Vol.33 No. 3 May-June 2025

Our 33rd Year of Publication

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

CONFERENCE SPECIAL ISSUE

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Technology Display show 2025

EXHIBITION

23rd IMDI Conference

Medical Device Conference Focus

- Medical Device Manufacturing & Productivity
- Innovations, New Developments, Trends &Opportunities
- Quality, Regulations, Testing, Materiovigilance,
- New Technologies/ Materials/ Medical Textiles
- Medical Polymers, Processing & Packaging
- Medical Electronics, Electro-mechanical & Other Devices.

Field Visits & Workshops

- Bureau of Indian Standards
- CIPET : Institute of Petrochemicals Technology

Focus on Tamil Nadu Medical Device Industry Ecosystem

More Highlights

- Industry - Institute Linkages
- Panel Discussions
- Case Studies
- New Technologies

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

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- Skin Sensitization Testing (ISO 10993-10)
- Irritation or Intracutaneous Reactivity Test (ISO 10993-23)
- Acute Systemic Toxicity Test (ISO 10093-11)
- Material Mediated Pyrogen Test (ISO 10093-11)
- 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

2. Chemical Characterization /Extractable & Leachable Testing of Raw Material & Finished Medical Devices

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

4. Microbiological Testing Services

5. Packaging Testing & Transport Validation Study

6. Stability Testing Services

7. Mask, PPE, Gloves & Textile Testing

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Appreciation And Best Wishes From Industry Leaders & Readers

Rajiv Nath
Forum Coordinator - Association of Indian Medical Device Industry (AIMED)

Thanks to the excellent organization skill of Shri D L Pandya and his dedicated hard working team, the Conference this year at Ahmedabad was a great success with highest ever participation by Manufacturers and Developers and Vendors Government Officers and Students to the Medical Device Industry and a large number of International Exhibitors.

We are indebted to the initiatives taken by the humble and unassuming friend of the Indian Medical Device Industry, Shri Pandya to bring all Stakeholders at one Forum.

Shri Himanshu Baid
Managing Director, Poly Medicure 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 the very best of health and success.

I look forward to receiving from time to time all future editions.

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 vey useful for SME industry.

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

Dr. J K Sharma
MD & CEO , AMTZ & Advisor, Health & Med. Tech., Govt. of A.P., Visakhapatanam

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

Indian Medical Device Industry

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Day 1, Aug. 29, 2025,
Conference Focus:

- Medical Device Manufacturing & Productivity
- Innovations, New Developments, Trends & Opportunities
- Quality, Regulations, Testing, Materiovigilance,
- New Technologies/ Materials/ Medical Textiles
- Special Session On Medical Plastic Disposables, Medical Polymers, Processing & Packaging
- Special Session on Medical Electronics, Electro-mechanical & Other Devices.

Day 2, Aug. 30, 2025.
Field Visits & Demonstrations

- **Visit to Bureau of Indian Standards**
  - Presentations on Medical Device Standards, Availability, Implementation and Regulatory Requirements
- **Visit to CIPET : Institute of Petrochemicals Technology**
  - Presentations & Demonstrations on Medical Plastic Components Manufacturing

Profile Of Expert Speakers

- Industry Leaders & Experts from Frontline Companies
- Machinery, Materials & Technology Providers
- Authorities From Regulatory & Govt. Organizations
- Research, Training & Quality Certification Organizations
- Medical Device Industry Professionals
- Academia and Allied Professionals

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Technology Display show 2025

EXHIBITION

An Exhibition Displaying Materials, Adhesives, New Technologies, Manufacturing / Testing Equipments, Packaging / Sterilization Equipments And Services For Medical Devices, Implants & Diagnostics Industry

EVENT ORGANIZER:

IMDI Conferences & Technology Show Exhibitions are organized by "Classic Computer Services, a company providing information resources for Medical Technology and Markets through Publications, Internet Portals, Exhibitions, Conferences and Market Research since last 31 years.

The organization designs and develops conference programs aimed at specifically targeted audiences in order to provide strategic and timely information. Through a production process focused on end-user research and design, our team is able to understand the immediate business concerns of today's leading executives.

Keynote presentations, case studies and panel discussions are delivered by industry leaders with extensive knowledge of their respective sectors and specialties. Exhibitors showcase New Developments, Technologies, Innovations and Services.

EVENT CO-ORGANIZERS:

Association of Tamilnadu Medical Device Industry.

ATMED brings together Tamil Nadu's medical devices, equipment, and IVD sectors under one cohesive platform to foster the growth of MSME manufacturers and promote high-quality, sustainable healthcare products. The association offers comprehensive support in academic collaboration, regulatory guidance, statutory compliance, infrastructure development, and strategic networking. By enabling a strong ecosystem, ATMED empowers local manufacturers to innovate, scale, and compete globally. With a focused commitment to reducing import dependency, ATMED actively supports the 'Make in India' initiative. Through unified efforts, it aims to build a self-reliant, resilient, and innovation-driven medical device industry that contributes to national and global healthcare advancement.

Society of Plastics Engineers India (SPE-INDIA)- Medical Plastics Division :

Society of Plastics Engineers (SPE) is a global loader with prosecco in 84 countries and having 60,000 plus stakeholders founded in 1942 with an objective of uniting professionals worldwide through knowledge sharing, networking, training, events etc.

The SPE- Society of Plastics Engineers India Medical Plastics Division (MPD) exists to encourage the Interchange of technical and regulatory information on the polymer materials/components used in medical devices and in device containers among the scientists and engineers who are working in medical device and related industries.

Profile of Exhibits

- Manufacturing Equipments
- Medical Components / Sub-assemblies
- Polymeric / Other raw Materials
- Packaging, Printing & Sterilization Supplies
- Adhesives, Clean Room Supplies
- Laboratory Equipments & Supplies
- Services For : Manufacturing, Quality Testing, Quality Certification, Technology, Marketing etc.
- Industry Association, Publications & Information Providers

Who Can Attend The Conference And Visit The Exhibition

- Medical Device Manufacturers
- Research Organisations
- Regulatory Agencies
- Manufacturers Of Tubes And Injection Moulded Components
- Medical Plastics Processors
- Machinery Suppliers
- Financial Institutions
- New Entrepreneurs
- Drug Packagers
- Quality Certification Agencies
- Designers
- Manufacturers Of Clean Room & Sterilisation Supplies
- Plastics and Additive Producers
- Universities and Testing Laboratories

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MEDICAL PLASTICS
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Table of Contents

Vol. 33 No. 3 May-June 2025

MEDICAL PLASTICS
DATA SERVICE

Table of Contents

Vol. 33 No. 3 May-June 2025

Flashback

MEDICAL PLASTICS DATA SERVICE

Select Article Index

Nov. 2022 - Jan. 2023

- **Market Selection - Global Market :** Some Quick Export Opportunities - Countries Where Medical Devices Registration Is Not Needed (November – December 2022)
  - **Mr. Amit Dave,** M. Pharm, MBA, Former CEO - Brazil Operations/ Vice President Export - Zydus Cadila/Claris Lifesciences...
- **Global Trends :** Companies announce medical grade nylon based products (November – December 2022)
- **Global Trends :** Grade A: the trends in medical grade plastics for in-vitro diagnostics (November – December 2022)
- **Did You Know? :** About 3D Printer For Implant Grade Silicone (November – December 2022)
- **Cover Story : About Safety of Materials Used in Medical Devices**

  Manufacturers have to perform an evaluation of their device to determine if there is a potential adverse biological response resulting from contact of the device's materials with the body and whether the associated risks are acceptable. (January- February 2023)
- **QUALITY : SCTIMST)-Your Partner For Testing And Bilogical Evaluation Of Medical Devices & Biomaterials**
  - **Sandhya C G,** Scientist F, SCTIMST

  In the selection of materials to be used in device manufacture, the initial consideration is the fitness for purpose with regard to characteristics and properties of the material, which include chemical, toxicological, physical, electrical, morphological and mechanical properties…(January- February 2023)
- **MedTech Start-Ups : SCTIMST-TIMed : Catalyse Your MedTech Ideas**
  - **S. Balram,** CEO, SCTIMST-TIMed

  TIMed extends incubation support to startups and entrepreneurs who are involved in medical device or healthcare technology development. Incubatees are provided with mentoring support on various aspects including idea validation, technology and technical assessment, business plan development, preparation for fund raising, pitch deck preparation and also providing clinical, industry and vendor connects…(January- February 2023)

Did You Know?

About Challenges facing injection moulding of micro sized parts for medical industry

A growth opportunity & technical challenge exists for injection moulders to manufacture micro sized plastic parts for medical industry as manufacturers increasingly design small devices such as hearing aids, ear canal implant devices, micro pumps, and micromanipulators.

Medical device manufacturers are designing products with micro features that require tolerances in microns. Hence the micro moulding process is gaining momentum for producing plastic parts with such micro features.

Precision mould building is key to the micro moulding process. Micro scale features with high aspect ratios require advanced mould building techniques. It is commonly assumed that as a mould gets smaller, the cost of material and labour decreases, but micro moulds do not adhere to common pricing models. The equipment and methods required to create micro features and hold micron-level tolerances typically create an inverse relationship between mould cost and part size.

The micro moulding process requires machines with precise control over the metering and injection of the plastic melt. Injection capacity increases as the part size becomes smaller. Shot weights of less than a gram are normal in micro moulding.

To meet these requirements, machine manufacturers have recently developed machines with electric servo drives to enable the machines to produce smaller injection units for more precise process control. Downsizing of injection units to minimize the residence time or introduction of an extruder and plunger concept are also among the new developments. The minimized residence time improves quality of plastic melt quality, which is critical to the mechanical properties of the moulded part.

Tight tolerances for plastic parts with micro features require advanced measurement technology.

https://www.plastemart.com/plastic-technical-articles/challenges-facing-injection-moulding-of-micro-sized-parts-for-medical-industry/859

MEDICAL PLASTICS
DATA SERVICE

EDITOR
D.L.PANDYA, B.E.(Chem), M.I.E.

ASST. EDITOR
MIHIR VYAS

PUBLISHED BY :
Classic Computer Services
B-4, Mandir Apartment, Opp. Jodhpur Char Rasta
BRTS Bus Stop, Ahmedabad-15, India
Phone : 98254 57598 (10am to 2pm), 98254 57563
E-mail: info@medicalplasticsindia.com
Website : www.medicalplasticsindia.com
Reg. No. GUJ-ENG-00446/23/ALL/TC/94 dt. 3/8/94

DESIGNED AND PRINTED BY :
Image Virtual Creation, Ahmedabad-54
Ph:098795 55948

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From the Editor's Desk

"IMDI 2025: The 23rd Two Day National Conference and Technology Show Exhibition on "Medical Devices / Medical Plastics: Changing Scenario and Way Forward"

In continuation of our mission for creating interaction between various stakeholders of Indian Medical Device Industry, we are happy to announce the event in Chennai on Aug. 29-30, 2025 jointly with "Association of Tamil Nadu Medical Device Industry (ATMED) and SPE INDIA Medical Plastics Division. The event is supported by major National Associations in Medical Devices and Plastics Sectors.

"IMDI" Conferences are being organized since year 2001 – this being 23rd event. We are grateful to industry leaders from medical devices and plastic industry for their support, mentoring and hand holding which motivates us to carry on so long.

Coming event is focused on techno-commercial & regulatory issues of importance to promote Medical Plastics & Medical Device Manufacturing in India. The event will be participated by delegates from Industry, Research Institutions, Professionals and Academic Institutes from India and abroad.

"Technology Display Show" exhibition to be held in conjunction with the conference will showcase Technology, Materials, Machinery, Products and Services required for Medical Device Manufacturing. The event also includes visits to related institutions for demonstrations and workshops. Detailed information is available @ www.imdiconferences.com We highly appreciate support by "Association of Tamil Nadu Medical Device Industry Association (ATMED)"

Medical Device Industry Clusters in India.

According to Porter, industry clusters are a source of highly localised strategic competitive advantage and clustering appears to be a central feature of advanced economies.India's medical device industry is experiencing significant growth, with clusters and parks emerging across the country to support domestic manufacturing. Several states have established dedicated medical device clusters and parks, including Uttar Pradesh, Gujarat, Maharashtra, Haryana, Telangana, Andhra Pradesh, and Tamil Nadu. More states /regions are being identified / developed as Medical Device Clusters.

Tamil Nadu Medical Device Industry Ecosystem

In order to introduce one such cluster, we are covering Tamil Nadu Medical Device Industry Ecosystem in this issue. The ecosystem includes all major stake-holders including: Industry Associations, Regulatory Agencies, Institutions providing Product Quality Standards &Testing Service, Academic, Training & Research Institutes, Start-up and Incubation support organizations as well as Infrastructure, Raw Materials, Machinery and Services Providers.

As rightly mentioned by one a leading innovation expert, "….A system truly poised to innovate is one in which collaboration happens across disciplines, sectors and stakeholders. Such regions gain competitive advantage. We feel proud to mention that Tamil Nadu Medical Device Industry is such a group of industry.

One more important article by Dr Shatrunjay Shukla from Indian Pharmacopoeia Commission highlights the need for a Safety Surveillance System for medical devices and introduces the Materiovigilance Programme of India (MvPI).

Other important issues covered in this issue include Medical Plastic Components injection moulding, Global Trends, Association, Regulatory and Industry News as well as important coming events.

D L Pandya

Medical Device Industry Clusters in India: Growth Dynamics

Porter (1998) defined clusters as “geographic concentrations of interconnected companies and institutions in a particular field”. According to Porter , clusters are a source of highly localised strategic competitive advantage and clustering appears to be a central feature of advanced economies.

There is significant real-world evidence of industry clustering in geographic concentrations. For example, Japan has captured 98 % of the global market in flexible endoscopes and 31.9 % of Magnetic Resonance Imaging (MRI) systems. There is evidence of knowledge-sharing and proximity aiding innovation and competitive advantage.

Clusters give individuals access to knowledge, social ties, and resources to start new ventures, hence entrepreneurial tendency is greater in a cluster. Clusters also improve non-commercial stakeholders, for example, academic institutions in clusters have more impact and are cited 81 % more than institutions outside a cluster.

India's medical device industry is experiencing significant growth, with clusters and parks emerging across the country to support domestic manufacturing. Several states have established dedicated medical device clusters and parks, including Uttar Pradesh, Gujarat, Maharashtra, Haryana, Telangana, Andhra Pradesh, and Tamil Nadu. More states /regions are being identified / developed as Medical Device Clusters.

