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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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  - Global Medical Elastomer Market
- **Manufacturing: Medical Plastic Injection Molding**
  - Micro Injection Moldings for Medical Devices
  - Molds: The Next Leap for India's MedTech Industry
- **Quality**
  - ISO/FDIS 10993-1:2025: Recent Updates and Their Implications for Medical Device Manufacturers
- **Markets**
  - Global Markets for Medical Devices: A Strategic Perspective
- **Environment**
  - Single-Use Plastics in Healthcare: Circularity and Decarbonisation Strategies
- **4th National Seminar on**

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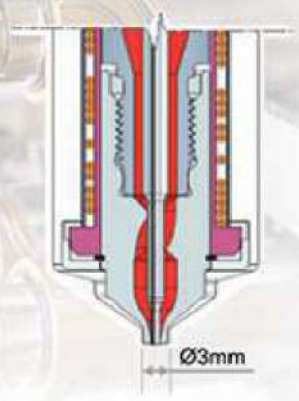

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- EN 1186 Migration Study
- ISO 18562-2: Emission of Particulate Matter from Gas Pathways
- ISO 18562-3: VOCs from Gas Pathways
- ISO 18562-4: Condensate Leachables from Gas Pathways
- ASTM D7823-18: Residual Phthalate Testing
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- 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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- TOC, THC as per ISO 19227:2018; BS EN 1484:1997
- Particulate Matter as per USP <788> and EP 2.9.19, ISO 19227:2018
- Syringe Tests as per ISO 7886-1
- Nitrosamines and NDSRIs Method development and Validation
- USP <661> Plastic Packaging Systems and Their Materials of Construction
- Unknown peak identification and characterization
- Forced degradation Study
- Residual solvents analysis
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- Elemental analysis as per ICHQ3D & USP<233>

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MEDICAL PLASTICS DATA SERVICE

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- **MATERIALS : KLJ Group: Rolling out Total Solutions for Plasticizers & Polymer Compounds**

  - Jagdish Parmar, DGM- Sales & Technical, KLJ Group, Mumbai, India

  KLJ Group is a multi-product and multi-locational business conglomerate, with a turnover of INR 109 billion (US$ 1.40 billion) having manufacturing capacity of over 1.40 million tpa and a 2200+ dedicated and qualified personnel persistently pursuing Innovation, Development and Growth... (January- February 2023)

- **MATERIALS** : KRAIBURG TPE offers innovation and superior support for medical and pharmaceutical TPE Aapplications

  - Aditya Purandare, Managing Director, India. Kraiburg TPE Pvt. Ltd.

  When selecting any materials for medical device and pharma packaging applications, the primary focus should be on the choosing the right materials to accomplish the application requirement, complemented by reducing the risk to a minimal. (January- February 2023)

- **GLOBAL MARKET** : MEDICAL DEVICES Marketing Strategies By The Indian Medical Devices Exporters: A Detailed Study

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

  The study finds very useful information about promotion models, distribution set ups and pricing strategies followed by the Indian medical device exporters... (January- February 2023)

- **GLOBAL TRENDS :** • Liability Risks faced by Polymer Suppliers and its negative impact on downstream innovation in medical implants Liability laws designed to compensate for harms caused by defective products may also affect innovation.

  The study mentioned above examined this issue by exploiting a major quasi-exogenous increase in liabilityrisk faced by US suppliers of polymers used to manufacture medical implants (January- February 2023)

- **AiMeD & REGULATORY UPDATES:**
- Rajeev Singh Raghuvanshi Appointed As The New Drug Controller General Of India
- DCGI Calls For Medical Devices Testing Laboratories To Register With Its Network Of Laboratories

Did You Know?

About Plastic Miro Injection Moldings For Medical Devices

Micro molding for medical devices is a specialized injection molding process that produces extremely small, high-precision components with micron-level tolerances for use in medical devices, implants, surgical instruments, and drug delivery systems. This process enables the miniaturization of devices, leading to less invasive procedures and improved patient care, and requires expertise in biocompatible materials, advanced tooling, strict quality control, and specialized equipment to meet regulatory requirements.

