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# MEDICAL PLASTICS DATA SERVICE

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

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## Medical Grade Polymers

- Defining Medical Grade Plastics Materials
- Poly Vinyl Chloride Compounding of Non-toxic PVC
- PVC In Medical Tubing and Blood Bags, Safety and Biocompatibility Concerns
- Emerging Trends for Use of Medical Plastics in IVD Industry: Opportunities & Challenges
- Innovations in Medical Polymers
- Bioabsorbable Polymer Based Medical Devices

### Circularity For Hospital Plastic Waste

- Medical plastic waste into new contact sensitive packaging materials.

### Quality

- Personal Protective Equipment (PPE): Testing & Ensuring Quality And Safety

### Global Market

- Vietnam Medical Devices Market

spe MEDICAL PLASTICS

**4th National Seminar on**
"Plastics for Medical & Healthcare Industry : New Materials, Developments and Opportunities". Bangaluru, December 12, 2025.

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- 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)
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- ISO 10993-14: Identification and quantification of degradation products from ceramics
- ISO 10993-15: Identification and quantification of degradation products from metals and alloys
- ISO 10993-17: Toxicological Risk Assessment (TRA) of medical devices, packaging materials and CCS
- ISO 10993-18: Chemical characterization of medical device. (Exaggerated/Exhaustive extraction studies and study designing).
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- EN 1186 Migration Study
- ISO 18562-2: Emission of Particulate Matter from Gas Pathways
- ISO 18562-3: VOCs from Gas Pathways
- ISO 18562-4: Condensate Leachables from Gas Pathways
- ASTM D7823-18: Residual Phthalate Testing
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- Toys testing for nitrosamines and phthalates as per EN 14350:2020, EN-71-12, EN-73-14
- REACH Study as per regulation (EC) No.1907 etc.
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# 4th National Seminar On
# Plastics For Medical Devices & Healthcare Industry : New Materials, Developments and Opportunities

Dec 12, 2025. 9.00 AM to 6.00 PM; Venue : The LaLit Ashok, Kumarakrupa, Bengaluru.

**Jointly Organized By**

SPE INDIA MEDICAL PLASTICS DIVISION

INDIAN PLASTICS INSTITUTE
BANGALORE CHAPTER

**Supported By**

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MEDICAL PLASTICS DATA SERVICE
A Techno-Economic News Magazine For Medical Plastics, Medical Devices, Diagnostics And Pharma Industry

AIMED Association of Indian Medical Device Industry

KSPA

## FOCUS

- Medical Polymers & Processing
- Quality Requirements & Testing
- Domestic & Export Market Opportunities
- Packaging & Sterilization
- Enterpreunerships & Start-up Opportunities
- Recycling & Sustainability

## INTRODUCTION

The Medical Technology Industry is making important contributions to advances in healthcare supported by emerging polymeric materials and technologies for processing of the materials. The global medical technology industry invests heavily in Research and Development. This has resulted in a significant impact on medical technology through advances in polymeric material science thereby growth of the medical polymers' market.

In 2020 , over 32 billion pounds of healthcare plastics were produced globally, and is expected to grow to 48 billion pounds by 2025. The Indian MedTech industry with significant contribution from Medical Polymers is also expected to grow at more than 15%. This growth is driven by increasing healthcare expenditure, rising demand for minimally invasive surgeries, and the prevalence of chronic diseases.

## OBJECTIVES

- To discuss the latest trends in the Medical Device and Medical Plastics Industry and the challenges in the areas of Technology, Material science, Testing and Policy framework.
- The opportunity for existing players to showcase their products and technology and to seek growth opportunities.
- To seek investments into the state and to attract new entrepreneurs in the sector

## SPEAKERS

- Industry Leaders & Experts from Medical Polymers, Medical Devices, Medical Packaging Frontline Companies.
- Policy Makers From Government and Public Sector Executives, Experts from Research and Academic Institutions.
- Technology, Services, Materials & Manufacturing Professionals, Consultants

## EXPERT PRESENTATIONS / PANEL DISCUSSIONS HIGHLIGHTS

Keynote presentations, case studies and panel discussions by industry leaders with extensive knowledge of their respective industries and specialties.

## ORGANIZERS

**Ramesh Parasuraman**
President, SPE INDIA

**Rajiv Sanghavi**
International Counsellor, SPE India

**D. L. Pandya**
Vice Chairman, SPE India Medical Plastics Division

### Society Of Plastics Engineers ( SPE ) INDIA Medical Plastics Division

SPE, founded in 1942, with 60,000 stakeholders from 84 countries unites plastics professionals worldwide - helping them succeed and strengthening their skills through networking, events, training and knowledge sharing. SPE INDIA Medical Plastics Division encourages the interchange of technical and regulatory information on polymer materials / components used in Medical Devices among scientists and engineers who are working in Medical Devices and related industries.

### Indian Plastics Institute ( IPI ) - Bangalore Chapter

IPI is a strong Professional Body of Industrialists, Plastic Technologists, Academicians, Economists and Students, spread over 14 Chapters across India and 2 Overseas Association partnerships with Sri Lanka & Nepal. It is engaged in Education, Training, Manpower Development, and Dissemination of Knowledge on the latest technological developments in the worldwide Plastics Industry.

**Dr. Samir Joshi**
Chairman, IPI

**Vijay Kumar**
IPI Banglore Chapter

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### WHO SHOULD PARTICIPATE?

All the people directly or indirectly associated with Plastics & Medical Devices Companies, Start-ups, Entrepreneurs interested in diversification & Industry Professionals.

### CONTACTS :


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**15** SPEAKERS **20** EXHIBITORS **160** DELEGATES

### PREVIOUS EVENT REPORT held on

Jan 20, 2023 Seminar, Jan 21, 2023 Industry Visit
Venue : Hotel Appolo Dimora, Thiruvananthapuram


### Held on

March 26, 2022, Venue : Federation of Telangana Chambers of Commerce and Industry, Hyderabad.

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# Flashback

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- **AiMeD & REGULATORY UPDATES:**
- Gujarat FDCA Starts Issuing RCs To Medical Devices Manufacturers As Part Of Transitioning To New MD Regime
- Medical Devices Industry Seeks Clarity On Misbranded And Adulterated Medical Devices In New Drugs Bill
- NCC-MvPI Identifies 119 New MDAEM Centres In Various States To Report Medical Device Adverse
- **Events.** (January- February 2023)
- **INDUSTRY NEWS**
- Syringe Cos Feel The Pain As Vaccination Rate Dips
- Central PSU HLL Launches Menstrual Cups
- Berry Invests In Indian Healthcare Market With New Facility
- Mandaviya Urges Medical Device Entrepreneurs To Reduce Import Dependency
- Med-Tech Sector Scouts For Export Incentives Under RoDTEP To Boost R&D Ecosystem (January- February 2023)
- **DID YOU KNOW?**
- About Making Medical Plastics Sector More Sustainable (January- February 2023)

**COVER STORY**

- **Medical Plastics Tubing:** Application, Quality & Extrusion Process Challenges Medical Tubing and Extrusion Technology, Material, Process & Quality Requirements For High-Quality Extruded Tubing, Medical Tubing Configurations, Tubes and Catheters Sizing, Challenges Of Meeting Standards For Medical Tubing (March-April 2023)
- Micro Extrusion Contribute To Improvements In Medical Device Production & Patient Satisfaction The definition of what constitutes microextrusion. With minimally-invasive surgery becoming the wave of the future, microextrusion is allowing device manufacturers to provide products that otherwise would be difficult to achieve or expensive. Also Potential Applications (March-April 2023)

**FAST FACTS**

- Plastic Based Medical Disposables For Dialysis The use of disposable dialysis devices, largely made from plastics, increases patient safety and, as a result, reduces any serious risks during the dialysis process…
- The Real Economics Of Extrusion Extrusion is usually a 24-hour continuous operation. If you don't run around the clock you are idling equipment, paying for frequent starts and stops and, therefore, greatly increasing production costs. (March-April 2023)

# Did You Know?

## About Innovations in Medical Polymers

Innovations in medical polymers focus on enhanced biocompatibility, controlled biodegradability, and smart properties, leading to advanced drug delivery systems, tissue engineering scaffolds, and customized 3D-printed implants. Key developments include biodegradable polymers like PLA and PCL for sutures and implants, high-performance polymers such as PEEK for orthopedic devices, and smart polymers with responsive capabilities for targeted therapies and diagnostics. Emerging trends involve sustainability, personalized medicine via 3D printing, and integration with nanotechnology to improve patient outcomes.

Key Areas of Innovation

- **Biodegradable Polymers:** Designed to degrade safely within the body after serving their purpose, eliminating the need for follow-up surgeries.
- **Applications:** Used in drug delivery systems, sutures, and as scaffolds for tissue engineering.
- **Examples:** Polylactic acid (PLA) and polycaprolactone (PCL) are common examples that break down into non-toxic byproducts.
- **Biocompatible Polymers:** Newer resins minimize the body's immune response and inflammation, promoting better tissue integration.
- **PEEK:** A high-performance, radiolucent polymer used in spinal implants and joint replacements due to its strength and compatibility with imaging techniques.
- **Smart Polymers:** Respond to specific stimuli in the body, such as temperature or pH changes, for targeted drug delivery or monitoring.
- **3D Printing and Personalized Medicine:** Allows for the creation of custom-made medical devices, implants, and prosthetics tailored to individual patient needs.
- **Tissue Engineering Scaffolds:** Polymers provide the structural support for cell growth and tissue repair, helping to regenerate damaged tissues and create artificial organs.
- **Theranostics:** The development of polymers that combine diagnostic and therapeutic functions, allowing for simultaneous monitoring and treatment.

Emerging Trends

- **Sustainability**
- **Nanotechnology**
- **Wearable Devices and Biosensors**

## In a Nutshell....

*"Medtech startups rarely fail because of weak technology. They fail because the commercial model was never built to win".*

*-Aaron Tutwiler*
*CCO/VP of Biz Dev.*

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# From the Editor's Desk

**How do we Define Medical Plastics Materials?**
As explained in elaborated in this issue of magazine, there is no accepted and agreed definition for Medical Plastic Materials. Not even regulatory definition of a medical grade polymer and no prescriptive regulatory requirements for raw materials used in medical devices.

**How do we then differential commercial Plastic Materials from Medical Grade Materials?**
Regulatory norms do require certain essential qualities and testing needs for raw materials used in medical devices and hence in practice, medical device manufacturers or manufacturers of Medical / Pharmaceuticals packaging materials select polymers that are certified.The cover story article gives detailed explanation including major requirements as well as critical aspects related to end use.

**One of the most commonly used Material is PVC** which as we all know is compounded along with various additives before converted into injection moulded parts, extruded tubes etc required as components for Medical Devices. Mr Divyanshoo Thakur, Segment Leader – Medical Business, Shriram Polytech Ltd, in his article has explained not only various applications but also the safety and biocompatibility concerns for using PVC Compounds. He has also given elaborate information on various quality standards to be followed.

**Plastics Used for Hygiene Products :** As explained by Dr Renjith S, Scientist, Central Analytical Facility, BMT wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram in his article has described various quality and testing requirements for Personal Protective Equipment (PPE) – an important hygiene product not only for Medical Professionals but also for personal safety of people at large. Non-woven PP is the most commonly used raw material for the development of medical PPE fabrics, such as gowns, coveralls, surgical masks, and air/water filters. The article describes not only the quality requirements but it elaborates of methods to test important quality parameters.