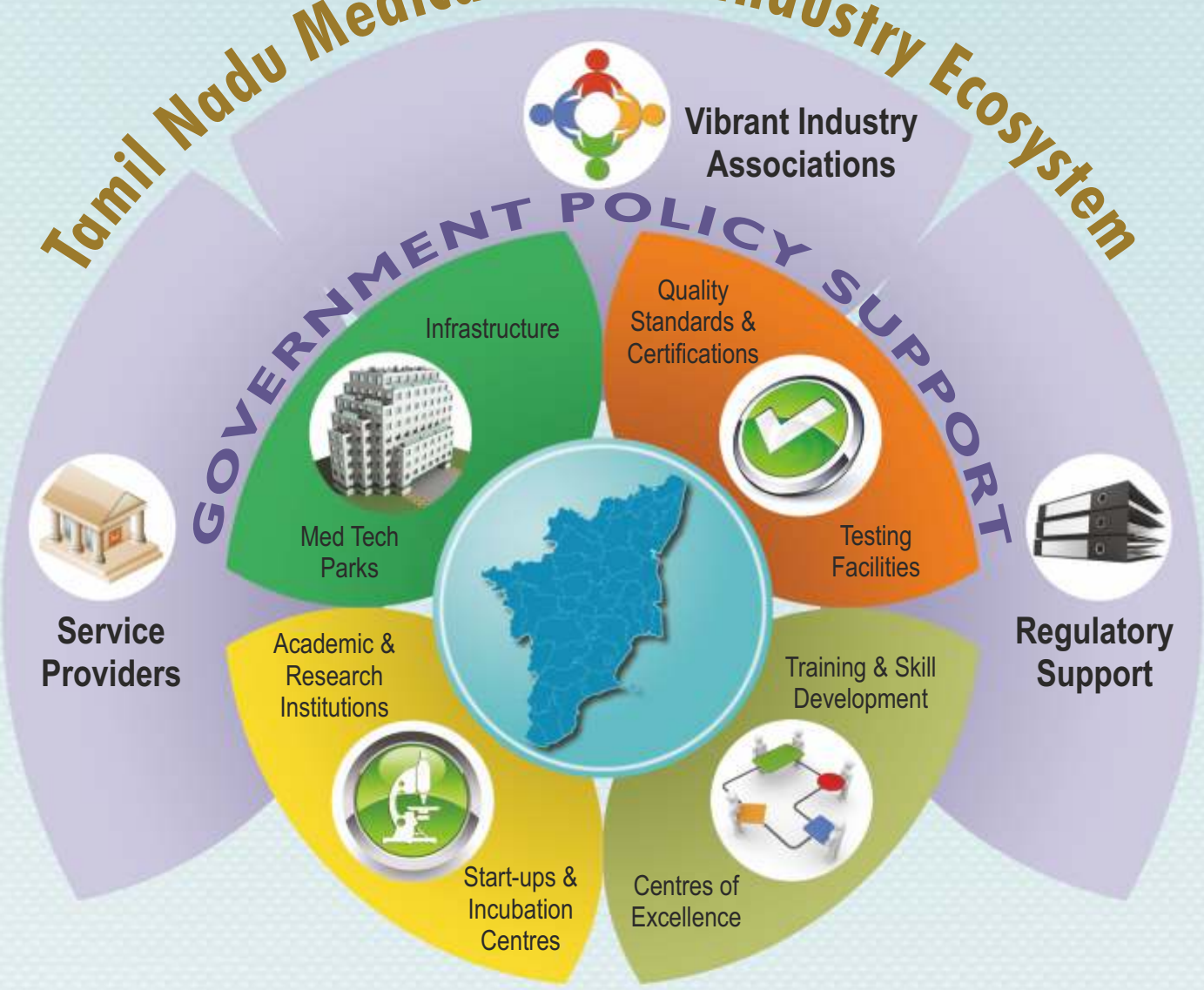
Government of India has identified Medical Devices as a priority sector for the flagship “Make In India” program and committed to strengthening the manufacturing ecosystem. Based on a study conducted by Department of Pharmaceuticals on Medical Devices Clusters, the Department has already introduced number of Policy Initiatives. These initiatives aim to reduce production costs, foster innovation, and enhance the competitiveness of the Indian medical device sector.

In order to introduce one such cluster to start with, we are covering Tamil Nadu Medical Device Industry Ecosystem in this issue. The supplement highlighting the ecosystem includes all major stake-holders.

To give one more opportunity for interaction between the stakeholders in the cluster, we are organizing a two day conference and technology exhibition jointly with “Association of Tamil Nadu Medical Device Industry (ATMED).

(https://www.sciencedirect.com/science/article/pii/S2199853123002706)

Tamil Nadu Medical Device Industry Ecosystem



Association of Tamil Nadu Medical Devices Industry (ATMED)

www.atmedindia.com

Focus on Tamil Nadu Medical Device Industry Ecosystem

Association of Tamil Nadu Medical Devices Industry (ATMED)

Samuel Williams George
(President)

Jayasing Morris
(General Secretary & Coordinator)

Tamil Nadu's Industrial Ecosystem: A Fertile Ground for Medical Device Industry Growth

By **Jayasing Morris**
Coordinator & General Secretary, Association of Tamil Nadu Medical Device Industry (ATMED)

Tamil Nadu, long recognized as the industrial powerhouse of India, continues to set benchmarks in manufacturing excellence, infrastructure development, and policy innovation. Known for its thriving automotive, textile, and electronics industries, Tamil Nadu is now emerging as a significant hub for the medical device sector — a transformation driven by its robust ecosystem and strategic foresight.

A Strong Industrial Base

Tamil Nadu boasts one of the most diverse and mature industrial bases in India. With over 45 industrial parks and SEZs, a highly skilled workforce, and seamless connectivity through ports, airports, and highways, the state offers a conducive environment for high-tech manufacturing. The government's proactive policies — including the Tamil Nadu Industrial Policy 2021 and Tamil Nadu Medical Devices Policy 2023 — have created a framework that supports innovation, ease of doing business, and investment promotion.

Rise of the Medical Device Industry

The global demand for high-quality, affordable medical devices has surged post-COVID-19, and Tamil Nadu is well-positioned to lead this transformation. The creation of the Tamil Nadu Medical Devices Park in Oragadam-Chengalpattu, supported by the Tamil Nadu Industrial Development Corporation (TIDCO), marks a milestone in the state's ambition to become a national and global hub for medical device manufacturing.

Key Enablers of Growth

Several factors underpin the medical device industry's growth in Tamil Nadu:

Skilled Talent Pool: With top-tier engineering and life sciences institutions, Tamil Nadu offers a steady pipeline of professionals trained in biomedical engineering, electronics, and materials science. Strong Ancillary Support: Tamil Nadu's mature manufacturing ecosystem ensures easy access to suppliers of plastics, metals, electronic components, and packaging — all critical for medical device production.

Policy Backing: The Tamil Nadu Medical Devices Policy focuses on end-to-end ecosystem development, from R&D support to regulatory facilitation, making it easier for both MSMEs and large manufacturers to thrive.

Innovation and Startups: The state's innovation ecosystem — supported by incubators such as TICEL Bio Park and the Biotechnology Industry Research Assistance Council (BIRAC) — fuels the growth of medical device startups working on cutting-edge technologies.

Role of ATMED

The Association of Tamil Nadu Medical Device Industry (ATMED) plays a catalytic role in shaping the future of this sector. By bridging the gap between industry and government, advocating for favorable policies, and building networks for collaboration and exports, ATMED supports sustainable growth and global competitiveness for its members.

The Road Ahead

As healthcare infrastructure expands and India aspires to become a global hub for medical technology, Tamil Nadu's integrated industrial ecosystem provides an ideal foundation. With continued investment in R&D, manufacturing, training, and regulatory capabilities, Tamil Nadu is poised to emerge not just as a leader in India, but as a key player in the global medical device landscape.

Who Can Become a Member?

Primary Member: Individual/Institution
- Manufacturer of Medical Devices
- Manufacturer of IVD products
- Manufacturer of Medical Equipment
- Manufacturer of healthcare products

Associate Member: Individual/Institution
- Technology Providers

ATMED

- Product Testing Labs
- Raw materials
- Clean room Equipment providers
- Medical Machinery suppliers
- Healthcare Institutions
- QMS/regulatory consultants
- Certification assessment bodies

Affiliate Member

- Regulatory/statutory organizations
- Other related Associations
- Industrial Development organizations
- Industrial Funding organizations

Others

- Student (Medtech Industry)
- Startups (Medtech Industry)

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Murali Deva
(Conference Co - convener)

Lloyd

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As a co-convenor, it is my privilege to highlight ATMED's unwavering dedication to the advancement of medical technology in Tamil Nadu. Our association consistently conducts a wide spectrum of seminars, workshops, and conferences, designed to foster welfare, facilitate knowledge transfer, and promote vibrant networking among medtech stakeholders. At the heart of this dynamic initiative lies a passionate team of young and versatile professionals, each striving to ensure that our state remains at the forefront of Medtech innovation.

Our collective efforts are directed towards nurturing talent, sharing the latest advancements, and building lasting professional connections. The enthusiasm and commitment of our team guarantee that Tamil Nadu is not only enriched by these meaningful activities but stands as a leader statewide. We remain steadfast in our mission to empower the medtech community and look forward to creating ever-greater opportunities for learning and collaboration. Together, we propel Medtech in Tamil Nadu to new heights.

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IPI – Indian Plastics Institute
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www.atmedindia.com

SPE India Medical Plastics Division

Regulatory Guidance - Central Licensing Authority (CLA) - South Zone

Dr.K.M.Srinivasan
Deputy Drugs Controller(India)

The globe has witnessed a remarkable transformation of India's medical device industry from an import dependant ecosystem to a globally significant manufacturing hub in the past ten years i.e., from 2015 to 2025. This change was driven by the introduction of the Indian Medical Devices Rules in the year 2017 as well as the acute demand for life saving drugs, devices and vaccines during the covid pandemic.

Currently, Indian medical device market is valued at US$12 billion in 2023-24 and is projected to reach US$50 billion by 2030, with India's global market share set to grow from 1.65% to 10%-12% over the next 25 years.

The Central Drugs Standard Control Organisation (CDSCO) an apex national regulatory of India for medical device sector headed by Drugs Controller General (India), has played a vital role in equipping Indian medical device sector to align itself to ever-changing global regulatory landscape. As India being an affiliate member of the International Medical Device Regulators Forum (IMDRF), CDSCO participates in global collaboration and harmonization of medical device regulations ensuring adoption of safety and performance standards and best practices across the manufacturing units in India.

The CDSCO with its Headquarters at New Delhi, six zonal offices, four sub-zonal offices, 13 port offices and seven laboratories serve domestic manufactures and importers in bringing advanced and affordable devices in Indian market. The adoption of new regulations among the stakeholders are effectively supervised by CDSCO through its online Sugam portal. CDSCO has published various guidance documents, FAQs, classification lists, medical devices grouping guidelines etc., to give more clarity on the regulatory requirements of various devices. The transition was further made smooth by CDSCO through a phase wise implementation of the regulations based on the risk class of the device to maintain the availability and continuity of the medical devices in the country. Low risk devices of class A & B risk class are under the licensing regime of respective State Licensing Authority (SLA) based on the recommendation of Notified bodies, whereas high risk, Class C &D devices are approved after inspection of technical documents and Quality Management System of manufacturing facilities by CDSCO zonal offices followed by CDSCO HQ Medical Device Division. The provision of medical devices testing laboratory (MDTL) that are registered under CDSCO facilitates testing to ensure the safety and performance of devices for initial submission of licensing application as well as for continual monitoring and compliance. Further, the Materiovigilance program of India (MvPI) launched by the CDSCO in collaboration with the Indian Pharmacopoeia Commission (IPC), systematically collect and analyse data on adverse events related to medical devices and issue safety recommendations ensuring public safety and continual compliance.

Government of India's continuous initiatives such as Production Linked Incentive (PLI) scheme, Make in India initiative, medical device parks, and liberalized foreign direct investment has a positive impact on boosting domestic manufacture and reducing import dependence. However, deficiencies in raw material supply chain, insufficient testing, clinical evaluation and sterilisation facilities as well as dearth of quality manpower are a major impediment. CDSCO's regulations and policies addressing these hurdles will make a long way in reinforcing the sector's focus on quality, safety, and innovation.

The CDSCO offices has approximately approved 20,400 devices under Import License MD-15 in India. By far CDSCO South Zone in Chennai alone has completed approval of more than 1800 devices in Form MD-9 Licence which includes manufacturing of various high-risk devices such as cardiac stents, blood bags, heart valves, spinal implants, surgical sutures and dialysis concentrates etc. The different forms of Medical Devices are as follows,

Stakeholders	Application	Approval License	Authority
Manufacturing Class A or B	Form MD-3 or MD-4	Form MD-5	State Licensing Authority
Manufacturing Class C or D	Form MD-7 or MD-8	Form MD-9	Central Licensing Authority
Import Class A, B, C and D	Form MD-14	Form MD-15	Central Licensing Authority

Medical Device Industry: Tamil Nadu's Next Growth Story in Manufacturing

Tamil Nadu is emerging as a significant hub for the medical device industry in India. The State hosts several medical device clusters and is actively working to attract further investment and manufacturing in this field. The state also supports MedTech start-ups through incubation programs.

Medical Device Regulation in Tamil Nadu: A Public Health Imperative

Mr. P. U. Kartikeyan
Director of Drugs Control i/c,
State Licensing Authority Government of Tamil Nadu

Medical devices are vital in the healthcare system alongside with healthcare professionals and medicines. From life-saving implants to diagnostic kits, their reliability and quality are essential to patient safety. These devices might range from basic equipment as thermometers and tongue depressors to sophisticated as pacemakers, Magnetic Resonance Imaging (MRI) machines, and robotic surgical systems. The World Health Organization (WHO) defines a medical device as any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material, or another similar or related article, intended by the manufacturer to be used, alone or in combination for a medical purpose

The Government of India introduced comprehensive regulations for medical devices aimed at aligning the country's regulatory framework with globally accepted standards and framed dedicated Rules—the Medical Devices Rules, 2017, under the Drugs and Cosmetics Act, 1940.

State Government's Mandate: Licensing and Enforcement
The State Licensing Authority is competent authority for enforcement of Medical Devices Rules, 2017 in matters relating to,

- Manufacture for sale or distribution of Class A or Class B medical devices.
- Sale, stock, exhibit or offer for sale or distribution of medical devices of all classes.

The State Government is entrusted for monitoring of availability of safe and quality Medical Devices across the State of Tamil Nadu as per MDR, 2017. The State Government is also responsible for availability of medical devices without shortage and at the prices fixed by the Central government.

Bridging Compliance and Industry Growth:

Tamil Nadu has emerged as a medical device manufacturing hub in South India, particularly in areas like Coimbatore, Chennai, and Hosur. Tamil Nadu is the 4th largest Medical Devices manufacturing State in the Country with 13% share in national exports.

With a growing base of MSMEs and start-ups entering this space, our department remains committed to balancing regulatory compliance along with industrial growth.

Our department not only monitor the compliance of regulations by the Stakeholders, but we commit ourselves to issue Licences for Manufacture and Sale of Medical Devices in timely manner and guide the stakeholders on regulations of Medical Devices, thus upholding the industry growth.

