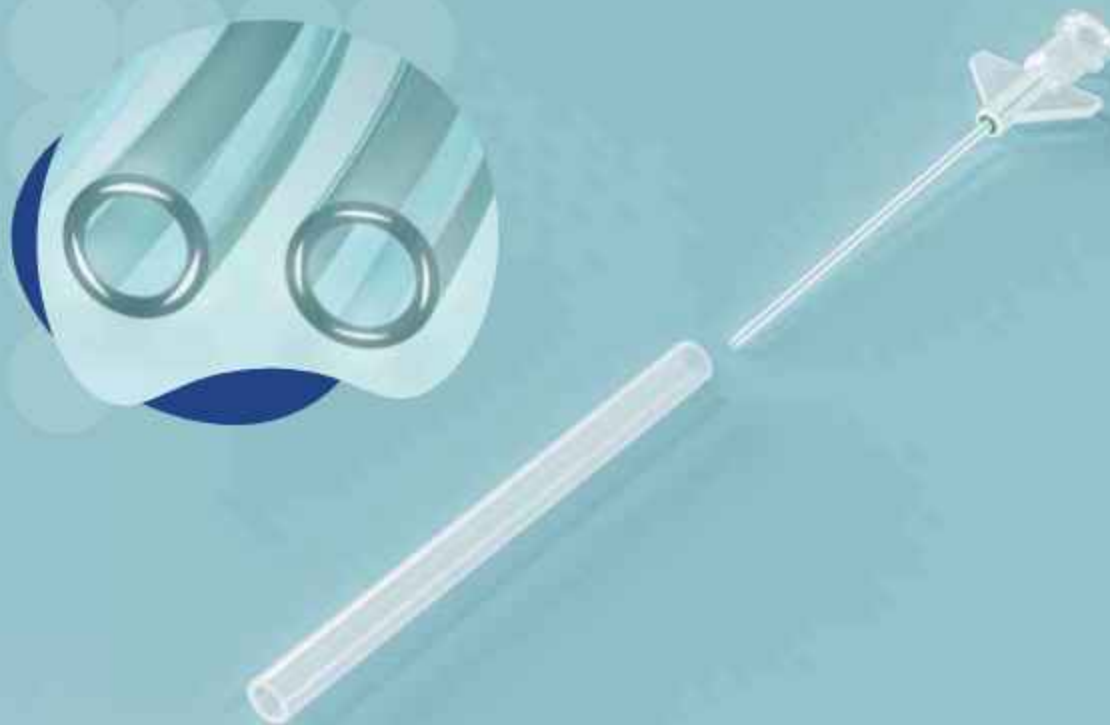
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