**Plastics For In-Vitro Diagnostics (IVD) Products:** One more well researched article by Dr Usha Jain, Consultant -Genomic Medicine, Healthcare & Medical Device, explains how Medical Plastic Materials are integral to the advancement of IVD industry, offering versatility, efficiency and innovation. Selection of appropriate medical-grade plastic for IVD manufacturing is a multifaceted process that ensures device safety, performance & regulatory compliance. It describes some of the critical criteria to consider when choosing plastics for IVD applications.

**Bioabsorbable Polymers and Their Applications:** One of the recent developments is in Bioabsorbable Polymers. The "Global Trends" column introduces Bioabsorbable Polymer based Medical Devices. As explained, the development of innovative medical devices is a major driver of the bioresorbable polymer applications. Technologies such as bioresorbable stents and scaffolds are transforming cardiovascular and orthopaedic treatments.

**Innovations In Medical Polymers:** The "Did You Know" column in this issue highlights Innovations in Medical Polymers using different materials and the key developments including various biodegrable polymers. .

This issue covers regular columns including Industry News, Global Markets, Events and more.

D L Pandya

# Defining Medical Grade Plastics Materials

It is interesting to know that a **globally accepted, agreed-upon definition and standard does not exist.**

Globally, the **vast majority** of polymers produced are **used in industrial and consumer segments**, with only a small percentage the polymer volume being used in medical devices.

Currently there is **no regulatory definition of a medical grade polymer** and no prescriptive regulatory requirements for raw materials used in medical devices, so material **suppliers** and others in the medical device industry **have assigned their own meaning to "medical grade polymer."**

The **manufacturer of a medical device** can therefore theoretically **choose any kind of plastic** for a given application, so long as the manufacturer has ensured **that the material complies with the various regulatory requirements.**

In Practice, medical device manufacturers or manufacturers of Medical / Pharmaceuticals packaging materials **select polymers that are certified.**

**Considerations are given not just to product specification and required performance attributes but the robustness of quality systems, manufacturing consistency, management of changes and understanding the possible implications on a finished device so the process is well managed by the supplier and effective communication systems are in place.**

## Then What is Medical Grade Plastic ?

Polymeric plastics and refined plastic preparations and formulations (masterbatches, blends, com-pounds) are called "Medical Grade Plastics" (MGP) when they are **intended for use by a given manufacturer in the manufacture of finished products** in the following application areas:

- medical devices in accordance with Regulation (EU) 2017/745
- in-vitro diagnostics in accordance with Regulation (EU) 2017/746
- primary pharmaceutical packaging in accordance with various guidelines

Plastics are further subject to thermal, mechanical, and radiation stresses that can affect the properties of the plastic.

**Some Major requirements of Medical Grade Plastics include:**

- Biological Performance (Biocompatibility, Biostability, Hemocompatibility, Infection Risk)
- Application Performance (Strength, Flexibility, Fatigue Resistance)
- Heat and/or Electrical Resistance
- Chemical Resistance (Product cleaning Resistance, Drug Resistance)
- Sterilization Stability, Processibility
- Thermal Methods (Extrusion,Molding,Forming etc)
- Solvent (Casting, Dipping, Spinning)
- Secondary Assembly (Reflow, Bonding)
- Compatibility with other materials within the Device

**Regulatory and Other Requirements:**

- Does the material contain REACH, RoHS or other substances of concern?
- Has the material been used in devices cleared by regulatory agencies?
- Cost : Volume Specific Pricing , Annual access, licencing and/or royalty fees

With the growing need for new and innovative devices, selecting right Materials has become more critical.

There are **hundreds of polymers to choose from,** but where do we start from ?

The material selection process **requires a preliminary understanding of polymers, additives and their properties. Preselection is a valuable tool** for helping product designers find materials that comply with safety standards

It greatly **reduces time and cost associated with final end product testing, certification and development** thereby **speeding time to market.** Also helps manufacturers maintain a **competitive advantage** turnaround time. Also allows product **designers to determine the function of a component in the end product application.**

Selection is also based on polymers meeting **environmental requirements.**

**Some other critical aspects related to end use to be considered include:**

- Will the component be in contact with body tissues or drugs? If so, for how long?
- Is the product a single use instrument/device?
- To what humidity and temperature (maximum and minimum) will the product be exposed? How long will it be exposed?
- Is dimensional stability in a wet or humid environment critical? What tolerances must be met?
- Is UV resistance needed?
- Does device need to be visible under a fluoroscope or X-ray?
- Is flame rewardability a requirement?
- Is the colour of the material is an important factor?
- Will the part be used outdoors?

Following Table give overview on Application Based Selection of Polymers :

| Sr. No. | Application of Medical Devices | Polymer Selection |
|---|---|---|
| 1 | **Non-contact with human body, e.g.** syringes, blood storage bags, glucose drip bags | PVC,PA,PE,PS, Epoxy resins |
| 2 | **Short-term contact with human body, e.g.** catheters, feeding tubes, drainage tubes, surgical instruments | Silicone rubber, Natural rubber, PVC, Polyure-thane, PE, PP, Polyester, PEEK, Polyphenylsulfone, Nylon, Teflon, PeBax |
| 3 | **Medium term contact with human body, e.g.** cultures, ligatures | Nylon, PP, Polyester |
| 4 | **Long term contact with human body, e.g.** implants, drug delivery devices | PE, UHMWPE, PET, Silicone rubber, Polyure-Polyurethane, PMMA, Polysulphones, Hydrogels Polyphosphazenes, Thermoplastic elastomers, Polydimethylsiloxane |

# Poly Vinyl Chloride

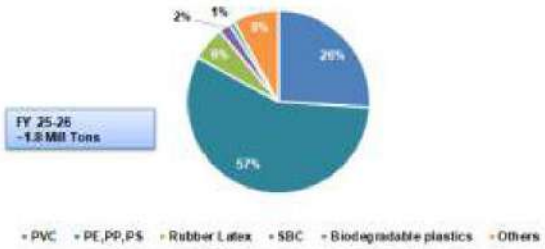
## Compounding Of Non-toxic PVC, PVC In Medical Tubing and Blood Bags, Safety And Biocompatibility Concerns

**Mr. Divyanshoo Thakur**
Segment Leader – Medical Business, Shriram Polytech Ltd.

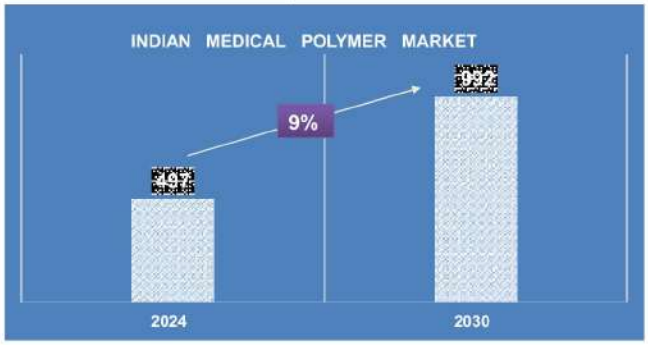
- The polymer in the market device sector was valued at $ 5,786 million in 2024 and is anticipated to grow to $ 5,955 million in 2025, further expanding to USD 7,491 million by 2033, with a compound annual growth rate (CAGR) of 2.91% during the forecast from 2025 to 2033
- Rapid economic growth and increasing healthcare spending are boosting demand for advanced medical devices made from polymers
- The large and aging population in Asia Pacific is driving a rise in chronic diseases, increasing the need for medical interventions
- The market for polymer medical devices is expanding, driven by a new trend towards biodegradable polymers, which is envisioned to see a 42% increase in implants and structures. Meanwhile, thermoplastic elastomers (TPE) have replaced latex-based materials for catheters and globes, reflecting a 35% rise
- Biodegradable polymers, including Polyethylene Glycol (PEG), Polylactic Acid (PLA), and Polyvinyl Alcohol (PVA), have gained significant attention due to their biodegradability, low toxicity, and capacity to replicate natural tissues

### Polymers in Healthcare Industry - Global


*Polymers In Medical Device*




### Indian Healthcare Polymer Market




- The Indian medical device market was valued at approximately **US $522 million in 2025** and is expected to grow at a **CAGR of around 9%, reaching US $992 million by 2030**
- Medical devices currently contribute about **2.5% to the overall Indian healthcare market,** indicating a niche but rapidly expanding segment within the industry
- Indian is the 3rd fastest growing markets in Asia, with a major global supplies of low cost disposables (Syringes, blood bags, IV sets)

- As India's medical device sector matures, there is a growing focus on **advanced materials** like **biodegradable polymers** and **implant-grade polymers,** driven by innovation in surgical, orthopedic, and drug delivery applications. The push for **self-reliance (Atmanirbhar Bharat)** and import substitution has further accelerated developments in this space

To boost the domestic manufacturing of medical devices and reduce dependency on imports, the **Government of India** has introduced several **schemes and policy initiatives**

- Production Linked Incentive (PLI) Scheme for Medical Devices
- Promotion of Medical Devices Parks Scheme
- Make in India Initiative

## Market Growth and Future Opportunity

### India Medical Plastic Market Growth Drivers

- **Rising Demand for Disposable Medical Devices**
  Disposable medical devices, such as syringes, IV tubes, and gloves, have seen increasing adoption due to their role in preventing cross- contamination and infections.
- **Advancements in Medical Technology**
  Innovations in healthcare technology have driven the demand for sophisticated medical devices that require high-performance materials. For instance, minimally invasive surgical instruments and advanced diagnostic tools rely on medical plastics for their lightweight, durable, and precise properties. These advancements are fueling the growth of the India medical plastic market.
- **Stringent Regulations and Biocompatibility Standards**
  Governments and regulatory bodies worldwide emphasize the safety & biocompatibility of materials used in medical applications. Medical plastics meet these stringent requirements, offering non-toxicity, chemical resistance, and the ability to withstand sterilization processes.

### India Medical Plastic Market Future Opportunities

- **Development of Bio-Based Plastics**
  The focus on sustainability presents significant opportunities for the development of bio-based medical plastics. Innovations in biopolymers and biodegradable materials will address environmental concerns while meeting the needs of the healthcare industry.
- **Expansion of Emerging Markets**
  Emerging markets in Asia, Latin America, and Africa offer vast growth potential due to improving healthcare access and infrastructure. Manufacturers can capitalize on these opportunities by establishing local production facilities and distribution networks.
- **Collaboration and Partnerships**
  Collaborations between medical device manufacturers, material suppliers, and research institutions can drive innovation and accelerate the development of advanced medical plastics. Partnerships can also help navigate regulatory challenges and expand market reach..

## Indian Medical Grade Polymer Market

| Properties | Commodity Plastics | Engineering Thermoplastic | Specialty Thermoplastic |
|---|---|---|---|
| Percent usage in medical device applications | 70% of all plastics | 20% of all plastics | 10% of all plastics |
| Types of plastics | • Polyethylene<br>• Polypropylene<br>• Polystyrene<br>• Polyvinyl chloride | • Polyamides, nylons<br>• Polyesters<br>• Polycarbonates<br>• Polyurethanes<br>• Acrylics<br>• Acetals | • Polyimides<br>• Polyetherimides<br>• Polysulfones<br>• Polyether ether ketone<br>• Polyphenylene sulfide<br>• Fluoropolymers<br>• Liquid crystalline polymers<br>• Biopolymers<br>• Thermosets and adhesives |
| Medical device applications | • Tubing<br>• Films, packaging<br>• Connectors<br>• Labware<br>• IV bags<br>• Catheters<br>• Face masks<br>• Drug-delivery components<br>• Housings<br>• Luers<br>• Connectors<br>• Membranes<br>• Sutures<br>• Syringes | • Surgical instruments<br>• Balloons<br>• Blood set components<br>• Blood bowls<br>• Blood oxygenators<br>• Syringes<br>• Moving parts and components<br>• Luers<br>• Catheters | • Surgical instruments<br>• Surgical trays<br>• Syringes<br>• Implants<br>• Dental implants<br>• Bone implants<br>• Moving parts and components<br>• High precision parts<br>• Electronic components<br>• Luers<br>• Biomaterials sutures |

## PVC in Medical Device industry

### Extensive Versatility

Used in IV tubing, catheters, blood bags, and oxygen masks. PVC can be adapted to various mechanical needs and remains stable in both forms.