Advisories to Stakeholders for Ensuring Device Quality and Safety:

To ensure continuous supply of quality, safe and effective Medical Devices to Public, we expect the industry to,

- Ensure compliance with regulatory requirements: Adhere to quality and safety standards, such as ISO 13485 and ISO 14971, to guarantee the safety and efficacy of medical devices.
- Implement robust quality management systems: Establish and maintain quality management systems that ensure consistent production and distribution of safe and effective medical devices.
- Accurate labeling and documentation: Ensure that labeling and documentation, including instructions for use and patient information, are accurate, clear, and compliant with regulatory requirements.
- Provide adequate training: Provide users with adequate training and support to ensure safe and effective use of medical devices.
- Monitor and report adverse events: Establish systems for monitoring and reporting adverse events, including serious injuries and deaths, to regulatory authorities.
- Conduct post-market surveillance: Regularly collect and analyze data on medical device performance to identify potential safety concerns and take prompt action.
- Stay up-to-date with regulatory changes: Monitor regulatory updates and changes to ensure ongoing compliance with regulatory requirements.
- Ensure compliance with local regulations: Comply with local regulations and standards, including those related to registration, licensing, and labeling.
- Collaborate with regulatory authorities: Engage with regulatory authorities to ensure compliance and address any concerns or issues that may arise.
- Be transparent about device performance: Provide transparent and accurate information about medical device performance, including any potential risks or limitations.

By following these advisories, medical device manufacturers can ensure compliance with regulatory requirements, prioritize patient safety, and maintain trust in the industry.

Tamil Nadu Healthcare Sector

Tamil Nadu has been consistently ranked high in the health sector. A robust public health system has enabled the State to stay ahead in many of its key health indicators. Chennai, as a major medical tourism hub, contributes to the demand for high-end medical devices and treatment.

Medical Product Standardization - Bureau of Indian Standards (BIS) - South Zone

Smt. G. Bhavani,
Scientist F Senior Director and
Head Chennai Branch Office at Bureau of Indian Standards

Bureau of Indian Standards(BIS) is the National Standard Body of India established under the BIS Act 2016 for the harmonious development of the activities of standardization, marking and quality certification of goods and for matters connected therewith or incidental thereto.BIS has been providing traceability and tangibility benefits to the national economy in a number of ways – providing safe reliable quality goods; minimizing health hazards to consumers; promoting exports and imports substitute; control over proliferation of varieties etc. through standardization, certification and testing.

BIS under Medical Equipment and Hospital Planning department (MHD) formulates standards medical devices, services and test processes. Medical Device Rules 2017 mandates the compliance to standards laid down by Bureau of Indian standards under the Clause 7.

With the recent release of the National Medical Device policy NMDP 2023 by Department of Pharmaceuticals DOP, BIS plays an important role in the streamlining the regulations in India and the formulation of standards for ensuring the reliable products in the market.

The Bureau of Indian Standards (BIS), as the national standards body, plays a significant role in formulating and promoting standards for medical devices. These standards are essential for ensuring Safety and Quality, facilitating market access, enhancing consumer confidence and promoting innovation. By setting clear standards, BIS encourages manufacturers to innovate within a defined framework, leading to the development of advanced medical technologies.

The two-day national seminar and technology exhibition on medical devices and medical plastics by the Association of Tamil Nadu Medical Industry will offer a comprehensive platform for learning, networking, and exploring innovations that can contribute to the advancement of a robust and globally competitive medical device sector in India.

Academic Knowledge - Anna University

Dr. Sasikala,
Professor and Head of the
Department of Biomedical Engineering
at Anna University and CEO of CCTME.

Engineering Health: Anna University's ecosystem for biomedical Innovation and its role in shaping the future of medical devices in India

The healthcare sector in India is fast zooming towards 'Atma Nirbharata' or self-reliance and innovation and Anna University, Chennai is emerging as one of the national leaders in the development of cost-effective, high-quality medical technologies. At the centre of this transformation is the Department of Biomedical Engineering, born from a legacy of pioneering work in the field and seasoned through decades of research in interdisciplinary domains, industry involvement thus achieving a real-world impact.

What began in 1975 as a visionary experiment by the creation of the Medical Electronics Laboratory within the Department of Electronics and Communication Engineering, has now grown into a full-fledged biomedical innovation ecosystem. With the establishment of the Centre for Medical Electronics in 1998, there was a definite shift from pure academic work to that involving industry. The launch of undergraduate and postgraduate engineering programs not just expanded the University's reach but also aided in creating a continuous stream of skilled talent equipped for both research and medical device development.

This initiative attained its pinnacle in 2011 with the launch of the National Hub for Healthcare Instrumentation Development (NHHID) supported by the Department of Science and Technology (DST), Government of India. The hub has the honour of being India's first national platform dedicated to indigenous medical device development, validation and commercialisation, directly contributing at the forefront of the Government of India's "Make in India" mission.

Over the years, NHHID has progressed into an integrated innovation ecosystem, mentoring clinical startups, MSMEs in transforming healthcare concepts into viable, regulation-compliant products. Its contributions is evident in the diverse array of devices that has churned out from its laboratories including the Smart Thermometer for COVID, Automated Antibiogram Device, Point of Care Anemia Detectors and Infant Theft Prevention Systems etc, most of which have been successfully deployed in clinical settings. NHHID is offering technical consultancy, mentorship and regulatory guidance for scalable, market-ready innovations. In addition, a Calibration facility, Limited & Smart manufacturing and EMI/EMC testing facility including PCB Design and Assembly etc. are also offered to the Industry professionals.

The Department of Biomedical Engineering is committed to deliver quality education in Biomedical Engineering, develop innovative and affordable medical devices, provide healthcare solution and prioritize training and skill development. Cutting-edge research is carried out in the areas of Biosensors and Instrumentation, Biomedical signal and image processing, Brain control Interface, Assistive Technologies, Wearable devices, IoT, Artificial Intelligence, Biomaterials, Tissue Engineering, BioMems, and Gait Analysis. The students are provided with a four-week training in Hospitals and Medical Industries, a unique feature of the curriculum, that equips them with practical insights to understand the needs of the market and develop products accordingly.

Now, as the country is ramping up its infrastructure for indigenous device production, Anna University is poised to play a pivotal role in shaping the upcoming Medical Device Park at Oragadam,

Chennai, serving as the Technical and Knowledge partner. This synergy between Anna University, DST and the Government of Tamil Nadu is a pointer of a larger goal: to make India self-reliant in medical technology, to reduce dependency on imports and to promote cost-effective healthcare solutions rooted in indigenous research and development.

The Medical Device Testing and Calibration Centre, accredited by NABL has already tested and calibrated more than 15,000 medical devices thus reflecting upon its leadership in setting national benchmarks for device reliability and safety. The University has also been recognised as a University with Potential for Excellence by the UGC and with this it has further strengthened its role as an enabler of MSME innovation as well. To further this mission, an MoU is soon to be signed between Anna University and Association of Tamilnadu Medical Device Industry (ATMED). This is a big leap in the domain of medical devices with a perfect amalgamation of Academia and Industry being made possible to ensure the best care is offered to the patients.

The Biomedical Engineering Department is all set to take forward this legacy to the next level by pushing the boundaries of interdisciplinary healthcare research, by bridging academia and industry and making 'Made in India' a global standard for affordable, high-quality healthcare technologies.

केंद्रीय पेट्रोरसायन अभियांत्रिकी एवं प्रौद्योगिकी संस्थान (सिपेट)
Central Institute of Petrochemicals Engineering & Technology (CIPET)
(Formerly Central Institute of Plastics Engineering & Technology)
Department of Chemicals & Petrochemicals,
Ministry of Chemicals & Fertilizers,
Govt. of India

Mr.S.Ilangovan,
Principal Director & Head,
CIPET : IPT - Chennai

Materials Knowledge - Central Institute of Petrochemicals Engineering & Technology (CIPET)

The **Central Institute of Petrochemicals Engineering & Technology (CIPET),** under the Ministry of Chemicals & Fertilizers, Government of India, plays a pivotal role in supporting the polymer and plastic industry, particularly in **medical device development** and manufacturing. CIPET is an ISO-certified national institution that focuses on **skill development, academic research and technical support.** The **Chennai center,** established in 1968, was the first of its kind and has diversified its operations to include training, product development, testing and high-end technical services.

CIPET : IPT - Chennai offers B.Tech Plastics Technology (accredited by NBA), B.E. Manufacturing Engineering, M.Tech. Plastics Technology, M.E. CAD/CAM in affiliation with **Anna University and** M.Sc. Applied Polymer Science in affiliation with **University of Madras**. CIPET : IPT - Chennai in accreditation with AICTE / NBA also offers Diploma in Plastics Mould Technology, Diploma in Plastics Technology, Post Graduate Diploma in Plastics Processing & Testing and Post Diploma in Plastics Mould Design.

CIPET : IPT - Chennai offers Vocational Skill Development training programs with the sponsorship of Tamil Nadu Skill Development Corporation and other PSU's to meet the Human Resource requirements of polymer & allied industries especially for the automobile sector who have set up units in & around Chennai.

Technical Services at CIPET, Chennai:

CIPET Chennai provides end-to-end technical services in **product development, mould manufacturing, plastic processing,** and **material testing:**

- The **Tool Room** is equipped with advanced CNC machinery including EDM, wire cut machines, milling equipment, grinders, and high-precision inspection tools. It fabricates moulds and special components for both government and private clients.
- The **Processing Division** supports the industry by offering mould proving and job work through machinery like injection moulding, extrusion, blow moulding, compression moulding, and thermoforming units.
- The **Plastics Testing Centre (PTC)** is NABL-accredited and considered one of Asia's premier testing labs. It evaluates materials across multiple domains - Rheology, Mechanical, thermal, Microbiological, optical, electrical, and chemical as per global standards like ASTM, ISO, and IS. Facilities include advanced instruments such as DMA, FTIR, GC, AAS, TGA,

DSC, Cone Calorimeter, torque rheometers, thermal analyzers, and weather chambers.

Testing services also cover **rheological** and **microbiological properties,** including sterility and biodegradability, as per international pharmacopeia standards. CIPET's expertise ensures that polymer materials meet high-performance standards for medical and industrial use.

Role of Plastics in Medical Devices:

Plastics are integral to modern healthcare. Their **lightweight, durable, transparent, sterilizable, and moldable** nature makes them ideal for medical devices ranging from simple disposables to complex implants. Due to the need for hygienic, cost-effective, and flexible materials, plastics have become essential for producing syringes, catheters, IV tubes, surgical instruments, and advanced diagnostic devices. Post-COVID, there has been a significant surge in demand for medical-grade plastics in items like masks, ventilators, gloves, and other disposable supplies.

Medical plastics are formulated to be **chemically resistant, antimicrobial,** and **biocompatible.** Some even include **radiopaque additives** that make them visible under X-rays. Advanced materials and nano-additives enable innovations like miniaturized surgical tools and implantable devices. The **global shift toward disposable and sustainable healthcare products** is also driving demand for recyclable plastics and biodegradable polymers.

Devices are categorized into:

- **Non-disposable devices** such as MRI machines and monitors, which prioritize durability and structural integrity;
- **Implants** like stents and pacemakers, which require biocompatibility and long-term safety;
- **Disposable items,** where cost-efficiency and single-use sterility are key.

While **commodity plastics** dominate simpler applications like tubing and containers, **engineering and high-performance plastics** are critical for surgical and diagnostic uses.

In summary, CIPET plays a crucial enabling role for India's growing **medical device industry,** ensuring the materials used meet international quality and performance standards. It provides a robust ecosystem for **education, testing, and technical services,** making it an indispensable part of India's healthcare manufacturing landscape.

We sincerely commend the Association of Tamil Nadu Medical Device Industry (ATMED) for its unwavering commitment to strengthening the medical device ecosystem. We are confident that the Association will continue to be a driving force in addressing the dynamic needs of the industry and will contribute significantly to the advancement of Tamil Nadu's healthcare and manufacturing sectors.

INFRA support - State Industries Promotion Corporation of Tamil Nadu (SIPCOT)

Dr. K. Senthil Raj
I.A.S, Managing Director,
SIPCOT, Tamil Nadu.

Oragadam's MedTech Leap: Tamil Nadu's Vision for a Healthier India

In a decisive move to position Tamil Nadu as a national leader in the MedTech manufacturing space, the State Industries Promotion Corporation of Tamil Nadu (SIPCOT) is developing a state-of-the-art Medical Devices Park (MDP) across 350 acres at Oragadam, Kancheepuram District. With a total project cost of ₹286 crore, this ambitious initiative is not just about infrastructure—it's about catalyzing innovation, advancing healthcare, and reinforcing India's self-reliance in the medical devices sector.

At the heart of the MDP lies robust infrastructure worth ₹153 crore, designed to provide both strategic support and technological edge to enterprises. To date, plots totaling 58 acres have already been allotted to 25 forward-thinking industrial units. These units benefit from plug-and-play facilities, subsidised lease rates, and a full waiver of stamp duty and registration charges—making the park an attractive destination for both established firms and emerging startups.

What sets this park apart is its designation as one of just four medical device parks approved by the Department of Pharmaceuticals (DoP), Government of India, qualifying it for a central grant of ₹100 crore. SIPCOT, with backing from the DoP, is constructing advanced Common Infrastructure Facilities (CIF) that include a gamma irradiation centre, an EMI/EMC testing lab, a calibration centre, warehouse and cold storage, and a 3D printing prototyping hub, among others. These facilities are critical to maintaining global standards in product safety, efficacy, and innovation.

A major milestone was achieved in January 2025 with the signing of a Memorandum of Understanding between SIPCOT and the Board of Radiation and Isotope Technology (BRIT) to build and operate the gamma irradiation facility—an essential asset for sterilization processes in medical device production.

Moreover, the park is not growing in isolation. Through active collaboration with the Association of Tamil Nadu Medical Devices Industry (ATMED), the park benefits from a feedback loop that ensures infrastructure and services are aligned with industry needs. ATMED's role in shaping the ecosystem has been pivotal, enabling rapid development and targeted enhancements that match global industry trends.

As India's medtech market accelerates, Tamil Nadu's focused investments and industry partnerships at Oragadam signal a strong commitment to excellence, competitiveness, and a healthier tomorrow—for India and beyond.

Testing and validation facility - SITRA

Dr. R. Guruprasad
SITRA's Centre of Excellence for Medical Textiles
Head – CoE Medical Textiles

The South India Textile Research Association (SITRA), a pioneering textile research organization since 1956, has established a Centre of Excellence for Medical Textiles (CoE-Meditech) under the Ministry of Textiles' Technology Mission on Technical Textiles. This state-of-the-art centre is dedicated to fostering innovation, skill development, and industry growth in medical textiles, positioning SITRA at the forefront of India's textile research and development landscape.

Medical Textile Testing:

The Centre of Excellence for Medical Textiles, with its well-equipped competency for medical textile testing, has established dedicated laboratories to meet various functional requirements.

- CoE Medical Textiles – Physical Laboratory
- CoE Medical Textiles – Microbiological Laboratory
- CoE Medical Textiles –Biotechnological Laboratory
- CoE Medical Textiles – Polymer chemistry Laboratory

The testing Laboratories are equipped with state-of-the-art instruments and provide testing services in accordance with national and international standards for medical products. Variety of health care and hygiene products medical textile products like surgical gown, drapes, face mask, coverall, sanitary napkin, diaper, underpad, incontinence pad, wipes etc., can be tested using the state-of-the-art testing instruments. Also, non-implantable products like Gauze, wound dressing, bandage, surgical cotton, compression stocking and pressure garments can be tested as per relevant standards.

The physical and chemical laboratories have been accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL), New Delhi, for complying with ISO/IEC 17025 guidelines for laboratory accreditation. SITRA is also a BIS empanelled and CDSCO recognised medical device testing laboratory.