Micro-scale Manufacturing creates components so small they can weigh less than a gram or have cross-sections smaller than 1 mm, with features measured in microns. It is a highly precise form of plastic injection molding that uses specialized molds and meticulously controlled processes to produce intricate and tiny plastic parts.

Reasons for use in Medical Devices are:

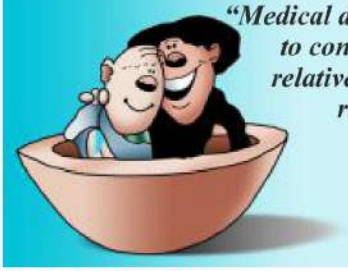
- **Device Miniaturization:** It allows for the creation of smaller, more complex medical devices, leading to less invasive surgical procedures and improved patient recovery.
- **Enhanced Functionality:** Micro molding enables the integration of more functions into a single, smaller device, facilitating more efficient and targeted diagnostics and treatments.
- **Biocompatibility:** The process uses materials that are safe for use in the body (biocompatible), which is critical for implants and internal medical components.

Key Aspects and Challenges for Miro molding are : Material Selection, Precision Tooling, Process Control and Quality and Regulation.

Applications

- **Surgical Instruments :** Micro molded components are used to create smaller, more precise surgical tools.
- **Implants:** Highly specialized, tiny implants and bioresorbable devices rely on micro molding for their precise dimensions.
- **Drug Delivery Systems:** Components for advanced drug delivery systems that require fine features and precision are often produced via micro molding.
- **Diagnostics and Wearables:** It is vital for producing components in advanced diagnostic tools and portable, wearable health devices.

In a Nutshell....



"Medical device manufacturers are likely to continue holding labor headcount relatively flat and insted rely more on robotic and vision system-based automation technologies... ".

-Steve Bieszczat
CMO, DELMIAWorks

MEDICAL PLASTICS
DATA SERVICE

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MEDICAL PLASTICS
DATA SERVICE

From the Editor's Desk

The IMDI 2025 – the 23rd National Conference and Technology Exhibition on the Medical Devices Industry – was held on August 29th and 30th at Anna University, Chennai. Organized under **IMDI Conferences promoted by "MEDICAL PLASTICS DATA SERVICE' with the Association of Tamil Nadu Medical Device Industry (ATMED) as co-organiser along with SPE INDIA Medical Plastics Division.**

The event also included visits and workshops at two prominent Institutes of National repute. Visit to the 'Bureau of Indian Standards (BIS) office for a workshop on latest developments in the Medical Device Standards and their implementations and the visit to CIPET to understand various plastics processing & testing technologies with focus on Medical Plastic applications.

The event was more than a conference. It was a celebration of innovation, collaboration, and knowledge sharing by combining technical sessions, success stories, One-to-one interactions, technology Show Exhibition and field visits. The event was a unique showcase for the next phase of India's journey in the global medical device industry.

Our Contribution Towards Human Resource Development for Indian Medical Device Industry :

Plastics play a major role in manufacturing of Medical Devices, Hygiene products as well as Pharmaceutical Packaging. As an important responsibility and contribution towards human resource development for the Indian Medical Device Industry, MPDS associated with two prominent Institutions as Knowledge Partner for Online and Off -line training activities.

01 Supported CIPET-IPT, Ahmedabad to successfully organize a 40 hours' Online course on "Fundamentals of of Medical Plastics"(June 16 – July 11, 2025)

The course was carefully curated to provide a comprehensive understanding of medical plastics, their applications, the materials used, their properties and their role in the development of medical devices and healthcare products. The course covered Regulatory Standards, Manufacturing Processes and Emerging Trends in the Field, as well As Career Opportunities in Medical Plastic Domain.

02 MPDS to be the Knowledge Partner for a 70 hours' off-line Skill Development Certificate Course for Plastics in Medical and Healthcare Industry by AIPMA's AMTEC.