### High Compatibility

PVC Is characterized by high biocompatibility, and this can be further improved by appropriate surface modification. PVC Is also compatible with all Pharmaceuticals products

### Cost Effective

No other polymer offers the same level of performance at such a low cost as PVC. Switching to an alternative material could result in up to a 30% increase in overall cost

### Benefit Range

PVC's unique technical properties include bio compatibility, Anti kinking, excellent transparency, chemical resistance and easy sterilization.

| Application Area | Use Case Examples | Role of PVC |
|---|---|---|
| Fluid Transport | IV tubing, blood transfusion sets, catheters, dialysis lines | Flexible PVC ensures softness, clarity, and kink resistance |
| Fluid Storage | Blood bags, IV solution containers | Non-toxic, plasticizer-containing PVC maintains sterility |
| Surgical & Examination | Gloves, gowns, curtains, drapes | Acts as a barrier to fluids and pathogens |
| Respiratory Equipment | Oxygen masks, endotracheal tubes | Offers flexibility and comfort for patients |
| Medical Packaging | Blister packs for pills, sterile packaging for devices | Rigid PVC offers durability and barrier protection |
| Enteral Feeding & Drainage | Feeding tubes, urine collection bags | Flexible, transparent, and safe for prolonged use |

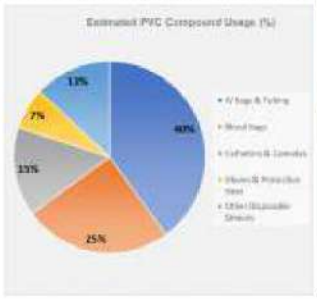
## Compounding of Non-toxic PVC

- Polyvinyl chloride is a synthetic polymer known for its excellent **chemical resistance, durability, and cost-effectiveness.** PVC can be rigid or flexible, depending on the specific additives and processing techniques used during its manufacturing. In medical device applications, flexible PVC compounds are commonly employed due to their ability to conform to complex shapes, making them suitable for a variety of healthcare products
- PVC's inherent versatility has made it indispensable in the medical field. However, safety concerns have led to a shift from traditional additives like DEHP and lead-based stabilizers to **non-toxic plasticizers (e.g., TOTM, DINCH,DOTP)** and **lead-free stabilizers (e.g., Ca-Zn systems).** Compounders are now engineering highly customized, medical-grade PVC formulations that comply with global safety and biocompatibility standards.

**Challenges and Considerations:**

- **Concerns Regarding Plasticizers:** The incorporation of plasticizers in PVC formulations has generated considerable discussion, particularly regarding the potential for **leaching over time.** To mitigate this issue, manufacturers are adopting alternative formulations, including the **use of non-phthalate plasticizers.**
- **Disposal and Environmental Implications:** Although PVC compounds provide numerous advantages in medical applications, their disposal presents environmental challenges. Ongoing efforts **in recycling and the creation of more sustainable alternatives** aim to tackle these issues.

## PVC in Medical Device




## PVC in Medical Tubing

- India medical tubing market size reached **USD 474.0 Million in 2024.** The market is expected to reach **USD 794.0 Million by 2033,** exhibiting a growth **rate (CAGR) of 5.9%** during 2025-2033. The increasing number of diverse healthcare settings, encompassing clinics, hospitals, ambulatory surgical centers, and medical laboratories, is primarily driving the market growth across the country
- It is usually made up of **polyethylene, thermoplastic elastomers (TPE), nylon, polyvinyl chloride (PVC), and silicone.** The utilization of medical tubing extends to diverse medical scenarios, including **fluid management, catheters, drainage systems, peristaltic pumps, intravenous (IV) setups, bio-pharmaceutical laboratory equipment, anesthesiology, and respiratory devices.**
- The properties of medical tubing, including **hardness, flexibility, durability, and resistance to temperature, pressure, and abrasion,** make it a versatile solution for medical applications. Manufactured from recyclable plastics, medical tubing is known for its biocompatibility, devoid of allergic or adverse reactions when in direct contact with the human body.

**Types of Tubes In Medical PVC:**

- Single-Lumen
- Co-Extruded
- Multi-Lumen
- Tapered or Bump Tubing
- Braided Tubing

## PVC in Blood Bag

- India Blood Bag Market size was estimated at **USD 51.82 Million in 2023.** During the period between 2024 and 2030, India Blood Bag Market size is projected to grow at a **CAGR of 5.23% reaching a value of USD 72.93 Million by 2030**
- India Blood Bag Market is bifurcated into **Collection Bag and Transfer Bag** segments. The collection bag segment holds a higher share in India Blood Bag Market by type. Collection bags are crucial in **blood donation** processes, designed for safe and hygienic blood collection across blood drives, banks, and automated procedures
- Based on volume, India Blood Bag Market is split into **PVC and PET** segments. The PVC segment holds a higher share in India Blood Bag Market and is expected to maintain its dominance. The **PVC segment holds a higher share** in the India Blood Bag Market and is expected to maintain its dominance by material during the forecast period
- Major players operating in India Blood Bag Market include **Terumo Penpol Pvt. Ltd., Mitra Industries Pvt. Ltd., Poly Medicure Ltd., HLL Lifecare Ltd., BL Lifesciences Pvt. Ltd., Innvol Medical India Limited, Imperial Biotech Private Limited, Fresenius Kabi India Private Limited, Advin Health Care, and Sai Kripa Enterprises.**

## Safety and Biocompatibility Concerns - Standards

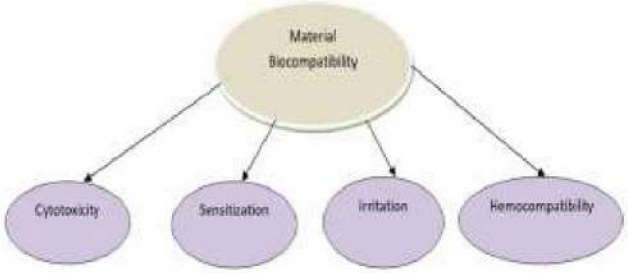
- **Biocompatibility:** A critical factor in the application of medical devices is biocompatibility. PVC compounds designated for medical purposes must comply with stringent biocompatibility standards to guarantee that they do not elicit adverse reactions upon contact with living tissues. ISO 10993 is a well-established standard that delineates the testing protocols and criteria for assessing the biocompatibility of medical devices.
- **USP Class VI Compliance:** The United States Pharmacopeia (USP) establishes standards for the quality, purity, strength, and consistency of medical products. PVC compounds utilized in medical devices frequently need to meet USP Class VI requirements, ensuring that the materials are non-toxic and appropriate for extended contact with bodily tissues.
- **ISO 13485:** This international standard outlines the requirements for a quality management system in the design, development, and manufacturing of medical devices. Manufacturers employing PVC compounds must comply with ISO 13485 to ensure the safety and effectiveness of their products.

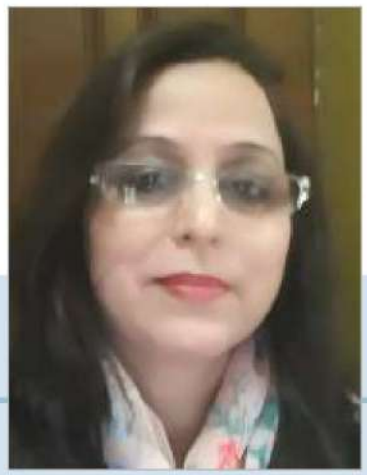

## Safety and Biocompatibility Concerns

- **Biocompatibility Requirements:** Medical PVC compounds must demonstrate high levels of biocompatibility, meaning they should not trigger adverse reactions when in contact with human tissues or fluids. This is critical for applications such as blood bags, IV tubing, catheters, and other implantable or skin-contact devices.
- **Leachables and Extractables:** Medical PVC compounds are scrutinized for leachable and extractables—substances that may migrate from the material under physiological conditions. Rigorous testing ensures that such substances are within safe limits, as uncontrolled migration can compromise drug efficacy

or cause toxic effects in the body.

- **Sterilization Compatibility** used in medical applications must remain chemically stable and functional after sterilization, whether by ethylene oxide (EtO), gamma irradiation, or steam autoclaving. Poorly stabilized compounds may degrade or release harmful by-products post-sterilization, affecting both safety and mechanical performance





# Emerging Trends for Use of Medical Plastics in IVD Industry : Opportunities & Challenges

**Dr. Usha Jain**
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**In Vitro Diagnostics (IVD)** refers to tests done on samples such as **blood or tissue** that have been taken from the human body. It is essential for **disease detection, monitoring & treatment decisions.** In recent years, the IVD market is experiencing significant growth due to advancements in **technology** & increased demand for **rapid diagnostics** due to **aging population,** rising **chronic disease prevalence** & advances in **personalized medicine.** A shift in **point-of-care (POCT) & home testing,** increasing **automation** & **digitization, AI** in diagnostics & more **stringent regulations** for plastic components are the major reasons for such a high surge in demand of medical plastics in recent years. Also, a growing demand for high-performance plastics that offer benefits such as **ease of sterilization, lightweight properties & enhanced functionality** for sophisticated diagnostic devices.

Various **categories of IVD Products** include **Clinical Chemistry Tests** that measure chemical components in bodily fluids (glucose tests, cholesterol panels, liver function tests); **Immunoassays that** detect specific proteins or antibodies using antigen-antibody reactions (e. g. pregnancy tests (hCG), thyroid function tests (TSH), infectious disease markers (HIV, hepatitis); **Molecular Diagnostics** analyses genetic material for mutations, pathogens, or gene expression (e.g. PCR tests for COVID-19, genetic testing for hereditary diseases, oncology panels); **Hematology Tests** assess blood components and functions ( e.g. complete blood count (CBC), coagulation tests (PT, APTT), hemoglobin levels); **Microbiology Tests** to Identify & characterize microorganisms causing infections (e.g. culture tests, antibiotic susceptibility tests, rapid strep tests); **Serology Tests** that helps to detect antibodies or antigens in serum (e.g. tests for HIV, hepatitis B and C, syphilis); **Point-of-Care Tests (POCT)** provide rapid results at or near the site of patient care (e.g. blood glucose meters, rapid influenza tests, COVID-19 antigen tests); **Companion Diagnostics** identify patients likely to benefit from a specific therapeutic product (e.g. HER2 testing for trastuzumab therapy in breast cancer) **Self-Testing Kits** allow individuals to perform tests at home (e.g. home pregnancy tests, ovulation predictors, HIV self-tests); **General Laboratory Use Products** support laboratory procedures without direct diagnostic claims( e.g. specimen receptacles, buffer solutions, general reagents)

Selection of appropriate **medical-grade plastic for In-vitro diagnostics (IVD)** manufacturing is a multifaceted process that ensures device safety, performance & regulatory compliance. Some of the critical criteria to consider when choosing plastics for IVD applications are as follows:

***Brief Introduction***

*She is a motivated senior scientist and manager with **27+ years of scientific leadership experience in Medical Genetics, Life Science, Biotechnology, Medical Device, Healthcare & Biobanking.** She possesses relevant experience in setting up processes, bring **technical expertise** to improve clinical outcome and implement new and **emerging technology** based **scientific research developments** for the **transformation of public health.** Her core competencies include intensive design & development of experiments and/or diagnostics, test validation/verification, budgeting, documentation, quality assessment and project management. It also includes guidance for procurement of cost-effective quality equipment and/or medical devices. She is well versed with **technical and scientific presentations, problem solving and troubleshooting.***

*She has helped set-up and expanded various lab facilities at **AIIMS, Sir Ganga Ram Hospitals, Gujarat Cancer & Research Institute, Gujarat University, Xcelris labs** etc from scratch. In recent past she has been a **technical & Communication expert for an Indo-German project** on medical devices, Jury to **JSS-DST startup schemes,** has also been a part of **accreditation team** for (ISO 20387,13485, 15189) as a technical expert at various institutes & laboratories ( e.g. **NLDB, New Delhi; CBR, IISc; THSTI, Faridabad & Karkinos, Kerela)***

**1. Biocompatibility**
The plastic must be non-toxic and should not elicit adverse reactions when in contact with human tissues or fluids. Compliance with standards like **ISO 10993 and USP Class VI** is essential to ensure materials are safe for their intended use.