Incubation Facility:

The Centre has served as a pillar for many businesses in the medical textiles market by providing technical assistance to both domestic and international manufacturers—from concept to finished product. Numerous techno-commercial programs have been conducted by the division to train technical personnel and support new entrepreneurial start-ups. Recognizing the significant role of textile materials in the medical technology field, the Centre has worked closely with market manufacturers, adding value at every stage by collaborating to solve complex problems. The world-class machinery installed at SITRA supports new entrepreneurs in incubating their business ideas and eventually establishing successful business models. Some of the machines available in the incubation centre are: Compression Stocking Knitting machine, Cartesian braiding machine, Sanitary napkin machine, wet wipe making machine, face mask production unit, coating and lamination machine, cotton wool roll making machine, ultrasonic welding machine, surgical gown/drape making setup.

Research on Medical Textiles:

COE Medical Textiles division undertakes projects to develop innovative products and instruments that are indigenously available at low cost for the industry and market. Some of the notable products developed by the division include:

1. Bifurcated Vascular Graft for replacing damaged blood vessels
2. 3D compression bandages for Lymphedema treatment
3. Spun-lace nonwoven wound dressings for malodorous infected wounds
4. Breathable Surgical gowns treated with Nano Finishes
5. Barbed bi-directional surgical sutures for knotless operation procedures
6. Hospital bed linens with enhanced thermal properties for coma patients
7. Chitosan coated cotton gauze for improved wound healing
8. Rotator cuff repair devices
9. Collagen coated Hernia Mesh for improved biocompatibility
10. Insole line for diabetic shoes
11. Cut resistant fabrics for producing garments and gloves
12. Breathable Viral Barrier Film for surgical gowns and coveralls
13. Transdermal Patches for controlled drug release
14. Natural polymer-based Nano-membranes for treating burn wounds
15. Haemostatic sponges for treating gunshot wounds
16. Embroidery-based wound care products for inducing angiogenesis
17. Leukodepletion Blood Filter for removing leukocytes from blood
18. Heat and Moisture Exchange (HME) Filter for ICU breathing circuits
19. Anterior Cruciate Ligament (ACL)
20. Clinical Heart patch fabrics
21. Evaluation of comfort index for surgical gowns

The division's work covers a wide range of medical applications, from wound care and surgical solutions to implantable devices and protective clothing.

SITRA has developed the following instruments for testing as per national and international standards:

1. Synthetic Blood Penetration Resistance Tester
2. Bacterial Filtration Efficiency Tester
3. Compression Bandage Pressure Measurement System
4. Equipment for producing knotless incision closure
5. Particulate Filtration Efficiency Tester
6. Advanced Splash Resistance Tester
7. Fluid Handling Capacity Tester
8. Puncture Resistance Tester
9. Wet Bacterial Penetration Resistance Tester
10. Dry Bacterial Penetration Resistance Tester

Participants interacting during the Entrepreneurship Development Programme on Medical textiles at the CoE Incubation Centre

Training Programs:

The division has successfully conducted numerous techno-commercial programs, training over 7,500 individuals and providing valuable support to new entrepreneurial start-ups. To date, SITRA has organized more than 260 training programs specifically designed for aspiring entrepreneurs looking to venture into the medical textiles industry. These programs have been conducted across various states, including Kerala, Andhra Pradesh, Maharashtra, Telangana, Karnataka, and Tamil Nadu.

The training initiatives have empowered new start-ups to launch full-scale business ventures producing medical textile products. Some of the key programs offered include:

1. Entrepreneurship Development Programme
2. Techno-commercial training for start-ups
3. Characterisation of Medical Textile Products
4. Preparation of Detailed Project Reports (DPR)
5. Diversification of products
6. Internship/Project/One Credit Course (for academicians)

These programs demonstrate SITRA's commitment to fostering innovation, entrepreneurship, and skill development in the medical textiles sector.

SITRA's international training programs have been a regular feature since 1974, benefiting over 1,800 professionals from 72 countries. These programs are sponsored by the Ministry of External Affairs, Government of India, under the Indian Technical and Economic Cooperation (ITEC) plan.

Testing Services offered by SITRA

SITRA's in-house developed Advanced Splash Resistance Tester for Face masks

Way forward:

The Centre has served as a backbone for many businesses in the Medical Textiles market by providing technical assistance to many domestic and international manufacturers right from concept to product. In the long term, SITRA aims to establish itself as a global leader in medical textiles, recognized for its expertise and innovation. The organization envisions creating a self-sustaining ecosystem of medical textile manufacturers, startups, and research institutions that drive growth and innovation in the sector. By collaborating with government agencies, SITRA will help shape policies and regulatory frameworks that support the industry's development in India. Furthermore, the organization will prioritize sustainability, environmental responsibility, and social impact in the development and production of medical textiles, ensuring a positive and lasting influence on society.

MDR Laboratories Pvt Ltd
committed to scientific & service excellence

Testing and validation facility - MDR Laboratories

Dr. T. S. Kumaravel, MD, PhD, DABT, FRCPath (American Board Certified and UK/EU Registered Toxicologist Chairman)

Dr. S S Murugan, PhD (Safety ToxicologistManaging Director)

MDR Laboratories Pvt Ltd offers cost effective and high-quality biocompatibility (ISO 10993) solutions for medical devices. We are an OECD GLP-certified and ISO/IEC 17025 accredited test facility. We currently work with medical device manufacturers in more than 60 countries and our reports are readily accepted for CE marking by notified bodies, and global regulators. MDR Laboratories is proud to have received the CDSCO FORM MD-40 [See sub-rule (3) of rule 83] - Certificate of registration as a Medical Device Testing Laboratory.

Our comprehensive services include a range of Biocompatibility Studies, covering critical testing areas such as cytotoxicity, sensitization, genotoxicity, implantation, and hemocompatibility, all adhering to ISO 10993 standards. MDR Laboratories also provides in-depth Chemical Studies, including chemical characterization, extractables and leachables analysis, and toxicological risk assessments. In addition, our Regulatory Toxicology Services encompass the development of biological evaluation plans, toxicology risk assessments, and biological evaluation reports. Each service is meticulously designed to meet stringent global regulatory requirements, ensuring medical devices are safe, effective, and compliant with standards set by regulatory authorities worldwide.

The basic strategy for testing of any medical device is as follows:

1. Biological Evaluation Plan
2. Identify relevant test requirements depending on which geographical market the device is intended to be marketed.
3. Chemical Characterization
4. Toxicological Risk Assessments
5. Biocompatibility testing:
   - In vitro
   - In Vivo: -
     - Short term
     - Long term
     - Specialised testing: such as implantation and hemocompatibility
6. Combining all the above results and write Biological Evaluation Report, which is a regulatory document to submit to regulatory agencies.

were the first in India to establish a dedicated regulatory toxicology team to better understand device-specific requirements and tailor biocompatibility testing accordingly. In fact, we were pioneers in launching a Contract Research Organization (CRO) in India focused exclusively on biocompatibility testing. We also led the way in introducing chemical characterization of medical devices in 2017 and were the first to initiate toxicological risk assessments in the country. Our multidisciplinary team includes medical doctors, veterinarians, pharmacists, biochemists, and biotechnologists.

We take pride in several key milestones and one of it is, active provider of training in biocompatibility to medical device companies, regulatory bodies, and notified bodies both in India and internationally.

With these resources, MDR Laboratories not only guides clients on implementing effective biocompatibility programs but also develops strategies for high-risk devices and provides troubleshooting for unexpected findings.

Startup & Innovation -Indian Institutes of Technology (IIT) Chennai

Prof. R. Krishna Kumar
Institute Professor

Medical Device Development at the Indian Institute of Technology Madras – New Initiatives

Indian Institute of Technology Madras

India is on the cusp of a new epoch in the medical device industry. Many recent studies have indicated that the market can be USD 30 billion by 2025. Though 80% of the products are imported, a floodgate of startups and many established companies sprucing up their research, this quantum is bound to come down. To aid the rapid development of the industry, leading technological institutes such as IIT Kanpur, IIT Kharagpur, IISc Bangalore and IIT Madras have started medical – engineering education programs.

Recognising that technology and basic sciences are the pillars of modern medical research, the Indian Institute of Technology Madras (IITM) established a biomedical engineering division in 1959. The division was nurtured by stalwarts like Dr Valiathan and Prof. T.M. Srinivasan. Today the Institute has a vibrant biomedical program, with several departments adopting and modifying the program to render different perspectives.

Today, IITM is well-poised to redefine biomedical device development and design through an innovative medical education program. The new department at IIT Madras, Medical Sciences and Technology, will seamlessly integrate medicine and engineering. The department will offer two crucial programs to produce leaders in the device development field. The first is to provide MS (by research) and PhD for clinicians. Many innovations in the past have come from clinicians, and this program will aid them in acquiring skills for realising their product vision and help them prototype and test it clinically. In a novel approach, the department will offer a twin PhD program to encourage device development. The clinician with an innovative idea registering for a doctorate will be coupled with an engineering PhD student, who will work out the engineering aspect through simulation and bench tests. The doctor's role is to work out a framework for converting an idea into a realisable product from a system perspective. The clinician will later conduct trials to prepare the product for the market. The department will also offer an entrepreneurial doctorate to the clinicians, a novel program in which doctors can develop a product and the IIT system will encourage and guide them to have a startup.

Biomedical engineering, the bridge that connects medicine and engineering, usually has no traffic; scholars rarely walk across the bridge. Recognising this lacuna, the department will introduce a BS in Medical Sciences and Engineering. The course will expose a student to the science of the human body and relevant engineering subjects. The subjects will be taught by engineering and medical faculty, along with exposure to treatment and diagnostics. Practical experience will be imparted by hospital exposure. The department will have some of the leading clinicians in the city as professors of practice. Contrary to the established biomedical education, the curriculum will cover organ-specific device development such as cardiac, nephrology, neurology etc. Hospital experience will also cover modern surgical procedures, a skill set necessary for innovation.

In sum, the Indian Institute of Technology Madras is poised to change the canvass for device development. With its programs, IITM will bring clinicians and engineers under one roof and provide all the tools required for device development. A seed money of Rs 15 crores to the institutes that have started medical education will be a great fillip for graduating to a higher plane

After all, innovation is the result of knowledge.

INDUSTRY EXPERTS

Dr.A.Muruganandam
MD & CSO

Affigenix Biosolutions Pvt. Ltd., part of the CREW Group, is a leading life sciences company providing customized diagnostic solutions to the Diagnostics, Biopharma, and Biotech sectors. Founded in 2012, Affigenix has developed 62 CDSCO-approved IVD kits since 2020, addressing diseases such as cancer and infectious conditions. The company operates a NABL-accredited, ISO-certified R&D center in Bangalore and a 10,000 sq. ft. ISO 13485-certified manufacturing facility in Chennai. Serving both Indian and international markets, Affigenix is trusted by government and private hospitals, laboratories, and research institutions. Backed by DBT-BIRAC and pother grants, it is actively advancing "Make in India" and next-generation diagnostics.

Amrith Rangan - CEO

AKAS Infusions specializes in infusion systems and patient temperature management products, including syringe pumps, infusion pumps, and blood & fluid warmers. Established in 1997, AKAS has over 25 years of experience in the medical device industry. The company is committed to innovating healthcare solutions that prioritize patient safety and precision. AKAS aims to be a global leader in infusion technology. Its products comply with international quality standards, holding certifications such as ISO 13485:2016 and CE marking under MDD regulations, with MDR compliance currently underway.

ATMED

Thangiah Immanuel
MD

Cephas Medical Pvt Ltd is a renowned medical devices manufacturing company with a legacy spanning over 24 years, since its inception in 2001. We specialize in manufacturing a diverse range of products, including Self-adhesive Male External Catheters (Silicone & Latex) for Urology, Amnicot for Gynecology, Medical Plastic Injection Molded components, Re-breathing bags, and Specialty dipped products in silicone and other polymers. Our commitment to quality is reflected in our esteemed certifications, including ISO 13485, CE, UKCA, and USFDA. With a global presence, we export our products worldwide, driven by a vision to be a people-first brand earning global trust. Our mission focuses on creating lasting customer value, driving excellence, and promoting sustainability with a global mindset, while continuously innovating and delivering customized medical manufacturing solutions.

Mr. Suresh Rajan
Founder & Chairman

Cistron Systems Private Limited, founded in 1993, excels in providing CSSD products (Sterilizers), Infection control consultation, critical care equipments, and Medical Gas Pipeline Systems (MGPS). With a certified manufacturing unit in Chennai and ISO 9001, 13485, 45001, BIS, and QCI standards, the company ensures quality and safety. The expert team offers complete hospital consultation and turnkey solutions. A nationwide sales and servicing network team provides customer support to Healthcare. With three decades of experience and innovation, Cistron Systems remains a trusted name in the healthcare industry, enhancing lives through reliable solutions and unwavering dedication to excellence.

Elango Devy
Managing Director

Diabetik Foot Care India is a manufacturer and distributor of medical devices for the management of diabetic foot complications, with a presence in over 25 countries since its incorporation in 2005. We specialize in diabetic foot management, offering innovative products for screening vascular complications, neuropathy, and plantar foot pressure mapping, including an all-in-one automated device that enables clinicians to measure all complications efficiently. Our mission is to provide quality medical devices at an affordable cost with care, and our vision is to enhance the quality of life for people with diabetes through early detection and management of foot complications. Our CDSCO-licensed manufacturing site is equipped with innovative test and quality equipment.

For more information, visit www.diabetikfootcareindia.com.

Jagan Somasundaram S
Managing Director

FederFlex, a brand of ALTDC CLOTHING PRIVATE LIMITED, is based in Coimbatore and specializes in the manufacturing of Graduated Medical Compression Stockings. Established in 2022, we combine advanced technologies and premium raw materials sourced globally to produce compression Stockings that meet international standards. Our product range includes Class 1, 2, and 3 Medical Compression Stockings, DVT stockings, compression calf sleeves, and lymphedema arm sleeves. Currently serving hospitals across Tamil Nadu, our short-term goal is to expand pan-India.

FederFlex is an ISO 13485-certified company, committed to delivering clinically effective and high-quality compression Products.

Samuel George
CEO

GESCO is a 60-year-old leader in Spinal , Neuro and Orthopedic implants that enhances lives globally with innovative, cost-effective technologies. ISO 13485 certified and USFDA inspected, our facilities ensure top regulatory compliance. We've secured international patents, including in the US, Japan, and Europe, becoming the first Indian orthopedic implant manufacturer to achieve this. Leading in innovation and R&D, we pioneered ceramic 3D printing in India and metal 3D printing for spine and Orthopedic applications. Gesco has an in house Forging facility. Vision – Transforming Lives Every day

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Dr. M. Dhanasekaran
Director Technical
& Admin

We're a pioneering diagnostics company with 17 years of market presence, specializing in the design, development, and manufacturing of In-Vitro Diagnostics (IVD) kits and analyzers. With an in-house R&D team that has consistently delivered innovative and cost-effective IVD assays, we made a significant impact during the Covid pandemic with our pioneering testing kits. Our product portfolio includes a wide range of IVD medical devices such as clinical chemistry, serology, blood grouping, lateral flow rapid assay, ELISA, CLIA, FIA, and IVD instruments. Our mission is to be the most respected company in the industry by continuously setting high standards in all aspects of manufacture and marketing. Our state-of-the-art IVD facility, spread across 2.4 acres at SIPCOT Medical Device Park in Oragadam, Tamil Nadu, adheres to international standards, ensuring the highest quality products for our customers.