**2. Sterilization Compatibility**
Materials should withstand common sterilization methods—such as **autoclaving, ethylene oxide (EtO) gas, e-beam or gamma radiation**—without degrading or losing **mechanical integrity** e.g. **polypropylene (PP) and polyetheretherketone (PEEK)** are known for their resistance to various sterilization processes.

**3. Mechanical & Physical Properties**
Depending on the application, plastics must exhibit appropriate **strength, flexibility, impact resistance & dimensional** stability e.g. polycarbonate (PC) offers high impact resistance & optical clarity, making it suitable for diagnostic equipment housings.

**4. Surface properties**
For many IVD applications, such as **microfluidics and immunoassays**, precise control over surface properties is essential. Untreated plastics often have a hydrophobic (water-repelling) surface, which can lead to bubble formation in microchannels or non-specific binding of proteins. **Surface modification techniques,** such as **plasma treatment,** are often required to control wettability & prevent fouling.

**5. Autofluorescence**
Some plastics, including **polycarbonate and polymethyl methacrylate (PMMA),** naturally emit light **(autofluorescence)** at certain wavelengths. This can interfere with fluorescence-based assays, Therefore, a careful material selection for optical application is essential.

**6. Microfluidic complexities**
Microfluidic devices rely on **complex microchannels** & the material selection is critical to their function. The properties of polymers—including chemical, thermal & mechanical characteristics—can greatly affect device performance, channel bonding, & reagent stability.

**7. Chemical Resistance**
When exposed to chemicals, disinfectants & bodily fluids, the selected plastic should resist degradation. Materials, like **polydimethylsiloxane (PDMS),** can absorb small molecules & proteins, affecting analytical accuracy. The presence of **leachables or extractables,** such as additives, from the plastic can also compromise assay results. Materials like **PEEK & polyphenylsulfone (PPSU)** offer superior chemical durability, ensuring long-term performance in harsh medical environments.

**8. Regulatory Compliance**
Materials must meet regulatory standards such as **FDA regulations, ISO 13485,** and other guidelines like **Central Drugs Standard Control Organization (CDSCO)** etc. Ensuring that the plastic complies with these standards is crucial for market approval & patient safety.

**9. Purity & Traceability**
Medical-grade plastics should be free from **contaminants** & have consistent **quality across batches.** Traceability is vital for quality control & in the event of recalls.

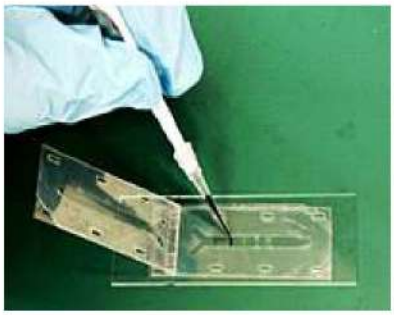
**10. Processability**
The plastic should be compatible with **manufacturing processes** like **injection molding** (for producing complex shapes with high precision); **blow molding** (for creating hollow containers like bottles) or **extrusion** (for making tubes & sheets); **thermoforming** (for creating trays & packaging). Good processability ensures efficient production & consistent quality of IVD components.

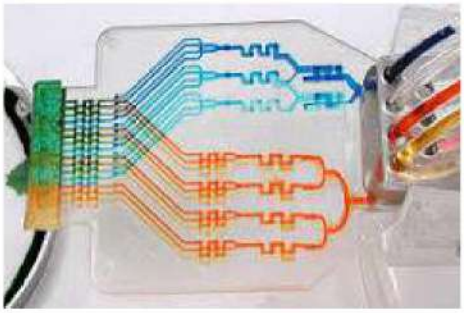
**11. Cost-Effectiveness**
While ensuring all the above criteria, the material should also be cost-effective, balancing performance with **budget constraints.** Sometimes, investing in higher-quality materials can reduce long-term costs by minimizing **failures & recalls.**

The most commonly used plastics in IVD devices are - **Polyethylene (PE)** known for its inertness & flexibility, used in fluid handling systems, catheters & diagnostic packaging; **Polypropylene (PP)** because of its chemical & steam sterilization resistance, it's used in test tubes & housing & packaging; **Polycarbonate (PC)** having high impact resistance & transparency, makes it suitable for components like lenses & devices that need to withstand high temperatures or radiation sterilization; **Polystyrene (PS),** a common material for petri dishes, diagnostic slides & vials, used for its optical clarity, rigidity & low cost; **Acrylonitrile Butadiene Styrene (ABS),** a rigid & tough thermoplastic, used for structural parts of devices & components where good chemical resistance is required; **Polyvinyl Chloride (PVC)** used in flexible forms for fluid containers & tubing, PVC's transparency is beneficial for monitoring fluids & gases within IVD devices; **Nylon (Polyamide)** due to tensile strength, abrasion & chemical resistance used in fluid dispensing systems & laboratory tubing, benefiting from its durability & flexibility; **Polymethyl Methacrylate (PMMA),** transparent, UV resistant & durable applied in incubators & viewing windows, where clarity & durability are essential; **Polyurethane (PUR),** flexible, strong, & biocompatible used in implant devices, feeding tubes, dialysis devices, and surgical drains, owing to its compatibility with the human body & resistance to wear; **Polyether Ether Ketone (PEEK),** high mechanical strength, thermal stability & chemical resistance, ideal for high-performance medical applications requiring durability & biocompatibility.

Globally, **IVD devices** developed & produced for **commercial**

**market** are regulated by **national authorities** to ensure their effectiveness & safety for use. In most countries, these devices are classified based on their **potential risk to patients** if the **diagnosis is inaccurate** & the level of control needed to ensure their safety. **Based on their classification,** devices will have to go through different **premarket processes** so that they can be **safely introduced** to the market.





**Compliance with regulatory requirements** is crucial for the **successful development** & **commercialization of IVD devices.** These **regulatory bodies** provide **guidelines & standards** that manufacturers must follow to ensure their products are safe &effective. Different countries have their own regulatory bodies and frameworks governing IVDs. In the **United States,** the **FDA** regulates IVDs under the **Federal Food, Drug, and Cosmetic Act (FD&C Act).** In **Europe,** the regulation of IVDs is governed by the In **Vitro Diagnostic Medical Devices Regulation (IVDR),** which replaced the **previous In Vitro Diagnostic (IVDD).** Despite challenges related to regulatory complexity, time and cost, data requirements, global harmonization & balancing innovation with regulation, a proactive & strategic approach enables manufacturers to ensure compliance & market their IVDs successfully. By adhering to regulatory standards, companies can contribute to improved patient outcomes, advance public health & foster trust in diagnostic technologies.

Though medical plastics have become a staple in IVD products as they are crucial for one-time use but this linear **"take-make-dispose"** economic model, where IVD products are used once & discarded, is fundamentally unsustainable. Therefore, designing IVD devices & packaging with recyclable or bio-based materials is a growing trend. The microfluidics market is now also taking advantage of the benefits of **polymer technology. Microfluidics** – often called **lab-on-a-chip technology** – involves the handling and manipulation of tiny amounts of liquid in scientific research & life sciences. Microfluidic **'chips'** are made up of networks of micro-channels & reservoirs that are moulded or patterned to control fluids. These innovations like **reusable diagnostic systems, microfabrication processes & point-of-care testing** can reduce material & energy consumption.

***To conclude, medical plastics are integral to the advancement of the IVD industry, offering versatility, efficiency & innovation. Ongoing research & development are essential to address current challenges & harness new opportunities.***

# Test Your Personal Protective Equipment (PPE): Ensure Quality And Safety

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Personal protective equipment (PPE) can be defined as anything that protects the body or body part of the wearer from a potential hazard or infection. PPE protects the wearer from threats posed by fire, chemicals, electricity, biological agents, and other sources. People working in areas involving hazardous chemicals, biological specimens, and microorganisms must wear adequate PPE for their protection. Gloves, helmets, masks, goggles, head covers, boot covers, and other similar items are common types of PPE that we frequently encounter. Unlike other sectors, the medical/healthcare sector faces stringent risks from various hazards, and hence, the usage of PPE is mandatory. In the healthcare field, PPE plays a crucial role by providing a barrier between patients, medical staff, and even the public to help them avoid contact with blood and bodily fluids or contaminated airborne particles, limiting the epidemic spread of pathogens. There's a huge demand for PPE globally as it's an inevitable requisite to safeguard people from occupational health hazards. As per the report of Fortune Business Insights, the global PPE market size is projected to reach USD 85.72 billion by 2026, at a CAGR of 7.3% during the forecast period.

PPE deployed in the healthcare sector is often made of synthetic polymers such as polypropylene (PP), poly(ethylene), polyesters, polyamides, etc. Among them, non-woven PP is the most commonly used raw material for the development of medical PPE fabrics, such as gowns, coveralls, surgical masks, and air/water filters. The hydrophobic nature of the polyolefin network, along with breathability and light weight, made PP a suitable candidate for PPE used in critical areas. Their hydrophobicity prevents the penetration of blood or body fluids of patients during treatments, and breathability provides comfort to the wearer in critical environments. Non-woven PP is also found to be suitable for developing air/water filters to maintain the quality of air and water in the healthcare sector. PP-based filter membranes are commonly used in surgical masks and ventilators. They could also be used as antimicrobial filters by suitable surface modification or by electrostatic charge generation.

As the role of PPE is too critical to maintaining the well-being of civil society, there should be adequate quality checks to ensure the suitability of the PPE being used. To be introduced in the public market, international standards set some benchmark qualities that PPE should meet.

Medical PPE, such as face masks, goggles, face shields, helmets, gowns, shoes, gloves, etc., should also meet specific benchmarks. They must be evaluated in line with international standards to ensure that they are qualified for the assigned purpose. The intention of PPE usage became fruitful only if the products had an acceptable quality. The end-user must verify whether the product complies with the quality standards before planning to use it. Poor quality or substandard items may create additional risks or disease conditions. Different types of PPE should pass specific tests to meet their quality standards. Details of necessary quality tests for each category of PPE are listed in Table 1 below.

Table 1. Tests applicable to various PPEs and reference standards

| Type of PPE | Name of the tests applicable | Reference standards |
|---|---|---|
| Surgical/ examination gloves | Dimension (length, width), freedom from holes, water tightness test, tensile strength, force/elongation at break, extractable protein from natural rubber gloves using the Lowry assay | EN 455-1,2 and 3 ASTM D3577, ASTM D412, ASTM D573 |
| Masks | Resistance to Penetration by Synthetic Blood, Bacterial Filtration Efficiency, Particulate Filtration Efficiency | ASTM F1862, IS 16289, ISO 16603, ASTM F2101, IS16288, ASTM F2299 |
| Protective clothing | Seam strength, resistance to penetration of chemicals and liquids, puncture resistance, trapezoidal tear resistance, Tensile strength, and burst strength<br>Resistance to Penetration by Synthetic Blood<br>Moisture vapor transmission rate (MVTR) | IS 17334, EN 13795-1, EN 29073-3, BS EN ISO 9073-4, ISO 139, ASTM D1776, ASTM D2261, IS 1966-1, ASTMD5733 ASTM F1670, ASTM F903, ISO 16603 ASTM E96, ASTM D1653, ISO 7783. |

CAF has been offering various tests for the quality evaluation of PPE for several years. Some of them are detailed below.

**1. Tensile strength of protective surgical clothing**

Surgical clothes are the inevitable protective barriers of clinicians to safeguard them while treating patients with a wide range of ailments. They include gowns, drapes, scrubs, surgical face masks, and other protective wear. The Indian standard IS 17334 and the European standard EN 13795-1 discuss the specification and performance requirements of surgical clothing, such as gowns and drapes. These standards also provide guidelines about the tests that need to be performed to ensure the quality of protective clothing, and tensile strength is among them. As

per the standard, the protective clothing should have a tensile strength greater than or equal to 20 N in both dry and wet conditions. The standard also indicates that the tensile strength analysis should be done in lateral and longitudinal directions following EN 29073-3.

Fig. 1. Tests of Personal protective equipment for medical use.

EN 29073-3 outlines the details of tensile testing. The PPE samples to be tested have to be prepared and conditioned before testing as per the international standards (ASTM D1776 and ISO 39). After conditioning, the specimens shall be tested using a calibrated UTM. Take note of the maximum breaking strength of the specimen in newtons (N), and the elongation corresponding to the ultimate breaking strength is recorded as the percentage of the nominal gauge length. For recording the tensile behaviour of wet specimens, the specimens have to be incubated in an aqueous solution of a non-ionic surfactant for a specific time period. After wetting, the specimens shall be analyzed immediately.

**2. Tear strength of protective clothing**

Tearing strength or Tear resistance is an important parameter to represent the quality of fabrics. It is defined as the resistance of the material against tearing. There are many methods adopted for evaluating the tearing strength of fabrics. Single Rip (tongue) procedure as per ASTM D2261 is among them. It is mainly used to analyze textile fabrics, knit fibers, blankets, bag fabrics, non-woven fabrics, etc. The trapezoidal method (as per EN ISO 9073-4 or ASTM D5733) is another important method used for estimating the tear resistance of non-woven fabrics like PPE.

Before testing, the samples will be conditioned as per ISO 139. Properly cut specimens as per standard dimensions will be secured in the UTM for analysis and extended at the specified extension rate given by the standard. The maximum force (if only one peak is present), or the average of 5 maxima (if more peaks are present) in Newtons, will be reported as the tear resistance of the sample.

**3. Bursting strength of PPE using UTM**

This test is used to assess the capability of the fabric to withstand pressure when a force is applied. IS 1966-1 and EN 13795 outline the burst strength determination of medical fabrics under wet and dry conditions, and give a threshold value of 40 kPa as the limit to qualify the requirement under different conditions. ASTM D3787 also describes the test method for the bursting strength of fabrics using the UTM, ball-burst test. This method employs a polished steel ball probe with a diameter of 25 mm to estimate the burst strength of fabrics.

**4. Synthetic blood penetration test**

The PPE used by the healthcare workers should be capable of resisting the penetration of blood and body fluids, spilled during the treatment of patients. The synthetic blood penetration test is one of the inevitable tests to evaluate the quality of PPE for medical use (ISO 16603). ASTM F1670 outlines the method to assess the resistance of PPE fabrics to the penetration of synthetic blood. As per the standard, the synthetic blood penetration tester should have a cell having a 50 ml volume capacity, and capable of holding the test specimens of specific dimensions. Once the sample is kept intact, the cell needs to be filled with 50 ml of synthetic blood (surface tension of 40±5 mN/m) prepared by dissolving an organic dye, Direct Red 81, and some thickening agents in water as per the ASTM F1670. After filling the cell with synthetic blood, the specimen should be kept for 5 minutes at 0 kPa (0 psi). Then apply a pressure of 13.8 kPa (2 psi) for 1 minute and keep the specimen at 0 kPa (0 psi) for 54 minutes. In this procedure, if no retaining screen is applied, it's called a type A procedure, and if one screen is used, it's termed type B. If the material allows synthetic blood penetration during the testing period, it is said to be failed and otherwise passed the test. It's mandatory to report the thickness and weight of the specimen along with the penetration test results.


Fig. 2. Synthetic blood penetration test of PPE.

**5. Water vapor transmission rate**

Water vapor transmission rate (WVTR) is another critical test to ensure the quality of protective clothing. ASTM E 96 outlines the determination of the WVTR of materials. This method is limited to materials with thicknesses up to 32 mm only. A desiccant approach or a water approach can be adopted for the analysis. Water vapor permeance is the time rate of water vapor transmission through a unit area of flat material or construction induced by a unit vapor pressure difference between two surfaces under specific temperature and humidity conditions. It's also known as the moisture vapor transmission rate (MVTR). High WVTR is desirable for spaces or situations likely to be wet. It's mainly because adequate evaporation and breathability ensure fast drying. Similarly, materials with low WVTR are required to protect equipment sensitive to moisture. For PPE in workplaces, sweat evaporation is a foremost requisite for which high WVTR is favored. Physical discomforts such as being too hot, sweaty, and too stiff are the major complaints received from PPE users. So, the PPE materials should have adequate WVTR to ensure the comfort of the wearer.

Payne permeability cups (Elcometer 5100) with a volume

capacity of 50 mL and an area of 30 cm2 are usually employed for the estimation of WVTR as per ASTM D1653, ASTM E96, and ISO 7783. The water vapor transmission rate of the sample in grams per square meters per day (g/m2.d) can be calculated as,

$$WVTR = 240 \times \Delta m/A$$

Where Δm is the rate of change of mass in mg/hours and A is the area in square centimeters. A for Elcometer 5100/2 is 30 cm2.

**6. Tensile tests for medical gloves**

The requirements and testing of physical properties of medical gloves for single use are outlined in the standard EN 455-2. The tensile strength of the gloves is one of the critical material properties, and it can be measured using the universal testing machine. As per this standard, the glove specimens should be tested at a temperature of 23±2° C and a humidity of 50±5 %. The properties of samples should also be checked after aging as per the standard EN 455-4 (70 ±2 °C for seven days). For testing a lot of gloves, the standard recommends the analysis of 13 dumbbell specimens (from 7 pairs of gloves) cut as per the standard dimensions. Condition the specimens for at least 16 hours and test using the UTM equipped with a suitable load cell and firm grips by extending the specimens at a 500 mm/min crosshead speed. As per EN 455-2, all surgical gloves should possess a median force at break greater than or equal to 9.0 N before and after aging. 6.0 N and 3.6 N are the acceptable limits of examination/procedure gloves and gloves made of thermoplastic polyvinyl chloride or polyethylene, respectively.

ASTM D3577 is another international standard that describes the requirements of rubber surgical gloves. As per this standard, five specimens of each glove sample should be cut using a standard dumbbell die (type C is preferred) and tested using the universal testing machine at 23±2° C and a humidity of 50±5 % at a crosshead speed of 500±50 mm/min as per ASTM D 412. For accelerated aging, the specimens can be subjected to 70 ±2 °C for 166 ±2 hours or 100 ±2 °C for 22 ±0.3 hours as per ASTM D573. The natural rubber gloves must have a minimum tensile strength of 24 MPa and an ultimate elongation greater than 750% before aging. The acceptable values after accelerated aging are 18 MPa and 560 %, respectively. Compounded or synthetic rubber gloves should have tensile strength and elongation of 17 MPa and 650% before aging and 12 MPa and 490% after aging. The test conditions, such as temperature, humidity, and crosshead speed, specimen dimensions, and aging criteria, are similar in both standards. The major difference is in considering the mean or median values of forces or tensile strengths for acceptance.

The Central analytical facility, a CDSCO-approved medical device testing facility in the BMT wing campus of SCTIMST, can offer the testing of various personal protective equipment, medical devices, and biomaterials in line with international standards. For your testing-related queries, please contact the **customer service cell, csc@sctimst.ac.in**

# Biomaterial and Medical Device Testing Services at SCTIMST

The medical device industry in India is one of the fastest-growing sectors in the country and plays a critical role in the healthcare ecosystem. As India's healthcare needs grow due to its large and diverse population, rising income levels, and an increasing focus on quality healthcare, the medical device industry is poised for significant expansion. We depend on imports for about 70-80% of our huge medical device demand.

To ensure the quality and performance of the medical devices, the testing and evaluation of medical devices and the biomaterials used are inevitable. The **Central Analytical Facility (CAF) at the Biomedical Technology Wing of Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST)** offers test services to evaluate the physicochemical properties of biomaterials and medical devices as per international standards. All testing activities of CAF are in line with ISO 17025:2017. Two tests offered by CAF, viz. compositional analysis of materials using thermogravimetric analysis (TGA), and determination of transition temperatures and corresponding enthalpy changes of materials using differential scanning calorimeter (DSC) are NABL accredited. The testing services of CAF are open to all customers through the customer service cell (CSC).

CAF offers the following tests for the customers.

- Material identification using spectroscopic analysis
- Alloy Identification using XRF
- Compositional analysis using TGA
- Residual solvent analysis
- Residual monomer analysis
- Residual plasticizer analysis
- Residual ethylene oxide analysis
- Residual cross-linker analysis
- RoHS compliance testing using XRF
- Extractable & leachable analysis
- Drug estimations
- Molecular weight estimation of polymers
- Corrosion analysis
- Crush resistance of devices
- Compression characteristics of devices
- Compression characteristics of dental materials
- Adhesiveness of patches
- Muco-adhesion of wound dressings
- Pealing force of adhesives
- Injectability/syringeability of bio-inks
- Burst strength of vascular graft
- Tensile analysis of PPE, films, sutures, tissues, and packaging
- Tear strength of PPE
- Water vapor transmission rate of PPE and wound dressings
- Synthetic blood penetration test of PPE
- Pasting strength and viscosity analysis of biopolymers
- Viscoelastic studies using compact rheometer
- Luminescent imaging of tissues, slides
- Raman chemical mapping, etc.

Besides testing, CAF organizes technical sessions for the benefit of students, researchers, and teachers. CAF is happy to provide technical advice and guidance to customers on their analytical needs.

For further information on tests and services offered, please contact:

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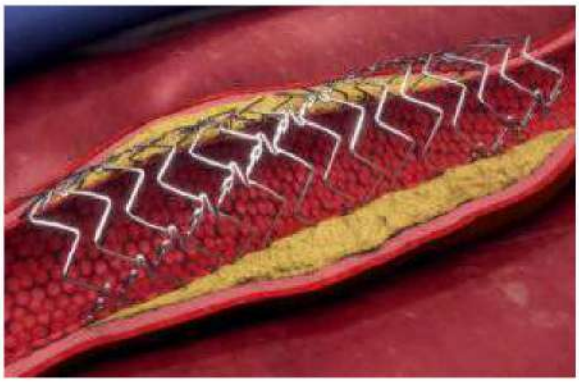
Website:https://www.sctimst.ac.in/About%20SCTIMST/Departments%20and%20Divisions/BioMedical%20Technology%20Wing/Central%20Analytical%20Facility/

# Bioabsorbable Polymer Based Medical Devices

## Understanding Bioresorbable Polymers

Bioabsorbable polymer-based medical devices are implantable materials that degrade and are safely assimilated by the body over time, eliminating the need for a second surgery for removal, thus reducing patient discomfort and healthcare costs. They are commonly used in medical devices such as stents, sutures, and drug delivery systems. Popular examples of these polymers include polylactic acid (PLA), polyglycolic acid (PGA), and polydioxanone (PDO).