Ritesh Hebbar
Partner - Noble

At Hebbar Surgical Instruments, an ISO, CE, and ISO 13485 certified manufacturer of the Hebson range, we are dedicated to serving surgeons with the highest quality surgical instruments crafted from the finest materials, leveraging our over 50 years of experience, professional knowledge, expert skill, production capability, and innovative spirit to maintain a leadership role in delivering value-for-money products backed by excellent after-sales service, with capabilities that include customizing and modifying instruments to fit individual needs, as well as developing new products in collaboration with surgeons and healthcare professionals, and we manufacture surgical instruments for General Surgery, Gastrointestinal and Bariatric Surgery, Urology, Obstetrics and Gynaecology, Cardio-Thoracic and Vascular Surgery, Neuro Surgery, Spine Surgery, Orthopaedics, Plastic and Reconstructive Surgery, and ENT Surgeries, proud to continue the tradition of quality and trust.

ATMED

Chinnasamy
CEO

HMS Medical Systems, established in 1994, is a leading Indian manufacturer specializing in physiotherapy and rehabilitation devices, including electrotherapy, ultrasound, traction, TECAR, shockwave, and combination therapy systems. With nearly three decades of market presence, HMS has built a reputation for delivering clinically effective, affordable, and high-quality solutions tailored for hospitals and clinics. Through continuous in-house R&D and innovation, the company integrates smart features and user-friendly designs that meet evolving clinical needs. Guided by a mission to make world-class therapeutic technology accessible and patient-focused, HMS operates a state-of-the-art manufacturing facility in Chennai, equipped for both prototyping and large-scale production. Certified with ISO 13485, its products are designed in compliance with global standards.

Harish Rajendra
Managing Director

Medevis Rubplast India Pvt Ltd specializes in urological catheters and a wide range of allied surgical disposable products. With over 10 years of market presence, the company has achieved significant technological growth through continuous product innovation focused on patient safety and infection control. Our mission is to offer affordable, reliable, and globally compliant medical solutions that enhance healthcare outcomes. Medevis operates advanced manufacturing facilities with Class 10,000 cleanroom environments and specializes in latex, silicone and soon will be also into plastic processing. We hold ISO 13485 & GMP certification with select products aiming towards EU-MDR and US-FDA standards, enabling us to serve both domestic and international markets with confidence

Jayasing Morris
Director

Morrisons specializes in sterile single-use medical devices including infusion therapy, urology, respiratory care, general, and laparoscopic surgery products. With over 15 years of market presence, we've achieved significant technological growth through product innovation and advanced R&D. Our mission is to deliver safe, affordable, and high-quality healthcare solutions globally. Equipped with state-of-the-art, ISO-certified manufacturing facilities, we ensure precision, scalability, and compliance. We hold global certifications including ISO 13485 and CE under EU-MDR. Our commitment to quality and innovation positions us as a trusted partner in global healthcare.

Nandakumar S
CEO

Perfint Healthcare, with 20 years of global presence, specializes in image-guided interventional solutions, particularly in oncology and neurosurgery. Its key products—MAXIO, ROBIO, NAVIOS, and DISHA X—reflect continuous innovation in stereotactic planning and navigation technologies.

Mission: Together with Physicians, improve quality of life of those fighting Cancer and Pain.

Vision: Bring innovative advances to the field of Image Guided Therapies. Perfint is certified for R&D activities with DSIR certification.

Perfint's manufacturing facilities are ISO 13485:2016-certified and support end-to-end production, including design, assembly, calibration, inspection, and final testing. The infrastructure includes clean environments and controlled conditions for labelling, packaging, and delivery.

It holds global certifications including US FDA, EU MDR, Health Canada, India IMDR, China NMPA, and Russia GOST-R, ensuring compliance, quality, and ethical practices across all operations.

S Murali Director
CEO

We St Johns First Aid Kits Pvt Ltd one of the leading First Aid Kits, Sterile Surgical Dressing, Postmortem Kits, Cadavar Bag manufacturer in India for last 16 Years. Proud to say that all the components are "Made in India" out of this most of the components we make our own which ensure the Quality, Pricing and Committed Delivery. Owned a world class facility with ISO 9001:2015, EN ISO 13485:2016 certified Company with ZED Gold certification. www.stjohnsfirstaid.net

Naveed
Director

SynerHeal is a pioneering health organization dedicated to designing, developing, and delivering result-oriented advanced wound solutions, leveraging nanotechnology-based collagen wound healing innovations. Founded by a team of passionate experts, our solutions have been proven to reduce healing time by over 50% compared to other wound healing products, while also lowering overall costs by 40%. As an India-based organization with a global vision, we specialize in creating effective collagen-based products for Wound Care and Dental Implants, focusing on faster healing, better patient outcomes, quality, and patient satisfaction. Our innovative collagen-based dressings are revolutionizing healthcare, and we're committed to innovating affordable solutions that make a difference in patients' lives worldwide.

Vignesh Nagarajan
Founder and CEO
at VRP Medgands

VRP Medgands Pvt. Ltd. is a Chennai-based medical device manufacturer with over 2 years of expertise in ICU and OT equipment, specializing in blood and infusion warmers (Warmline®100), Patient Monitor. Backed by strong in-house R&D, the company focuses on innovative, affordable, and clinically effective solutions tailored for Indian and global healthcare needs. With a mission to enhance critical care outcomes and a vision to become a global leader in patient care technology, VRP Medgands operates a state-of-the-art manufacturing facility compliant with ISO 13485:2016 standards. The company is a CDSCO licensed manufacturer and is actively pursuing international certifications like EU-MDR and US-FDA to expand its global footprint.

ATMED ACTIVITIES : HIGHLIGHTS

ATMED stall at IMDI Conference.

The medical device industry in Tamil Nadu witnessed a significant milestone as the Association of Tamil Nadu Medical Device Industry (ATMED) was officially inaugurated on August 26, 2023, during the IMDI 21st National Conference held in Chennai.

Parliamentary Standing Committee meeting at ITC Grand Chola

Stakeholders Coordination meeting with Commissioner - Thiru.R. Lalvena, I.A.S. (Director of Drugs Control TamilNadu)

Meeting with Smt. G. Bhavani, Scientist F/ Senior Director and Head Chennai Branch Office at Bureau of Indian Standards for an engaging and fruitful discussion on the future of India's medical device standards and testing ecosystem.

Meeting with Dr. Sasikala, Professor and Head of the Department of Biomedical Engineering at Anna University and CEO of CCTME for a powerful academic-industry partnership.

Collaboration in action! Co-ordination meeting with Dr. Aravind Chand, Chief Operating Officer, SIPCOT Medical Devices Park, Thiru. N. Ananda Gopalan, Assistant Engineer SIPCOT Oragadam and Thiru Uthamacholan R - Associate Vice President,Guidance Tamil Nadu, Thiru Jothi Narayanan - Senior Manager,Guidance Tamil Nadu.

Courtesy Visit Submission of Representation to Thiru M.N Sridhar (Director of Drug Controller of Tamil Nadu).

Association of Tamil Nadu Medical Devices Industry (ATMED)

www.atmedindia.com

I am pleased to extend this invitation to join as a member of the Association of Tamil Nadu Medical Device Manufacturers (ATMED). Established with the aim to provide comprehensive support to medical device professionals and industrialists in Tamil Nadu, ATMED endeavors to address the challenges faced by the industry and facilitate opportunities for growth and development.

ATMED membership offers numerous benefits including, but not limited to, networking opportunities, interactive sessions and coordination meetings with regulatory, licensing, and statutory authorities, regular updates on new medical device regulation guidelines, Access to seminars conducted by industry experts, special discounts on events, programs, and exhibitions, advertising opportunities, a job recruitment fair for industry, the opportunity to connect with B2B customers, access guidance for business growth, and resolving grievances and challenges addressed by the concerned authorities.

I encourage you to consider the benefits of becoming a member of ATMED and look forward to the prospect of your participation.

For further details, please feel free to Contact Us.
T. Jayasing
Coordinator (ATMED) M. 9677010126

M. : 9444080126 • email@atmedindia.com • www.atmedindia.com

Who Can Become a Member?

Primary Member
- Manufacturer of Medical Devices
- Manufacturer of IVD products
- Manufacturer of Medical Equipment
- Manufacturer of healthcare products

Affiliate Member
- Regulatory/statutory organizations
- Other related Associations
- Industrial Development organizations
- Industrial Funding organizations

Associate Member
- Technology Providers
- Product Testing Labs
- Raw materials
- Clean room Equipment providers
- Medical Machinery suppliers
- Healthcare Institutions
- QMS/regulatory consultants
- Certification assessment bodies

Others
- Student (Medtech Industry)
- Startups (Medtech Industry)

Scan the QR code and become a member

Materiovigilance in India: Strengthening Safety Surveillance for Medical Devices

Dr. Shatrunajay Shukla,
Indian Pharmacopoeia Commission,
Ministry of Health & Family Welfare, Government of India

Pioneering a culture of proactive monitoring and risk mitigation in medical devices.

"A faulty device doesn't just fail. it can compromise lives. Materiovigilance is our safety net."

Abstract

The rapid growth of the medical device sector in India demands an equally robust system to ensure device safety and protect patient wellbeing. Materiovigilance, the systematic monitoring of adverse events related to medical devices, emerges as a critical pillar in this endeavour. This article explores India's evolving materiovigilance landscape, highlighting the establishment of the Materiovigilance Programme of India (MvPI) as a proactive safety surveillance mechanism. Through coordinated efforts involving healthcare professionals, manufacturers, regulators, and patients, MvPI fosters timely detection, reporting, and mitigation of device-related risks. Leveraging digital reporting tools, strategic training, and regulatory oversight under the Medical Devices Rules, 2017, India aims to build a culture of vigilance and accountability. The programme not only safeguards public health but also supports domestic innovation and aligns with the broader vision of self-reliance under Atmanirbhar Bharat. This review underscores the importance of sustained collaboration, awareness, and technological advancement to transform materiovigilance into a cornerstone of patient safety and healthcare quality across India.

Need for a Safety Surveillance System

In today's rapidly evolving healthcare landscape, medical devices from simple wound dressings and medical gloves to complex implantable pacemakers are central to diagnosis, treatment, and patient care. While innovation enhances performance, safety remains paramount. Unlike pharmaceuticals, adverse events from medical devices often arise from design flaws, user errors, material degradation, or manufacturing defects (Figure 1). This highlights the urgent need for a dedicated safety surveillance system, Materiovigilance to monitor, assess, and mitigate such risks.

Materiovigilance aims to identify and address adverse events, malfunctions, or safety concerns early on. Timely action not only enhances patient safety but also helps maintain public trust in healthcare systems. Post-market surveillance is a critical component of medical device regulation. Even after thorough pre-market evaluation, certain issues may only surface during actual use. Materiovigilance provides a structured approach to monitor devices once they reach the market. By collecting and analyzing data on adverse events, malfunctions, and related trends, this system helps identify emerging safety signals. Ongoing surveillance enables timely interventions such as product recalls, label changes, or corrective actions. Materiovigilance also promote continuous improvement in medical devices by identifying opportunities to enhance design, manufacturing, and user education. Surveillance data helps stakeholders detect and correct common flaws, improving device safety, usability, and effectiveness. It also ensures transparency and accountability by enabling reporting from healthcare professionals, patients, and manufacturers. It supports research and development by identifying trends and guiding regulatory decisions.

Regulatory authorities mandate that manufacturers, importers, and stakeholders report adverse events linked to their medical devices. Materiovigilance programmes support this by providing a structured framework for documenting and analyzing such events. This ensures that essential data is collected, assessed, and communicated to regulators, enabling informed decisions on device safety and oversight.

Figure:1 Reports of suspected adverse events related to medical devices featured in mainstream media coverage

Overview of the Materiovigilance Programme of India (MvPI)

Ensuring patient safety and enhancing the quality of healthcare delivery are fundamentally dependent on the robust monitoring of adverse events associated with the use of medical products, including drugs, medical devices, and vaccines. Without a comprehensive system in place to detect, report, and address these adverse events, patient outcomes and public health can be severely compromised. Therefore, it is imperative to implement a systematic surveillance mechanism capable of identifying potential risks and facilitating timely interventions to mitigate harm.

In alignment with this vision and with the overarching goal of improving the quality and safety of medical products available in India, the Government of India under the leadership of Prime Minister Shri Narendra Modi, launched the Materiovigilance Programme of India (MvPI) in 2015. This was a landmark initiative, as India previously lacked a structured programme focused on monitoring the safety and performance of medical devices including in-vitro diagnostics and their associated adverse events.

To implement MvPI at the national level, the Indian Pharmacopoeia Commission (IPC) was entrusted with the responsibility of operationalizing the programme across the country. Since 2018, IPC has been working diligently to fulfil the programme's objectives through a multi-pronged approach, including:

- Systematic data collection on adverse events associated with medical devices including in-vitro diagnostics used in India.
- Capacity building by conducting training sessions and providing technical guidance to healthcare professionals, manufacturers, and other stakeholders.
- Development of user-friendly tools to support reporting by license holders, consumers, and healthcare providers.
- Providing evidence-based recommendations to the national regulatory authority i.e. CDSCO for informed decision-making and policy interventions.

Under the active guidance of the Ministry of Health & Family Welfare, MvPI has made significant progress in strengthening India's medical device safety ecosystem. The programme has:

- Identified number of medical colleges (Govt./Pvt./NGO-supported), academic institutions and healthcare settings as Medical Device Adverse Event Monitoring Centres (MDMCs) pan India to effectively collate adverse events and impart training to peripheral healthcare settings/healthcare professionals on the materiovigilance. State-wise presence of MDMCs operational under the MvPI scheme is displayed as figure 2 and can also be assessed using following link:

  https://ipc.gov.in/images/547_MDMC_Centre_Upload_Website.pdf

- Raised awareness among healthcare professionals and the general public about the importance of reporting adverse events (https://ipc.gov.in/mandates/materiovigilance-

Figure 2: Pan India presence of monitoring centres under MvPI

programme-of-india-mvpi/mvpi-resource-material/8-category-en/637-mvpi-e-newsletters.html).

- Equipped stakeholders with digital tools and platforms for effective and accessible communication (Tools developed under MvPI can be assessed using following link: https://ipc.gov.in/mandates/materiovigilance-programme-of-india-mvpi/mvpi-toolkit.html). Also refer to Annexure -1.
- Built a substantial national database of adverse events linked to medical devices.
- Enabled the Central Drugs Standard Control Organisation (CDSCO) to make timely, evidence-based regulatory decisions to safeguard public health.