## Advancements in Medical Devices

The development of innovative medical devices is a major driver of the bioresorbable polymers market. Technologies such as bioresorbable stents and scaffolds are transforming cardiovascular and orthopedic treatments. These devices provide temporary support to the body's tissues and gradually dissolve, reducing the need for additional surgeries and improving patient outcomes.

## Rising Demand for Minimally Invasive Procedures

The shift towards minimally invasive procedures is fueling the growth of bioresorbable polymers. These materials enable the creation of devices that can be inserted through small incisions, minimizing tissue damage and recovery time. Bioresorbable polymers are increasingly used in endoscopic procedures, laparoscopic surgeries, and other minimally invasive techniques.

## Growing Applications in Drug Delivery Systems

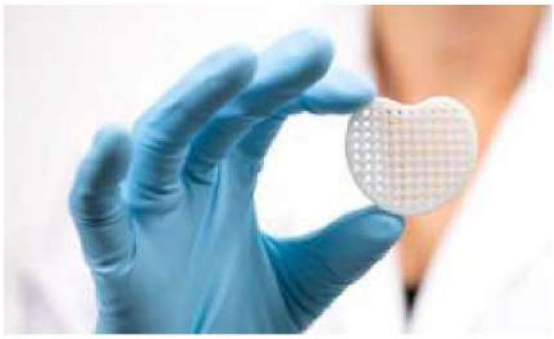
Bioresorbable polymers are gaining traction in drug delivery systems due to their ability to provide controlled release of therapeutic agents. These polymers can be engineered to release drugs over a specific period, improving the efficacy of treatments and reducing the need for frequent dosing.

## Focus on Patient Comfort and Safety

The emphasis on patient comfort and safety is driving the demand for bioresorbable polymers. By eliminating the need for implant removal surgeries, bioresorbable materials enhance patient comfort and reduce the risk of complications associated with permanent implants.

## Types of polymers

- **Synthetic:** Polydioxanone (PDO), polyglycolide-co-lactide (PGLA), polylactic acid (PLA), and polycaprolactone (PCL) are common examples.
- **Natural:** Some devices incorporate naturally-derived polymers like collagen.
- **Blends:** Advanced polymers are engineered by combining different types to achieve specific properties, such as a desired degradation rate or mechanical strength.



## Manufacturing and processing

- **Extrusion:** Polymers can be extruded into fibers, yarns, and films.
- **Textile-based:** They can be used to create knitted and braided structures for applications like sutures and meshes.
- **3D Printing:** Additive manufacturing allows for the creation of complex 3D parts with precise geometries.

# SABIC & Zuyderland Collaborate To Drive Circularity For Hospital Plastic Waste, Presenting Closed Loop Pilots With Ecosystem Partners

Amsterdam, The Netherlands, October 7, 2025 - SABIC, a global leader in the chemical industry, has collaborated with Zuyderland medical center in The Netherlands to help transform medical plastic waste into new contact sensitive packaging materials. In collaboration with converters, Coveris and ACE, and brand owners Artivion and Mölnlycke Health Care, the SABIC and its project partners have successfully proven the concept of recycling used medical plastic back into the medical materials stream in two innovative pilot projects.

Staff at Zuyderland launched a medical plastic waste collection program in June 2024 to help address unmet needs and challenges of plastic waste that would otherwise be incinerated. The program consists of a novel collection system for non-contaminated plastic waste that has not come into contact with patients, blood, or bodily fluids. With the support of specialized transport company L'Ortye, the plastic waste was prepared and transported to SABIC to be converted into pyrolysis oil leveraging advanced recycling processes. SABIC then used this alternative feedstock to produce virgin-like certified* circular polyethylene (PE) from its TRUCIRCLE™ portfolio.

The new certified circular TRUCIRCLE PE has subsequently been used in two new healthcare applications:

- Coveris produced packaging with 25% content attributed to recycled medical waste[1] for Artivion's guide wire used in vascular surgery.
- Mölnlycke Health Care produced surgical drapes with 49% content attributed to hospital-generated plastic waste* to be delivered in the ProcedurePak® solution made with semi-finished product by ACE.

Khaled Al- Jalawi, Global Circular Economy Director at SABIC stated: "We are excited about this pioneering circular business model pilot, which showcases the potential of circular plastic innovations when leading actors from across the medical ecosystem closely collaborate. Non-contaminated medical plastic waste represents a valuable feedstock opportunity, and SABIC TRUCIRCLE solutions could play a major role in advancing circularity in healthcare."

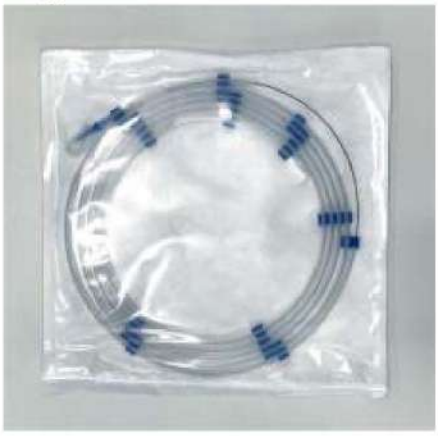
Roel Goffin, board member at Zuyderland, said: 'We are very proud of this breakthrough after bringing together leading partners in the value chain. Our own non-contaminated medical plastic waste has been successfully turned into new material and returned for use in our own operating rooms."

The collaboration also has the academic backing from Maastricht University, who has recently been awarded an Interreg EU grant for a 3-year project to help drive 'Circular Transformation of Health and Care Systems in the Meuse Rhine Region' with partners including SABIC and Zuyderland.

*https://www.pressreleasefinder.com/pr/SABICPR755/en/*

*SABIC and partners have successfully demonstrated the potential of recycling non-contaminated hospital waste back into virgin polymers that can met stringent healthcare applications.*

*Mölnlycke ProcedurePak® including surgical drapes produced by ACE, containing 49% recycled hospital-generated plastic waste, attributed using the mass balance approach.*



*Artivion's E-wire is used in catheter-based diagnostic and interventional procedures, sealed in packaging from Coveris produced with 25% content attributed to recycled medical waste using the mass balance approach.*


# Vietnam Medical Devices Market

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

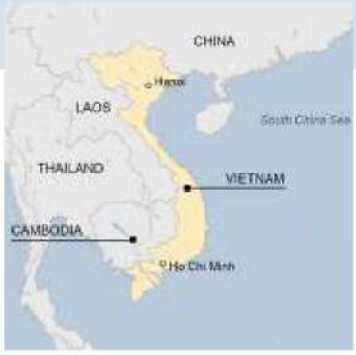
After covering practically all the major markets of Latin America, we will now shift our focus to the Asia Pacific region again, starting from this issue of the magazine.

## Country Profile

Vietnam is one of the fastest-growing economies of the Southeast Asian region. High levels of corruption and political control are also recorded in Vietnam. Since 1975, it has been a unified country. After bitter wars for three decades, the people fought against the colonial power of France and, after that, against South Vietnam, backed by the USA. For some years in the past century, Japan had also controlled Vietnam. There was little economic growth for over a decade after peace was established, mainly because of its political isolation, policies, and human rights violations. Since 1986, the policy has changed, and there has been strong economic growth. Vietnam now maintains a good political balance between the USA and Chinese influences. The capital city of Vietnam is Hanoi. The commercial capital, however, is Ho Chi Minh City (formerly Saigon). The population of Vietnam is about 10 crore. There are common land borders with China, Laos and Cambodia, while Vietnam shares maritime borders with Thailand, the Philippines, Indonesia, and Malaysia through the Gulf of Thailand and the South China Sea. Vietnam is a developing country with a lower-middle-income economy. Temperatures are considerably higher in southern plains (Ho Chi Minh city), while in Hanoi and the surrounding areas of the Red River Delta, the temperatures are lower (between 15 and 33 °C.), with occasional snowfalls over the highest peaks of the mountains near the Chinese border. Many areas receive heavy rains, like 150 to 200 cm per year. Storms in the areas next to the coast are also common.

## Medical Device Registration in Vietnam

IMDA (Infrastructure and Medical Device Administration) is the Medical Device regulation authority in Vietnam, under the Ministry of Health (MOH). The Medical Device registration requirements in Vietnam are currently in a state of flux,




which must be noted. The medical device classification system in Vietnam has the same four classes based on the risk involved:

- Class A (low risk)
- Class B (low-medium risk)
- Class C (medium-high risk)
- Class D (high risk)

Class A and Class B review processes are immediate, and the cost for all the classes is less than 250 USD (based on the exchange rates prevailing), which is not costly comparatively. For Class C and D products, though the prescribed time for registration is three months, in reality, it takes a year or more (as experienced in India sometimes). The Medical Device registration requirements in Vietnam are currently in a state of flux, which needs some more explanation. A set of new rules governing the registration of medical devices was published in November 2021. A 1-year transition period for documentation and some Class C and D products was provided at that time. However, since then, very few Class C and D product approvals have been issued, and old valid Import Licenses were extended under auto-renewal till December 31, 2024, via a fresh decree. Now again, the extension is granted till June 30, 2025. Readers are advised to read the latest changes or get information through their representatives in Vietnam for the changes after June 2025. The first step toward regulatory compliance is to identify the Class of product based on its risk

### Highlights

- High-growth market
- Low-cost registrations
- Very high imports and imports encouraged


level and use. The changing laws give a window where the requirement states a need for only administrative documents (and no technical file). There is a fairly long list of Class C and D products which can be given auto-approval. Both these points should also be checked with the local distributors.

## Medical Devices Market

A remarkable transformation of Vietnam from one of the world's poorest countries to a lower-middle-income country (GDP per capita of USD 4,086 in 2022) has also affected the healthcare market. The medical device market was estimated to be at 1.5 billion USD in 2022, with a growth forecast of 9.7% CAGR for the 2021-2026 period. The key market growth drivers are an ageing population (which will rise by 2 % in the last ten years), improving living standards (healthcare spending surged by nearly 25 per cent in recent years), and growing healthcare awareness (through improved education and internet access). Public hospitals dominate the healthcare system due to the socialist political system. These public hospitals account for 86% of the total number. These hospitals are upgrading their facilities and opening new departments for speciality treatment, providing opportunities. More than 90% of medical equipment in Vietnam is imported, and the authorities encourage the import of medical equipment because local production is not sufficient for the demand.

## Opportunities and Challenges

Market growth, very high import reliance and comparatively low registration cost are the biggest opportunities in this market, which appears highly prospective for the future. There is a golden ring (Indian distributors) in the market, and this can also be a positive factor. Registration through a consultation with transferability is also an opportunity. Local language is the only challenge, but not a big one.

**FAST FACTS**

While the outlook for medical device companies appears positive, the days of simply manufacturing a device, and selling it to healthcare providers via distributors, have long vanished. Value is the new byword for success, prevention the preferred clinical outcome and intelligence the new competitive advantage.


# ICMR Opens Opportunities For Start-ups And MSMEs In Medical Devices Sector

The initiative aims to help innovators refine these devices for large-scale production, prepare them for commercial use, and strengthen India's MedTech ecosystem in the process

To boost local manufacturing of medical devices and diagnostics, the Indian Council of Medical Research (ICMR) has invited start-ups, research institutes, and non-governmental organisations (NGOs) to make small-scale versions of their devices. The initiative aims to help innovators refine these devices for large-scale production, prepare them for commercial use, strengthen India's MedTech ecosystem, and improve preparedness for infectious diseases.

ICMR, under the Department of Health Research, is rolling out this support for test-batch manufacturing of indigenous devices and diagnostics, including software as a medical device, as part of its alignment with the government's Viksit Bharat@2047 vision.

The council had launched initiatives such as MedTech Mitra and Patent Mitra to guide the development of health technologies addressing national priorities. The latest effort is meant to bridge the gap between prototypes and full-scale production by funding and facilitating test batches that comply with regulatory standards.

Start-ups, micro, small and medium enterprises (MSMEs), Department of Scientific and Industrial Research (DSIR)-recognised research and development centres, medical colleges and registered NGOs can seek the opportunity, provided they hold or obtain an MD-13 test licence, which is the Medical Device Test Licence under the Drugs and Cosmetics Act, 1940.

According to ICMR, this step will allow innovators to validate quality, reduce scale-up issues, and accelerate preclinical and clinical evaluations. The Indian medical devices industry is expanding steadily. According to the India Brand Equity Foundation (IBEF), the sector was valued at $12 billion (Rs 1,02,660 crore) in FY24 and has been growing at a compound annual growth rate (CAGR) of around 15 per cent in recent years. A separate estimate by EY projects that the market could touch US$ 50 billion by 2030, supported by rising demand, favourable policies, and infrastructure improvements.

The diagnostics devices segment is also expected to see sharp expansion. Market Research Future estimates that it was worth $2.99 billion in 2024 and could grow to US$ 17.74 billion by 2034, implying a CAGR of nearly 19.5%, driven by preventive healthcare, early detection, and wider availability of diagnostic services.

Meanwhile, demand for quality and regulatory compliance is spurring growth in device testing. Grand View Research estimates that the Indian market for medical device testing services stood at $781 million in 2024, and could reach $1.41 billion by 2030, growing at a CAGR of about 10.4%.

"ICMR's drive to back Indian start-ups and innovators and teaming them with established large players puts locally made medical devices on the world map—powering Make in India and turning affordable health technology into India's next global export story," said Rajiv Nath, Forum Coordinator of the Association of Indian Medical Device Industry (AiMeD).

"A streamlined project management agency, a stronger focus on commercialisation, and procurement provisions rewarding innovation without creating monopolies would further strengthen the sector," he added.

*(Sep 17, 2025 .https://www.businesstoday.in/industry/pharma/story/icmr-opens-opportunities-for-start-ups-and-msmes-in-medical-devices-sector-494348-2025-09-17)*

# India EFTA TEPA Excludes Medical Devices

The India-EFTA Trade and Economic Partnership Agreement (TEPA) is a free trade agreement signed on March 10, 2024, between India and the European Free Trade Association (EFTA) countries: Switzerland, Norway, Iceland, and Liechtenstein. The agreement, which took effect on October 1, 2025, includes a first-time commitment to link investment and job creation to an FTA, with India expecting EFTA to invest around $100 billion and create 1 million jobs.

It explicitly excludes medical devices from tariff concessions to protect domestic industries. This exclusion is part of India's strategy to safeguard sensitive sectors like pharmaceuticals, dairy, and agriculture, and it aligns with its focus on supporting its Production Linked Incentive (PLI) schemes.

- **Exclusion mechanism:** The agreement specifies that sensitive sectors, including medical devices, will not receive duty concessions or tariff reductions.
- **Strategic protection:** This exclusion is a deliberate measure to protect the domestic medical device industry from external competition.
- **Alignment with policy:** It is consistent with India's cautious approach to trade and its efforts to maintain strategic policy flexibility over health-related goods and protect sectors driving domestic manufacturing and healthcare.
- **Other excluded sectors:** Other sensitive sectors protected by the agreement include pharmaceuticals, dairy, processed foods, and certain agricultural products.

# Industry Bodies Welcome CDSCO's Draft Guidance On Medical Device Software

New Delhi, Oct 22 (IANS) Industry bodies on Wednesday welcomed the draft guidance on medical device software issued by the Central Drugs Standard Control Organisation (CDSCO).

Medical device software is software that is either integrated into a hardware medical device (Software in a Medical Device or SiMD) or operates independently as a standalone application for medical purposes (Software as a Medical Device or SaMD).

The CDSCO, in an official notice on Tuesday, shared the draft of the guidance document to bring more clarity on regulatory aspects of medical device software and to align the requirements with best global practices.

"This guidance document provides scope, definition, classification, standards, requirements of technical documents, and Quality Management system applicable for Medical Device


Software. The applicants may refer to the documents during submission of application for grant of licence to manufacture or import Medical Device Software for sale and distribution in the country," Rajeev Singh Raghuvanshi, the Drug Controller General of India (DCGI), the head of CDSCO, in the notice.

Medical device software is used for diagnostics, treatment, and patient monitoring, and is subject to strict regulatory standards to ensure patient safety and effectiveness.

"We welcome the updated revised Government's draft guidance note on Software as a Medical Device (SaMD) as a timely and progressive step towards strengthening India's regulatory ecosystem. With digital health solutions playing an increasingly critical role in patient care, it is essential that our regulatory framework ensures both patient safety and innovation," Rajiv Nath, Forum Coordinator, Association of Indian Medical Device Industry (AiMeD)

Nath also proposed hosting a webinar to educate stakeholders and invite feedback, to align India's framework with the International Medical Device Regulators Forum (IMDRF) and other global best practices.

"This will ensure patient safety while enabling Indian innovations to thrive internationally," he added.

The Medical Technology Association of India (MTaI) also welcomed the draft guidance document and commended CDSCO for its proactive step in framing a comprehensive regulatory framework for SiMD and SaMD, including artificial intelligence (AI), machine learning (ML), and cloud-based medical applications.

"This draft guidance reflects CDSCO's commitment to keeping pace with the fast-evolving landscape of digital health technologies. By providing clarity on definitions, classification, and quality management requirements, it creates a foundation for safe, innovative, and globally competitive MedTech software solutions from India," said Pavan Choudary, Chairman, MTaI.

MTaI also suggested streamlining compliance requirements for low-risk SaMDs to ensure regulatory proportionality and ease of implementation; aligning technical and quality standards with global best practices; and providing greater clarity on clinical evaluation protocols and algorithm change management, particularly for AI/ML-based medical devices.

*(https://ianslive.in/industry-bodies-welcome-cdscos-draft-guidance-on-medical-device-software--20251022172107)*

## Dop Rolls Out Sensitisation Programmes to Guide Pharma, Medtech Industry on Amended PRIP Scheme

The Department of Pharmaceuticals (DoP) has initiated a series of sensitisation programmes to guide the pharma and medtech industry for smooth and seamless application on the revised Promotion of Research and Innovation in Pharma-MedTech Sector (PRIP) scheme amended recently.

The programmes have been designed to give a clear understanding of the PRIP revised scheme's structure, eligibility and ?funding support, walk through of the application form step by step and clarify doubts and answer queries to ensure a smooth application process.

The DoP has given deadline to register on PRIP Portal by November 3, 2025 and deadline for application submission by November 10, 2025.

While inviting applications, the DoP has notified amendments to the scheme and issued revised guidelines with a view to enhance the impact of the scheme and make it better suited to address the requirements of all stakeholders. The application window had opened on October 1, 2025 through a dedicated portal (https://prip.pharma-dept.gov.in) to drive a fully digital application process.

The PRIP scheme has been revised to increase financial support and streamline assistance for MSMEs and startups. With an approved outlay of Rs. 5,000 crore, the scheme is expected to catalyse a Pharma-MedTech innovation pipeline by supporting around 300 projects involving total R&D investment of about Rs. 11,000 crore in new medicines, complex generics, biosimilars and novel medical devices.

Under the amended scheme, for early stage projects, MSMEs and startups may apply for projects costing up to Rs. 9 crore for assistance of up to Rs. 5 crore. For later stage projects, projects of industry, MSMEs and startups costing up to Rs. 285 crore may apply for assistance up to Rs. 100 crore. The scale of financial assistance for early stage projects is 100% for cost up to Rs. 1 crore and 50% of additional cost beyond Rs. 1 crore, subject to a maximum up to Rs. 5 crore. The scale for financial assistance for later stage projects is 35% of project cost, subject to a maximum of Rs. 100 crore.

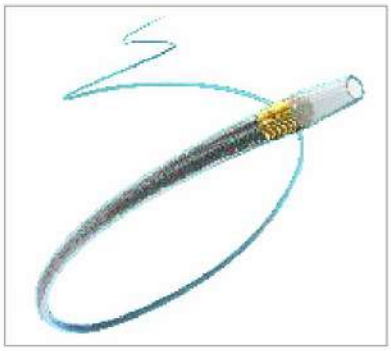
Moreover, the amended scheme offers several specific incentives to industry, MSMEs and startups to collaborate with academic and research government institutions of national repute, by providing for preference in selection for up to nine projects each at early and later stages, subject to collaborative development being significant and the collaborative partners/team having strong credentials. Further, industry, MSMEs and startups may use assistance provided under the scheme to in-licence research outputs developed by such institutions, thereby linking the strengths of academia in research with those of industry and startups in developing these into viable technologies and products and taking them to market. In addition, use of funds by an assisted applicant for creating public R&D assets in such institutions as part of their approved project is incentivised under the scheme.

Besides financial assistance, the amended scheme provides for development of strong institutional enablers to further nurture the innovation journey. Dedicated industry-focussed Centres of Excellence at the seven National Institutes of Pharmaceutical Education and Research (NIPERs) will serve as hubs of advanced research, while the NIPER Academia-Industry Coordination Committee recently constituted under Secretary, DoP with joint membership from all industry associations and NIPERs will institutionalise industry-institute linkages in these institutes.

*(October 13, 2025. https://www.pharmabiz.com/PrintArticle.aspx?aid=181808&sid=1 )*

# Terumo India Expands Interventional Cardiology Portfolio With The Launch Of FineCross™ M3 Mico-Guide Catheter

- FineCross™ M3 Coronary Micro-Guide Catheter combines a tapered tip, flexible distal segment, and optimized shaft design to deliver superior crossability, trackability, and guidewire support in complex coronary interventions.
- Built on Terumo's trusted global expertise in interventional cardiology, FineCross™ M3 empowers physicians +to perform safer PCI procedures, helping improve outcomes in patients with challenging coronary anatomies.



**India, October 07, 2025:** Terumo India, the Indian arm of Terumo Corporation (TSE: 4543), a global leader in medical technology, announced the launch of FineCross™ M3 Coronary Micro-Guide Catheter in India. The latest-generation catheter raises the bar for percutaneous coronary intervention (PCI), offering cardiologists enhanced crossing ability, guidewire support, and navigability in complex lesions that often hamper procedural success.

With coronary artery disease (CAD) continuing to be the leading cause of death in India, and a rising proportion of patients presenting with complex lesions it highlights the urgent need for advanced interventional tools. Addressing this challenge, FineCross™ M3 equips cardiologists to perform more efficient, predictable, and safer procedures, enhancing both clinical outcomes and procedural confidence.

Commenting on the launch **Shishir Agarwal, President and Managing Director, Terumo India** said, "Innovation at Terumo India is always guided by enabling physicians to deliver the best possible care to patients. With the launch of FineCross™ M3, we are proud to bring a globally trusted advancement in interventional cardiology to India. This milestone reflects not only our commitment to strengthening cardiovascular care in the country, but also Our Promise "Unwavering commitment to patients" that lies at the heart of everything we do."