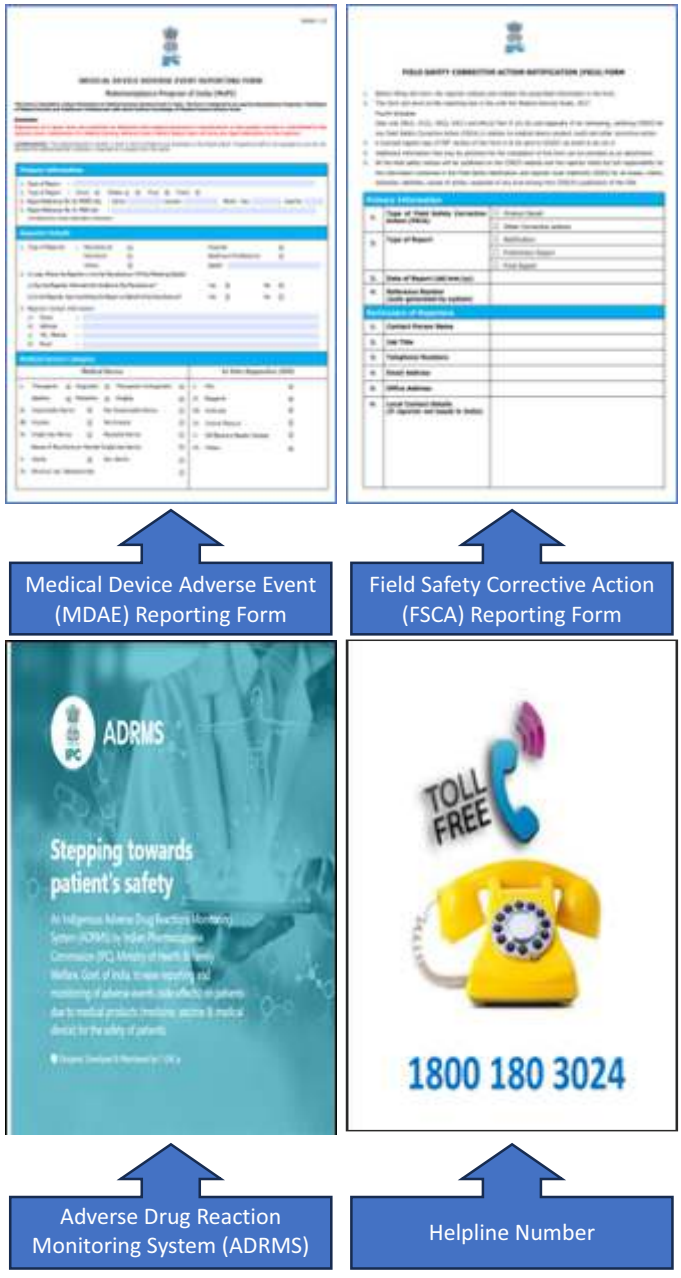
Beneficiaries:

- Central Drugs Standard Control Organization (CDSCO) as National Regulatory Authority - MvPI supports the CDSCO by providing scientific and technical insights that inform regulatory policies, guidelines, and enforcement actions.
- Manufacturers/Importers/Distributors of Medical Device: MvPI helps medical device manufacturers, importers and distributors in product improvement, risk management by providing real word device performance data and regulatory compliance by providing a structured way to report medical device adverse events. MvPI also helps them in building trust with healthcare professionals, hospitals and regulatory bodies.
- Healthcare Settings (Hospitals/Clinical Establishments): MvPI disseminate safety-related information to all relevant stakeholders, including healthcare professionals, and the public, with the aim of minimizing potential risks and improving safe usage practices. MvPI safety alerts and advisories help clinicians make better informed decisions by being aware of device-related safety issues. Based on the MvPI inputs, they can take corrective or preventive actions faster to protect the public health.
- Public Health: MvPI helps the general public by ensuring that medical devices used in hospitals, clinics, and at home are safe, effective, and reliable.
- MvPI enables IPC to evolve into a national centre of excellence for materiovigilance, serving as a reference point for best practices, research, and policy development in medical device safety monitoring. This scheme also foster collaboration with national and international healthcare organizations, enabling the exchange of safety data, harmonization of monitoring practices, and advancement of data-driven decision-making in the medical device sector.

Through these multifaceted objectives, MvPI not only strengthens India's medical device safety infrastructure but also contributes to Government's efforts in advancing patient safety and healthcare quality. MvPI also plays a pivotal role in advancing the goals of the Atmanirbhar Bharat Abhiyan by generating robust safety data on medical devices based specifically on the Indian population. This population-specific data is essential in multiple ways:

- It enhances the safety and performance monitoring of medical devices within real-world Indian healthcare settings.
- It supports the domestic manufacturing sector by providing critical safety data that enable manufacturers to produce high-quality, safe, and effective devices tailored to Indian needs.
- It contributes to the strengthening of India's regulatory framework by supplying evidence-based information that informs policy, standards, and compliance requirements.
- Moreover, it promotes innovation and research & development (R&D) by offering valuable local data that can guide the design, testing, and refinement of new medical technologies.

Through these efforts, MvPI not only ensures patient safety but also empowers India to build a self-reliant, globally competitive medical device ecosystem, aligned with the broader vision of Atmanirbhar Bharat.



1. **MDAE Reporting Form**
   Editable versions available in **English and Hindi**
   For use by **License Holders, Healthcare Professionals (HCPs) & Consumers/Users**
2. **ADRMS (Adverse Drug Reaction Monitoring System)**
   An indigenous, centralized software platform developed by IPC to facilitate **paperless, efficient, and standardized reporting** of adverse events related to medical devices, medicines, and vaccines.
   • Access ADRMS (Indian Pharmacopoeia Commission, n.d.)
3. **MvPI Helpline**
   • **1800 180 3024** (Toll-Free)
   • **Available: 9:00 AM – 5:30 PM,** Monday to Friday
   For guidance and assistance in reporting adverse events.

Innovation For Medical Plastics Injection Molding

Keyur Parikh
Founder, Engistart Consulting,
Ahmedabad

Latest Innovations in Medical Injection Molding

Revolutionizing Medical plastics with Precision, Safety, and Speed

The medical device industry demands precision, safety, and reliability, Injection molding continues to rise to the challenge. With rapid advancements in technology, today's medical injection molding processes are more intelligent, efficient, and capable than ever before. Here's a closer look at some of the most exciting innovations shaping the future of this vital field. This process helps doctors, hospitals, and patients by creating high-quality medical devices parts at a large scale and at an effective cost. From syringes to complex surgical tools, injection molding is changing how we make healthcare products bringing more precision, better safety, and faster production. Injection molding is a manufacturing process that creates plastic parts by injecting melted plastic into a mold. Once the plastic cools and hardens, it takes the shape of the mold. These parts must be made with medical-grade plastics that are safe to use as per manufacturer guideline & instructions. In healthcare, this advance process is used to make some of the parts like:

- IV components
- Surgical instruments
- Catheters parts
- Diagnostic devices etc.

The world of medical injection molding is advancing fast. New technologies and ideas are making it better and more efficient. Let's look at some of the key innovations:

Smart Machines and Automation

Today's molding machines are getting "smarter." They use high-tech sensors and artificial intelligence (AI) to check and control the process in real-time. This helps:

- Detect problems quickly
- Reduce waste
- Improve product quality
- Speed up production

Also, next gen robots are now used for packing, assembling, and checking the parts after molding. This reduces human error and improves safety.

Why is it So Important in Healthcare?

Injection molding is used in healthcare for many good reasons:

- **High precision:** It makes very accurate parts, which is important for parts that use for medical devices.
- **Mass production:** It can make thousands - even millions - of the same part quickly.
- **Cost-effective:** It reduces cost by using automation and producing at high volumes.
- **Safe and clean:** The process can be done in cleanrooms to prevent contamination.

Among the many processes in injection molding today, insert & thin wall molding is playing a key role in manufacturing medical plastic parts with precision and reliability.

Insert Molding with Robotics in Medical Injection Molding:

Insert molding, combined with robotics automation, is widely used in medical devices plastics parts manufacturing to encapsulate metal or electronic components within plastic in a single, seamless process. Robots precisely place inserts, such as sensors or threaded metal parts into the mold before injection, ensuring high repeatability.

Thin-Wall Molding: Clear, Clean, and Cutting-Edge: The Rise of Thin-Wall Injection Molding in Medical Plastics

In modern healthcare and laboratory settings, there's a growing

Keyur Parikh *is a seasoned Entrepreneur, with over 25+ years of experience in leading Manufacturing projects across diverse industries such as medical devices, pharmaceutical packaging, wellness product rigid packaging, FMCG and engineering. His expertise in leading projects, team building, strategic thinking, product development, automation, digital transformation and driving continuous improvement through Operation Excellence. He is actively engaged in academia, mentoring aspiring professionals and supporting their development into future industry leaders.*

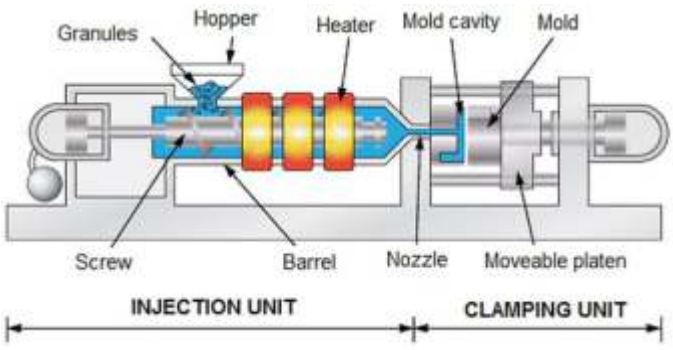
Services:
Manufacturing Project Development, Clean Room Projects for Medical Devices & Pharmaceutical Industries, Product Development, Plastics Moulding & Mould Expertise, Operational Excellence - Lean Management, Training on Team building & Leadership

demand for devices and consumables that are precise, lightweight, transparent, and sustainable. One powerful technology driving this shift is thin-wall injection molding, an innovation that's reshaping how medical and lab plastic components are made.

This process allows the production of parts with ultra-thin walls, often using optimum plastic while maintaining high strength, clarity, and dimensional accuracy.

When it comes to medical tools and devices, thin walls mean:

- Lighter and more comfortable items for patients to use or wear
- Faster production so hospitals and labs can get supplies quickly
- Less plastic waste, which is better for the environment
- More space inside devices for sensors or electronics



Sustainable Manufacturing:

Sustainability is now a big focus in manufacturing including in medical plastics. Many companies are:

- Installing **energy-saving machines – All-electric Injection molding machines**

All-electric injection molding machines play a key role in sustainability by consuming significantly less energy than traditional hydraulic machines. They offer higher precision, reduced cycle times, and lower noise levels, making them ideal for cleanroom environments in medical device manufacturing.

- Designing products that create less waste – **Hot Runner Technology**

Hot runner injections mold/technologies help reduce plastic waste by eliminating the need for runners, which are usually discarded in cold runner systems. This not only minimizes material waste but also improves production efficiency and part quality. Together, these technologies support greener, more cost-effective and resource-efficient injection molding processes.

By thinking about the environment, the industry is helping both people and the planet.

Faster Time-to-Market

In healthcare, getting products to the market quickly can save lives. Thanks to new software and design tools, manufacturers can now:

- Create molds faster
- Test designs digitally (before making real parts)
- Produce prototypes in days, not weeks or months

This speeds up the process from idea to final product, which is especially helpful in emergencies or during disease outbreaks. As healthcare becomes more personalized, the demand for custom medical parts is growing.

Challenges and Solutions

Of course, there are challenges in medical plastics injection molding too. These include:

- Regulatory requirements
- Cleanroom requirements
- High precision tooling & costs
- Skilled Manpower

To handle these, companies are investing in:

- High-tech machines
- Cleanroom facilities
- Digital tracking systems for quality control
- Better training for people working

The Future of Medical Plastics Molding

Looking ahead, the role of injection molding in healthcare will grow stronger. Here's what we can expect:

- **More use of smart machines and real-time monitoring**
- **Greater use of sustainable materials**
- **Better designs with fewer parts**
- **Increased use of automation and robotics**
- **Stronger global supply chains**

By keeping up with technology and focusing on patient needs, this field will continue to improve healthcare around the world. Medical plastics injection molding is more than just a way to make parts; it's a key driver of innovation in healthcare. It helps deliver safer, smarter and more affordable medical devices to people who need them. As technology and materials continue to improve, and as the healthcare industry grows, injection molding will play an even bigger role in shaping the future of medical devices.

Global Medical Devices Outsourcing Market

Medical device outsourcing is contracting out the process of developing medical devices, manufacturing, and other associated processes to external organizations. It helps medical device companies enhance efficiency, reduce cost, and leverage specialist expertise in different stages of the product life cycle.

Key Insights

- As per the analysis shared by our "facts & Factors" research analyst, the global medical devices outsourcing market size is estimated to grow annually at a CAGR of around 11.14% over the forecast period (2024-2032).
- In terms of revenue, the global medical devices outsourcing market size was valued at around USD 128.95 billion in 2023 and is projected to reach USD 300.09 billion by 2032.
- Growing difficulties in manufacturing engineered products are driving growth of global medical devices outsourcing market.
- Based on the services, the finished device manufacturing segment is growing at a high rate and is projected to dominate the global market.
- Based on the application, the general medical devices segment is projected to swipe the largest market share.
- Based on the device type, the class 2 devices segment is projected to witness a high CAGR during the forecast period.
- Based on the product, the finished goods segment is expected to dominate the global market.
- Based on region, North America is expected to dominate the global market during the forecast period.

Growth Drivers

Growing difficulties in manufacturing engineered products are driving the growth of the global market.

The ongoing technological advancements are making it difficult for one organization to manufacture, market, and legalize medical devices quickly. However, the presence of outsourcing companies gives access to specialized expertise that may not be available with in-house talent.

These organizations encompass all kinds of services that help medical device companies focus on their core competencies like innovation, development, and research while outsourcing non-core functions like manufacturing and logistics to service providers.

Therefore, such a landscape helps in regulatory compliance, quality, testing, and other needed processes. Therefore, all these factors lead to the growth of the global medical devices outsourcing market.

Market Segments

The global medical devices outsourcing market can be segmented into services, applications, device types, products, and regions.

On the basis of service, the market can be segmented into testing & regulatory support, assembly & packaging, finished device manufacturing, and prototype development. Finished device manufacturing accounts for the largest share of the medical devices outsourcing industry. Finish device manufacturing helps vendors cover the entire product life-cycle from start to end, including designing, prototyping, developing, production, and regulatory compliance. Outsourcing manufacturing processes helps in cost savings.

https://www.fnfresearch.com/medical-devices-outsourcing-market

DoP Modifies Guidelines On Capacity Building Scheme For Medical Devices

The Department of Pharmaceuticals (DoP) has stipulated that the financial support through the sub-scheme Capacity Building and Skill Development for Medical Devices, under the scheme strengthening of medical device industry, can be withdrawn from the universities and institutions if the admissions are less than 30% of the approved annual intake in the first academic year.

The Department has announced a few modifications to the provisions of the sub-scheme for which the operational guidelines were issued in November, 2024. The decision for modifications were taken in a Scheme Steering Committee (SSC) meeting held on April 9, 2025, said DoP.

The existing provisions were that the support will be withdrawn if the total number of students admitted in a particular academic session is less than 50% of its intake.

This provision has been revised now so that the support will be withdrawn, "If, against the annual student intake approved by DoP in its final approval letter, admissions are less than 30% of the approved annual intake in the first academic year, or less than 50% of the approved annual intake in the second or third year." The rest of the conditions for withdrawal of support, such as that the support will be pulled back if the core faculty strength is less than applicable student-teacher ratio, and delay in implementation of the programme, will remain the same.

On the provisions related to the final settlement of accounts, which stipulated that the grant paid by the DoP shall be refunded by the institution as and when the programme is discontinued midway or the detailed conditions as laid down and approved by the DoP are not followed, the modification adds that the expenditure incurred and claimed towards non-recurring expenses shall not required to be refunded.

The reimbursement provision has also been revised so that the financial support based on the number of students (Rs. 25,000 per student per month for diploma and Rs. 10,000 per student per month for certificate or skill development training programmes) will be provided on quarterly basis to the trainee institute for the number of students enrolled. Earlier, the timeline for reimbursement was not mentioned in the guideline.

When it comes to funding the institutions, the earlier provision was that the DoP will provide up to 75% of the cost of the course or Rs. 21 crore, whichever is lower, on reimbursement basis. This has been modified to state that the reimbursement will be as and when expenditure is incurred.

The financial assistance, as announced in 2024, will be provided to Central government universities/institutes for running multidisciplinary post-graduate courses in medical device with objective of building infrastructure for education and research in medical devices and developing skilled workforce adaptable to changing requirements of medical device sector.

With an aim to provide a big boost to the medical devices industry, the DoP launched the Strengthening of Medical Device Industry in November, 2024, with an outlay of Rs. 500 crore, launching new sub-schemes along with integrating the existing schemes related to the sector under the particular scheme.

This include the Capacity Building and Skill Development for Medical Devices with an outlay of Rs. 100 crore, Marginal Investment Scheme for Reducing Import Dependence for Rs. 180 crore, Common Facilities for Medical Devices Clusters for Rs. 110 crore, Medical Device Clinical Studies Support Scheme for Rs. 100 crore, and Medical Device Promotion Scheme for Rs. 10 crore.

The sub-scheme for capacity building and skill development for the medical device sector is to develop a skilled technical workforce capable of designing and developing MedTech products. The Central government will offer financial support for running various Masters' and short-term courses.

Under the sub-scheme support up to Rs. 21 crore for Masters' courses in Central government institutions; and Rs. 10,000 per candidate for short-term courses and Rs. 25,000 per candidate for diploma courses to NCVET approved institutes will be available, said DoP during the time.

https://www.pharmabiz.com/PrintArticle.aspx?aid=178409&sid=1#:~:text=The%20sub%2Dscheme%20for%20capacity,'%20and%20short%2Dterm%20courses.

Loan License Is No Longer Mandatory For Manufacturers Outsourcing Ethylene Oxide (ETO) Sterilization

A loan license is no longer mandatory for manufacturers outsourcing Ethylene Oxide (ETO) sterilization of medical devices in India. Instead, manufacturers can now utilize a third-party sterilization facility through a mutual agreement, provided the facility holds a valid license.This change, implemented by the Central Drugs Standard Control Organisation (CDSCO), allows manufacturers without in-house sterilization facilities to outsource this process without needing a loan license.

Key points about the change:

Relaxation of Loan License Requirement:

CDSCO has eased the requirement for loan licenses when outsourcing ETO sterilization.

Mutual Agreement:

Manufacturers can now enter into a mutual agreement with a third-party sterilization facility that holds a valid license.

Documentary Evidence:

The licensing authority requires evidence of the agreement and the sterilizing facility's license, along with details of the Quality Management System (QMS).

Sterilization Site on Label:

The license number of the sterilization site is also required to be mentioned on the device label.

Background:

Previously, manufacturers without in-house sterilization facilities needed a loan license (MD-6 for Class A/B or MD-10 for Class C/D) to utilize another manufacturer's premises for sterilization. The recent change simplifies this process, allowing manufacturers to focus on core competencies and potentially reducing costs associated with maintaining their own sterilization facilities.

Covestro Launches Production Of Medical-grade TPU In Asia Pacific

- **Changhua site meets international regulatory standards for global medical applications**
- **Enables faster, more flexible regional supply to meet growing demand**
- **Expands company's medical-grade TPU production beyond North America**

Covestro has launched production of its new Desmopan® Rx medical-grade Thermoplastic Polyurethane (TPU) at its Changhua site in Taiwan, which has recently been qualified for medical-grade TPU manufacturing. As Covestro's second facility worldwide—after New Martinsville in North America—qualified to produce medical-grade TPU, the Changhua site localized production of these high-standard materials in Asia Pacific, enabling more flexible and efficient regional supply to meet growing demand.

Global standards

The new Desmopan® Rx grades are engineered to meet stringent international requirements for medical applications and minimize contamination risks. The materials are verified for biocompatibility in accordance with ISO 10993 and China's YY/T 1557 standards for TPU used in infusion, transfusion and injection equipment. They are free from added plasticizers, exhibit low extractable and are compatible with multiple sterilization.

Enabling advanced healthcare solutions

The material is specifically developed for medical device components such as thin-walled flexible tubing, catheters, connectors, component housings, endoscopes, healthcare devices and wearables. Tubing made with this material can be effectively used in a wide range of clinical applications, including surgical procedures, haemodialysis, drug delivery systems and wound care.

In addition, the material is well-suited for medical nonwoven applications due to their compatibility with melt-blown processes. Nonwovens made from these grades combine functional performance with compliance to medical waste regulations, making them ideal for surgical drapes, wound dressings, gowns, sterile packaging and protective equipment.

Key material benefits include:

- Biocompatible formulation suitable for direct patient contact applications
- High clarity for medical observation
- Excellent kink resistance to reduce tubing blockage risk
- Superior flexibility and dimensional stability
- Strong chemical resistance against oils, cleaning agents and disinfectants
- Outstanding abrasion resistance for demanding applications

Medical Device Manufacturers Pushing For A Revised Special Economic Zone (SEZ) Policy

Medical device manufacturers are pushing for a revised Special Economic Zone (SEZ) policy, often referred to as "SEZ 2.0," to address challenges and ensure they can compete effectively in both domestic and international markets. They are seeking policy reforms to allow them to sell their products in the Indian market without facing significant disadvantages compared to manufacturers outside SEZs or those importing goods under Free Trade Agreements (FTAs).

Key Issues and Demands:

- **Level Playing Field:**

  SEZ units currently face higher duties on sales within India compared to manufacturers in the domestic tariff area (DTA) or those importing under FTAs.
- **"Export Only" Focus:**

  The current SEZ policy's emphasis on exports creates challenges when global demand fluctuates, potentially leading to underutilization of manufacturing capacity.
- **Policy Flexibility:**

  Industry leaders advocate for greater flexibility in SEZ regulations to adapt to changing market conditions and business needs.
- **"Make in India" Enabler:**

  The industry wants the SEZ policy to be reformed to effectively support and encourage domestic manufacturing.
- **FTA Impact:**

  Concerns exist that FTAs could make it more attractive for companies to import goods into India duty-free rather than manufacture them within SEZs.

Specific Examples:

- **High Duties:**

  SEZ units argue they should not be penalized with high duties (11% customs duty plus GST) for selling in the Indian market, especially when products can be imported duty-free from FTA countries.
- **Capacity Utilization:**

  The focus on exports can lead to underutilized capacity when global demand dips, impacting investment decisions and profitability.

In essence, the medical device industry seeks a policy that recognizes the evolving global landscape and promotes a more balanced approach to manufacturing and trade within India.

https://www.google.com/search

Qosina, a global leader in the distribution of single-use medical and biopharmaceutical components, is proud to announce a new strategic partnership with Sealed Air, a trusted name in high-performance packaging solutions. This collaboration introduces NEXCEL® BIO1250, a robust, co-extruded bioprocessing bag film, to Qosina's growing portfolio of bioprocessing solutions.

As an official distributor, Qosina now offers NEXCEL® BIO1250 bag chamber film in a 138-square-meter roll format. Designed for manufacturing single-use bioprocessing bags, this PE-based film delivers exceptional durability, chemical resistance and performance at ultra-low temperatures (down to -80°C). The unique dual EVOH barrier layer system significantly limits oxygen transmission, complemented by a low extractables and leachables profile that ensures critical product purity and biocompatibility. Engineered for exceptional durability, the film resists stress whitening as well as scuffs and scratches, to help maintain the pristine appearance of high-value, pre-sterilized RTU bioprocess chambers upon delivery and handling. The film's consistent performance and compatibility with a variety of ports, tubes and connectors make it ideal for bag manufacturers and single-use system integrators looking to deliver high-quality, reproducible results.

"We're proud to partner with Sealed Air, a company that shares our commitment to quality, innovation and customer-centric solutions," said Lee Pochter, CEO of Qosina. "This collaboration brings together our deep distribution expertise and Sealed Air's advanced material science to better serve the evolving needs of the bioprocessing industry, from early-stage research to commercial production."

To learn more about NEXCEL® BIO1250, visit https://bit.ly/4ipAcIT.

For 45 years, Qosina has been a trusted partner to medical device engineers, offering thousands of in-stock components and customizable solutions to meet the evolving needs of the healthcare industry. With over 5,000 components across 25+ product categories, same-day shipping, low minimums and ISO-certified cleanroom repackaging services, Qosina provides convenience, flexibility and confidence to customers worldwide.

About Sealed Air Medical and NEXCEL® BIO1250

Sealed Air Medical designs, manufactures and delivers a comprehensive range of medical packaging solutions for pharmaceutical applications, healthcare products and medical devices.

NEXCEL® BIO1250 film meets the demanding requirements of modern bioprocessing and is designed to support customers with scalable, high-quality materials engineered for consistent performance.

NEXCEL® is a registered trademark of Sealed Air Corporation (US).

Rachelle Morrow
Senior Manager, Communications
Qosina Corp. QOSMEDIX
Email: rmorrow@qosina.com
www.qosina.com www.qosmedix.com

https://omnexus.specialchem.com/tech-library/article/medical-grade-plastics#:~:text=Medical%20plastics%20must%20be%20compliant,irritation%2C%20systemic%20toxicity%2C%20et.

https://www.vidhata.co.in/post/manufacturing-plastic-components-for-the-medical-industry

Since childhood, you've likely heard warnings about plastic—that it's not good for health, even avoiding it for drinking water. Yet, walk into any hospital, and you'll find plastic everywhere: in syringes, medical packaging, blood bags, surgical tools, trauma implants and much more.

How can something viewed with such caution be trusted in the most sensitive medical applications?

The potential for plastics to interact harmfully with the body is a serious threat. Leaching substances, causing irritation, triggering immune responses – these interactions can be very dangerous and directly harm the body.

We've seen the devastating consequences: implants causing chronic inflammation and pain, IV lines leaching toxins leading to severe systemic complications, and packaging failures exposing life-saving devices to contaminants. These aren't just fears; they're hard lessons from instances where material biocompatibility was not sufficiently guaranteed, causing significant patient harm and costly recalls.

Moisture in medical plastic resins is a significant factor that can directly contribute to the serious problems you described.

It's not just about moisture being present in the final product. The critical issue happens during the plastic's processing – like extrusion or molding – which involves high heat.

When plastic resins containing moisture are heated, a chemical reaction called hydrolysis canoccur. This breaks down the polymer chains, causing degradation.

Medical Grade Plastics are rigorously tested, measured, and certified by essential guardians: international standards like ISO and USP Class VI.

ISO, particularly ISO 10993, provides comprehensive guidelines and tests for evaluating biological responses, ensuring materials are safe. USP Class VI is a crucial US standard for long-term contact devices, demanding extensive testing for the highest safety level.

In the precise process of transforming raw resins into safe medical plastics, controlling moisture is necessary. Bry-Air plastic drying equipment ensures resins are thoroughly dried, reaching dew points as low as -40 degrees, which is vital for material stability and purity. With features like a low footprint and energy efficiency, these systems play a quiet but critical role, helping manufacturers process medical plastics that can safely meet the demanding requirements of global safety standards.

SINCE 1994

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Advertisers' Index

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

No	Company Name	Website	Email ID
1	Alpha Medicare & Devices Pvt. Ltd.	www.alphamedicare.com	contact@alphamedicare.com
2	Alpha Therapeutics Pvt. Ltd.	www.atplworld.com	atplalpha@gmail.com
3	Angiplast Pvt. Ltd.	www.angiplast.com	asitt@angiplast.com
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6	Jimit Medico Surgicals Pvt Ltd	http://www.jimitsurgicals.com/	info@jimitsurgicals.com
7	Leelavathy Medical Devices Company	www.lmed.co.in	infolmdccatheter@gmail.com
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9	Morrisons Lifecare Pvt. Ltd.	www.morrisonslifecare.com	morrisonslifecare@yahoo.co.in
10	S.Nath & Company	http://www.snathco.com/	snathco@hotmail.com

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

No	Company Name	Website	Email ID
1	Beacon Plastics	www.beaconplastics.com	beaconplastics@hotmail.com
2	Carclo Technical Plastics Pvt. Ltd.	http://www.carclo-plc.com	Raghu.TG@carclo-plc.com
3	Celanese chemical	www.celanese.com	Tapasya.Khot@celanese.com
4	Cephas Medical Pvt. Ltd.	www.cephasmedical.net	immanuel@cephasmedical.net
5	Cosset & hygiene LLP		manish@cossetnhygiene.com
6	Covestro	www.films.covestro.com	yansy.chan@covestro.com
7	ET Elastomer Technik India Pvt. Ltd.	www.elastormer-technik.com	admin@elastomer-technik.in
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9	Jain Rubbers Pvt. Ltd.	www.jainrubbers.com	jainrubbers@gmail.com
10	KLJ Polymers and Chemicals Ltd.	http://www.kljindia.com/	rcgupta@kljindia.com
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12	Lakshmi Electrical Control Systems Ltd	www.lecsindia.com	boobalan.r@lecsindia.com
13	Lubrizol Life Science	www.Lubrizol.com/Health	Nidhi.Barot@Lubrizol.com
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22	SMC Medical Manufacturing Pvt. Ltd.	https://www.smcltd.com/	rajan.batra@smcltd.com
23	Surgi Pack (India) Pvt.Ltd.	www.surgipackindia.com	sales@surgipackindia.com
24	TekniPlex Healthcare	www.Tekni-Plex.com/healthcare	Dinesh.Rai@tekni-plex.com

03. Manufacturing Machineries, Equipments & Accessories..

No	Company Name	Website	Email ID
1	Ambica Medi Fab Pvt Ltd	www.ambicasterilizer.in	ambicamedicare@yahoo.co.in
2	BRY-AIR (ASIA) Pvt.Ltd	www.bryair.com	yashpardeshi@gmail.com
3	Eewa Engineering Co. Pvt. Ltd	www.eewaengineering.com	contact@eewaengineering.com
4	HighRichJa Precision Extrusion Machinery Co., Ltd.	www.chinahrj.com.cn	sales02@chinahrj.com.cn
5	Husky Injection Molding Systems (India) Pvt. Ltd.	www.husky.com	bdas@husky.ca
6	Sai Extrumech Pvt Ltd	www.saiextrumech.com	saiextrumech@gmail.com
7	Shiabaura Machine	www.shibauramachine.co.in	eswarmurthy.b@shibauramachine.co.in
8	Twist Engineering Works	www.twistplasticmachinery.com	info@twistplasticmachinery.com
9	Yizumi Precicion Machinery India Pvt Ltd	www.yizumi.com	secretary.india@yizumi.com

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

No	Company Name	Website	Email ID
1	Accuprec Research Labs Pvt. Ltd.	https://accuprec.com/	hr@accuprec.com
2	Carclo Technical Plastics Pvt. Ltd.	http://www.carclo-plc.com	Raghu.TG@carclo-plc.com
3	Cephas Medical Pvt. Ltd.	www.cephasmedical.net	immanuel@cephasmedical.net
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5	Lakshmi Electrical Control Systems Ltd	www.lecsindia.com	boobalan.r@lecsindia.com
6	Medicall	www.medicall.in	mohana@medicall.in
7	Messe Duesselfdorf India Pvt.Ltd. (Medical Fair India)	http://www.medicalfair-india.com/	VermaA@md-india.com
8	Pharmadocx (rapid facto)	www.rapidfacto.com	yd@pharmadocx.com
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11	SEC Global Consulting & Initiatives LLP	www.complianceforgrowth.com	info@complianceforgrowth.com
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Cephas Medical Pvt Ltd,
B13 MEPZ SEZ, Chennai 45, India
Mob: +91-9840330964
www.cephasmedical.net

Eewa Engineering has grown from manufacturing Impulse Heat Sealing Machinery to being a major corporate player and market in the manufacture of multifaceted range of products in Sealing & Packaging Machineries since 1967. Our first and foremost priority is the soundness of the product. We are exporting our products to 55+ countries and already secured 30k+ customers in India and across the world. Eewa's enormous strength comes from a wonderful combination of its highly efficient and professional management and a dedicated workforce of qualified and experienced engineers and technicians and marketing personnel, which in turn, leads to world-class manufacturing, testing and R&D, besides meeting requirements of client's specifications in India and world across.