FineCross™ M3 integrates Terumo's legacy of engineering excellence with new design enhancements that address real-world challenges in percutaneous coronary intervention (PCI).

Key features include:

- 1.7 Fr tapered distal tip for superior lesion crossability
- 15 cm floppy distal segment for exceptional trackability through tortuous vessels
- Tapered stainless-steel braided shaft for enhanced pushability and control
- Next-generation hydrophilic coating for unmatched lubrication and durability
- PTFE inner layer with radiopaque marker for smooth device delivery and precise visualization

Adding perspective on the product's clinical relevance, **Nitin Stephen Abel, Senior Director, Terumo Interventional Systems, Terumo India** said, "FineCross™ M3 represents more than just a product launch, it reflects our continued focus on advancing cardiovascular care in India in line with Terumo's mission of contributing to society through healthcare. Through globally trusted innovations, we aim to empower physicians in delivering better patient outcomes and create a meaningful impact where it matters most."

The launch of FineCross™ M3 adds to Terumo India's growing portfolio of advanced interventional solutions, further strengthening its role in shaping the future of cardiovascular care in the country.

**About Terumo India Private Limited**

Terumo India is a rapidly growing medical devices company dedicated to advancing access to high-quality cardiac, vascular, and other medical devices for patients and healthcare practitioners in India. As part of Terumo Corporation, a global leader in medical technology headquartered in Tokyo, Japan, Terumo India upholds a mission rooted in 104 years of history : Contributing to Society through Healthcare.'

Founded in 2013 and headquartered in Gurgaon, NCR Delhi, Terumo India has touched over 100,000 lives. The company is four times Great Place to Work® certified and was also recognized as one of India's Top 15 Workplaces™ in Pharmaceuticals, Healthcare, and Biotech in 2022. Terumo India also runs several acclaimed training and development programs, collaborating closely with customers and academic partners to address the skilling needs of India's healthcare system.

*For more information, visit https://terumoindia.com/*

**About Terumo**

Terumo (TSE: 4543) is a global medical innovation company. Guided by an unwavering commitment to patients, and driven by the passion of our associates, we strive to fulfill our Group Mission of "Contributing to Society through Healthcare." Founded in Tokyo in 1921, we provide a comprehensive range of solutions in the fields of therapeutic procedures, hospital operations, and life sciences in more than 160 countries and regions.

*For more information, visit https://www.terumo.com/*

# Gamma Radiation Centre To Come Up At Medical Device Park

Greater Noida: The Yamuna Expressway Industrial Development Authority (YEIDA) on Friday said it had accelerated the work on advanced scientific infrastructure in Medical Device Park in Sector 28.

Spread across 350 acres, the facility pays emphasis on common scientific facilities (CSFs) and a state-of-the-art gamma radiation centre, which will play a key role in research, testing, and manufacturing support for medical device and biotech industries. "We will soon sign a memorandum of understanding (MoU) with the Board of Radiation and Isotope Technology (BRIT)—an organisation under the department of atomic energy—to set up and operate a gamma radiation centre. This will enable sterilisation, material testing, and other bio-medical applications critical to the production of medical devices. BRIT's expertise will ensure adherence to atomic energy safety standards, provide regulatory guidance, and strengthen the technical robustness of the centre," said Shailendra Bhatia, officer on special duty of YEIDA.

The authority officials said the partnership meeting with BRIT has already secured approvals, and the work on MoU process is underway, adding that the collaboration will make the facility self-reliant in testing and sterilisation processes, while also

supporting regional industry needs.

In addition to the gamma centre, YEIDA is also collaborating with IIT Delhi to design and implement other CSFs, including 3D design and rapid prototyping labs, Internet of Medical Technology (IoMT) facilities, and electronics system design labs. Six major CSFs (CSF-1 to CSF-6) are being developed, with civil works for CSF-1 to 5 nearly complete. CSF-6, which will house the gamma radiation and bio-material testing facility, is now in the planning stage.

"The tendering process for equipping the CSFs with IIT Delhi's technical inputs is ongoing. Nine firms have bid for the 3D design and prototyping lab, while four have competed for the IoMT facility. Technical clarifications from bidders are being reviewed with IIT Delhi before finalising contracts," said Bhatia.

While the gamma centre is expected to involve significant capital investment, cost models and partnership structures are being designed to ensure financial sustainability. The Medical Device Park is designed as an integrated ecosystem, hosting medical manufacturing units, incubation and licensing centres, administrative offices, warehouses, exhibition halls, food courts, and recreational amenities.

*(Octo. 25,2025 . https://www.hindustantimes.com/cities/noida-news/yeida-expedites-work-on-scientific-infrastructure-at-medical-device-park-101761330890569.html )*

## SITRA, Coimbatore Introduces "Meditex Chronicle" A Quarterly Newsletter

The newly introduced Newsletter by CoE Medical Textiles, The South India Textile Research Association (SITRA) , Coimbatore will include R&D updates, new testing services, training programs conducted by SITRA along with industry perspectives, expert tips, or updates on their latest initiatives.

**SITRA – Centre Of Excellence For Medical Textiles**

SITRA has been designated as a Centre of Excellence (COE) for Medical Textiles by the Office of the Textile Commissioner, Ministry of Textiles (MoT), Government of India under Mini Mission I of Technology Mission on Technical Textiles (TMTT) in recognition of excellent research accomplishments in the field of Medical textile industries.

SITRA has set-up a state-of-the art facility for pilot scale manufacturing and quality evaluation of medical textile products. It has a dedicated group of textile technologists as well as experts in allied fields like Microbiology, Biotechnology and polymer chemistry to carry out research, training and consultancy to the textile industry as well fast emerging medical textile domains.

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. More details @ https://sitra.org.in/coe-medical-textiles/

## Press Release

QOSINA
Thousands of Stock Components

# Qosina Announces Strategic Partnership with Zenius to Expand Global Medical Device Development Support

Ronkonkoma, NY – September 30, 2025 – Qosina, a leading global supplier of OEM single-use components to the medical and pharmaceutical industries, is pleased to announce a new partnership with Zenius Corporation, a world-class one-stop solution provider for medical device development based in Japan.

This partnership enables Qosina to enhance support for Japanese customers by offering local expertise, faster turnaround and production quality aligned with the highest standards. It also expands global development services, ensuring customers have access to end-to-end solutions from concept through clinical trials. In addition, the design and development services provided by Zenius complement Qosina's broad component offerings, helping customers streamline the path from idea to market.

"We are excited to partner with Zenius to further expand our global presence and provide Japanese customers with seamless access to both components and design-to-manufacturing services," said Lee Pochter, CEO of Qosina. "Together, we will deliver speed, quality and expertise that accelerate medical device development."

Through this collaboration, Qosina strengthens its commitment to supporting customers in Japan and across the globe by combining its extensive catalog of medical device components with Zenius' expertise in design, DFM (design for manufacturability), rapid prototyping, quick-turn tooling, low-volume production and contract manufacturing.

**About Qosina**

Qosina is a leading global supplier of OEM single-use components to the medical and biopharmaceutical industries. With 45 years of experience, Qosina offers one of the world's largest selections of stock components—including connectors, fittings, valves, tubing and other critical parts—to help companies accelerate innovation and reduce time to market. In addition to its extensive catalog, Qosina provides custom sourcing, molding and assembly solutions. Headquartered in Ronkonkoma, New York, with a European office in Milan, Italy, Qosina serves customers worldwide with a commitment to quality, compliance and innovation.

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

## Product Gallery

# Bry Air Plastic Drying Equipment

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.


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

# HIGHLIGHTS

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

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## Target Readers

**All who are involved or interested in Medical Plastics user industries ranging from Medical Plastic Devices / Equipments Manufacturers / Marketing Companies, Diagnostic & Pharmaceuticals Industries, Hospitals, Doctors, Medical & Pharmacy Colleges, Research Institutes.**

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# Appreciation And Best Wishes From Industry Leaders & Readers

**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 very best of health and success. I look forward to receiving from time to time all future editions.

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

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

**Jitesh Shah**
Director, Suru International Pvt. Ltd., Mumbai

Congratulation sir and I wish you many more successes !

**Dr. S. S. Murugan** PhD, Safety Toxicologist,
Managing Director, GLR Laboratories Pvt Ltd., Chennai

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

**Anil Jauhri** (ex-CEO, NABCB), New Delhi

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

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

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

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

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

**Brian Reilly**
Marketing & Sales Director, Nusil Silicone Tech., USA.

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

**Rajiv Nath**
Managing Director, Hindustan Syringes & Medical Devices Ltd & Forum Coordinator. Association of Indian Medical Device Industry (AiMeD)

We appreciate Medical Plastic Data Service endeavor in creating awareness about Medical Device Industry in India and the insights and quality literature articles as well as your wonderful initiative for holding the technical conferences and technology show exhibitions for the benefit of Medical Device Industry.

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

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

**Dr. Sanjay Behari**
Director, Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram

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

**Dr. Roy Joseph** Scientist G
Biomedical Technology Wing, ( SCTIMST ) Trivandrum

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

**Dr. Renjith S** Scientist C
Biomedical Technology Wing, (SCTIMST) Thiruvananthapuram

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

**Dr. Richa Dayaramani**
Scientist - Grade F, Centre of Excellence in Medical Devices NIPER – Ahmedabad

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

**Tim Galekop**
TIGAMED, Global Consultancy Infection Prevention, Belgium

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

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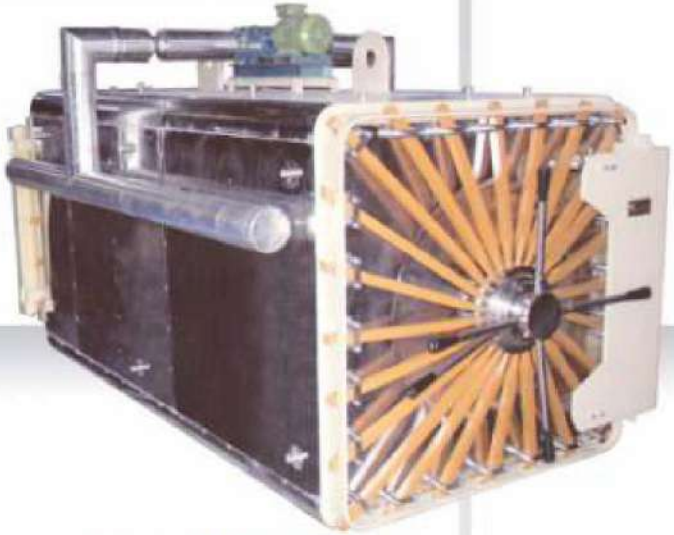

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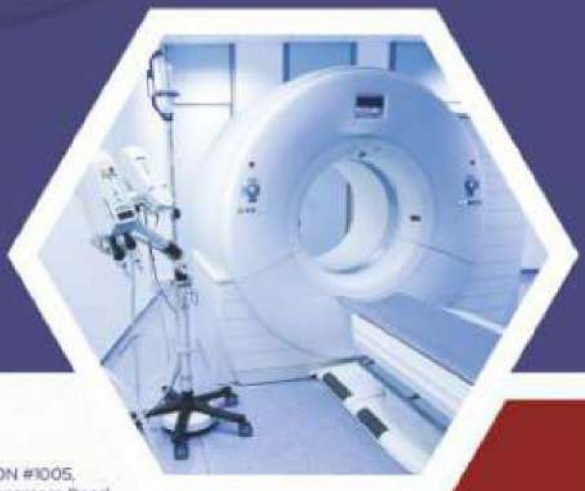

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