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Biplab Das
Regional Marketing Manager – South & Southeast Asia
Marketing & Communications
Husky Technologies™
I am based in India

Mobile & WhatsApp: +91 7845909562

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Mobile No. 9377000389 / 9517911553

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KLJ Medical Grade PVC Compounds: KLJ Polymer has been supplying medical grade PVC compounds to the Healthcare Industry for over 40 years. Our compounds find use in a variety of medical devices for moulding & extrusion applications. KLJ has non DEHP, Non Phthalate & FDA approved compounds

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For more information, visit www.lecsindia.com or contact us at **info@lecsindia.com / 0422 6616500.**

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Lubrizol, a Berkshire Hathaway company, is a science-based company whose specialty chemistry delivers sustainable solutions to advance mobility, improve well-being and enhance modern life. Every day, the innovators of Lubrizol strive to create extraordinary value for customers at the intersection of science, market needs and business success, driving discovery and creating breakthrough solutions that enhance life and make the world work better. Founded in 1928, Lubrizol has global reach and local presence, with more than 100 manufacturing facilities, sales and technical offices and more than 7,000 employees around the world.

Lubrizol's medical offerings include high-quality, medical-grade thermoplastic polyurethane (TPU) and comprehensive support for medical device OEMs. As a vertically integrated solutions provider, Lubrizol specializes in design, development, and manufacturing services for components and devices. With trusted regulatory guidance and collaborative efforts, Lubrizol empowers manufacturers to innovate from ideation to commercialization, ensuring success in the medical device industry.

Contact person Information:
Name: Mr. Rajnish Singh
Designation: Account Manager, Medical Devices
Email: Rajnish.Singh@Lubrizol.com
Contact Number: +91 98186 89669

MCPP India Private Limited
A MITSUBISHI CHEMICAL GROUP company

MCPP India Private Limited is a group company of Mitsubishi Chemical Group Corporation under the performance polymers division. MCPP has the presence in 13 countries with 27 locations.

MCPP India is specialized into the business of manufacturing and supplying of PVC Compounds & Tubes for various applications in medical disposable domain. Our technology and quality control are based on global "MCPP" platform.

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Contact Person: Raju P Veetil
Mobile: +91-9322739770
E-Mail: raju.veetil.ma@mcgc.com

MDR Laboratories Pvt. Ltd. offers cost-effective, high-quality biocompatibility solutions in accordance with ISO 10993 for medical devices. We have established a strong reputation as a specialist, mid-sized, independent biocompatibility laboratory, integrating biological evaluation, advanced analytical chemistry with deep toxicological expertise.

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In 2025, GLR was acquired by MDR Laboratories—a move that reflects our commitment to the medical device sector. This strategic partnership marks the beginning of an exciting new chapter, aligned with MDR's vision of growth, innovation, and global excellence.

Contact Details
Dr T S Kumaravel, Chairman – kumaravelts@mdrtox.com
Dr S S Murugan, Managing Director – siva.murugan@mdrtox.com
Mobile number : +91-9841212596, +91-9500064248

Milliken & Company is an American industrial manufacturer that has been in business since 1865. With corporate headquarters located in Spartanburg, South Carolina, the company is active across a breadth of disciplines including Specialty Chemical, Floor Covering (Carpets), Performance and Protective Textile materials, and Healthcare.

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R. Balaji Narasimhan, Country Manager – Plastic Additives
Milliken Chemical & Textile (India) Co. Pvt. Ltd.
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Padmini Innovative Marketing Solutions Pvt. Ltd is a leading Engineering Polymer Distributor in India. With expert technical consultation it provides to its customers, It has developed long term relationships with many manufacturers pan India in a short period of time by providing Super Engineering and Engineering polymers.

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Yashdeep Dahiya - Pharmadocx FDA Consultant
Sonipat Office : Opposite Dewan Mill, Old DC Road, Sonipat-131001. M:- 9896133556
Delhi Office : G-12, Pearls Best Heights-1, Netaji Subhash Place, Delhi-110034. Ph:- M:-8708385761,
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Yashdeep Dahiya - Pharmadocx FDA Consultant
Sonipat Office : Opposite Dewan Mill, Old DC Road, Sonipat-131001. M:- 9896133556
Delhi Office : G-12, Pearls Best Heights-1, Netaji Subhash Place, Delhi-110034. Ph:- M:-8708385761,
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Shibaura Machine is a global leader in advanced manufacturing solutions, with over 145 years of engineering excellence. Headquartered in Japan, the company specializes in highprecision Plastic Injection Molding Machines, Die Casting Machines, Machine Tools, and Precision Machinery.

In the medical industry, where safety, hygiene, and consistency are critical, Shibaura Machine provides reliable, high-performance solutions that meet the most demanding standards. Our advanced injection molding technology enables the production of medical components with exceptional precision and repeatability.

With a strong focus on sustainability and energy-efficient operations, we help medical manufacturers improve productivity while reducing environmental impact. Trusted worldwide for our product quality, technical support, and long-term reliability, Shibaura Machine remains a preferred partner for healthcare and medical device industries.

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ESWARMURTHY B,
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Founded in U.S.A. in 1988, SMC offers contract design and manufacturing services to the healthcare industry and focuses on single use diagnostics, drug delivery and medical device markets.

SMC has nine design and manufacturing facilities in U.S.A., U.K., Costa Rica and India. With over 1 million square feet dedicated to healthcare design and manufacturing, SMC provides full services from initial concept through final packaged devices including design and development, validation, program management, product manufacturing, clinical manufacturing, electronics integration, kitting and packing, sterilization management as well as global sourcing and supply chain management.

In 2016, SMC acquired Oval Medical Technologies, a cutting-edge parenteral technology company based in Cambridge U.K. and in 2024, SMC acquired a new facility in Concord, North Carolina, USA, to offer sterile drug fill-finish services.

ABOUT SMC Medical Manufacturing

SMC Medical Manufacturing started operations in 2006 in Bangalore and became a fully owned subsidiary of SMC in 2011. SMC's 35,000 sq. ft. facility is ideally located for serving domestic, emerging and mature markets and our capabilities are as follows:

- Design and design rationalisation services for medical devices, subassemblies and injection molded components
- Best in class new product development, engineering, validation, automation, robotics and sterilization services
- Global sourcing and supply chain management
- Design and build of injection molds, assembly and inspection fixtures
- Manufacture of medical injection molded components, subassemblies and finished medical devices in controlled environment including ISO Class 7 and Class 8 clean rooms
- Kitting, packaging and sterilization management services
- Quality and regulatory services

SMC India's value proposition is as follows:

- ISO 13485 certified, ISO 14001 certified, first facility to be MedAccred certified in India
- SMC's Bangalore facility is licensed/registered/certified regulatory authorities from U.S.A., Japan, Korea and India
- High skill low cost manufacturing
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For more information, please visit www.smcltd.com.

TekniPlex Healthcare is a global leader in advanced materials science, dedicated to developing and delivering innovative solutions for the healthcare industry. As one of two core divisions of TekniPlex, it specializes in critical applications across medical and diagnostic devices, drug delivery systems, and sterile barrier healthcare packaging.

With deep expertise in the pharmaceutical and medical landscape, TekniPlex Healthcare delivers high-performance barrier materials for drug containment and precision-engineered components for interventional and therapeutic procedures. As a full-service Contract Development and Manufacturing Organization (CDMO), the division supports the entire medical device lifecycle—from design and development to component manufacturing and final assembly.

Its expansive portfolio includes medical-grade compounds and tubing, metal and plastic components, and specialized engineering services—empowering healthcare innovators to bring high-impact medicines and life-saving technologies to market efficiently and reliably.

TekniPlex Healthcare is committed to enhancing patient outcomes and supporting healthcare providers worldwide.

Learn more at www.tekni-plex.com/healthcare

Dinesh Rai
Director of Sales, Healthcare India & SE Asia
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Trustin Analytical Solutions Private Limited is a leading medical device testing laboratory based in Chennai, Tamil Nadu, recognized for its NABL accreditation and extensive third-party testing services tailored for Medical Devices, Surgical Products. As a complete testing facility, we cater to manufacturers who require reliable and regulatory-compliant testing solutions all in one location. Our laboratory is equipped with the required approvals from NABL (ISO/IEC 17025:2017), CDSCO (MD-40), BIS, and UNFPA, and adheres to the stringent quality systems to meet the global market requirements. With state-of-the-art cleanrooms, advanced precision instruments, and a team of

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CONTACT DETAILS

M MAHENDRAN - QUALITY 9444307174
mahendran@trustingroup.in.

K SENTHIL KUMAR - TECHNO - COMMERCIAL 9884216380
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Preliminary boiler plate English for 2025:

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Vorläufige Boiler-Plate Deutsch für 2025:

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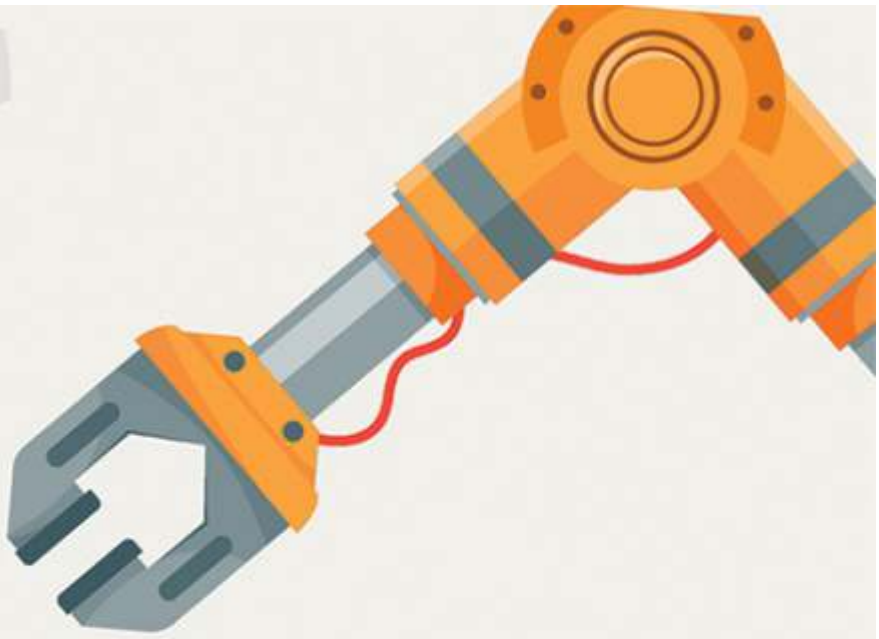

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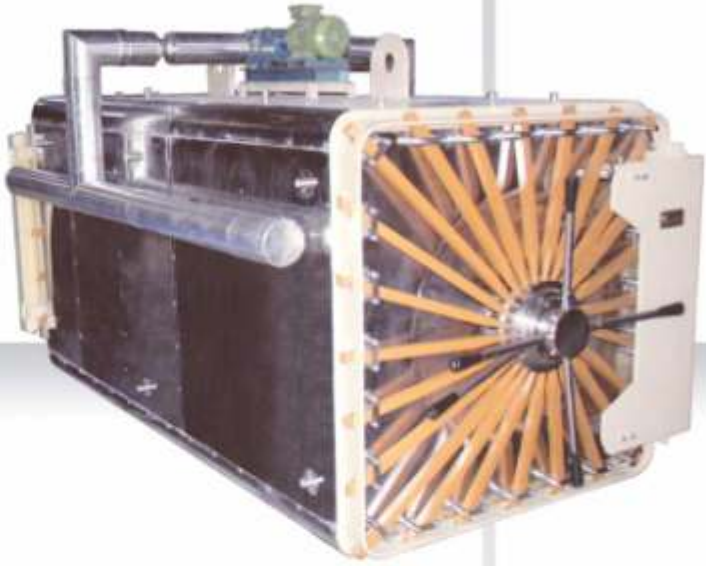

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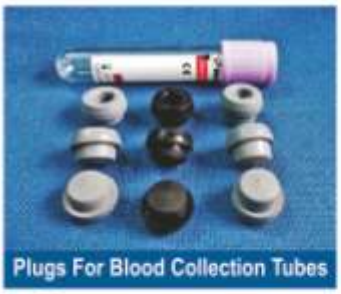
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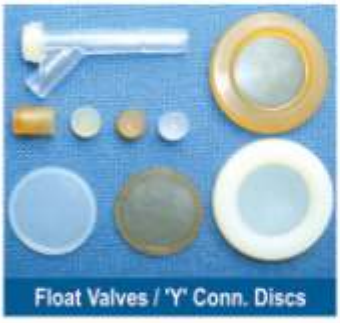
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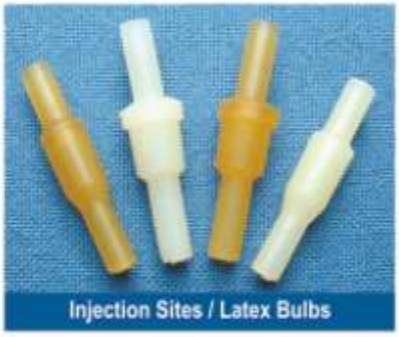
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- Biological Evaluation Report (BER/BSA)
- Consultations on Biocompatibility Strategy
- Specialised services for ISO 10993 and ISO 18562

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- Neurological
- Ocular
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- OECD-GLP
- ISO/IEC 17025
- CDSCO MD40

Test Facility
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Mathur, Chennai
600068
INDIA

UK
4 Exchange, Colworth
Science Park,
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