The Arvind Mehta Technology & Entrepreneurship Centre (AMTEC), represents a bold step toward bridging the gap between academic theory and industry practice backed by nearly eight decades of the All-India Plastics Manufacturers Association (AIPMA)s leadership in driving policy, innovation, and sustainability,

Through all these activities as mentioned above, our mission is to integrate important stake holders of Indian Medical Device Industry and provide support its healthy growth. We are sincerely grateful to a large number of Industry Leaders & professionals without whose help and contributions; we simply cannot carry out such knowledge-based activities.

This issue coverers very important and very well researched articles covering Materials, Manufacturing Processes, Quality, Environmental, Domestic & Global Markets, Regulatory, Association and Industry News.

D L Pandya

Indian Medical Device Industry

www.imdiconferences.com **IMDI Conferences**

EVENT REPORT

August 29-30, 2025. Chennai

HIGHLIGHTS

IMDI 2025 – the 23rd National Conference and Technology Exhibition on the Medical Devices Industry – was held on August 29th and 30th at Anna University, Chennai. Organized under IMDI Conferences promoted by "MEDICAL PLASTICS DATA SERVICE' with the Association of Tamil Nadu Medical Device Industry
(ATMED) as co-organiser along with SPE INDIA Medical Plastics Division.

The event highlights included:

- Inspiring Inaugural Session with Dr. Ezhilan Naganathan, MLA and Member of the State Planning Commission, Tamil Nadu as the Chief Guest along with a Galaxy of Dignitaries from Medical Device & Healthcare Industry, Research & Academic Institutions, Government Regulatory & Standardization Departments (CDSCO & BIS) as well as Industry Associations. The dignitaries shared their knowledge and vision on research, quality standards, biocompatibility, and India's drive to become a global MedTech hub.
- The Technology Show Exhibition showcased advanced medical devices, disposables, and electronic innovations, offering a unique platform for collaboration between industry and academia. It included all major partners of Medical Device Manufacturing Eco-System.
- A special session discussing Industry–Institute linkages and Start-up Success Stories.
- One focussed session on cutting-edge advancements in polymers and processing. From corrugated medical tubes to eco-friendly nanogel plasticizers, speakers high-lighted how materials science is reshaping safer, greener medical devices.
- Experts shared innovations in medical electronics and next-generation devices. Highlights included India's first indigenous Deep Brain Stimulator, fibre optic sensors for diagnostics, medical textiles, and compliance frameworks for global competitiveness.
- On the second day of the event participants had opportunity benefit for two visits:
  - Visit to the 'Bureau of Indian Standards (BIS) office for a workshop on latest developments in the Medical Device Standards and their implementations.
  - A visit to CIPET to understand various plastics processing & testing technologies with focus on Medical Plastic applications.

IMDI 2025 event was more than a conference – it was a celebration of innovation, collaboration, and knowledge sharing by combining technical sessions, success stories, One-to-one interactions, technology Show Exhibition and field visits. The event was a unique showcase for the next phase of India's journey in the global medical device industry.

Feedbacks from Expert Speakers, Exhibitors & Delegates

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. 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.

- Liked speakers and their content
- Also, the arrangement and execution over the 2 days
- Visiting the 2 reputed institutions and interacting with the people there was really valuable and got a lot of clarity while discussing with them.

Prasad Nivritti Bhagat (Ph.D.),
Co-Founder & CTO, Weinnovate BioSolutions Pvt. Ltd. Pune

Kishore Kumar
Technical Sales Support & Project Manager, Sterile World Technologies LLP. Maharashtra INDIA,

- Excellent networking opportunities with industry stakeholders
- Relevant topics covering current challenges and innovations in Medical Devices / Medical Plastics.
- Venue selection and lunch arrangements are good.
- Overall, a well-organized and impactful event.

- The panelists and the overall panel arrangement were excellent
- The event started on time and was managed efficiently without much delays
- The number of attendees was exactly as communicated in advance
- It was truly a great initiative that helped manufacturers clarify their doubts.

Snehadarshini R Scindia, TUV Rheinland India Pvt Ltd, Bangalore

- Liked the latest medical device technologies presentations
- Also, the inspirational speech especially by the owners of the Startup companies
- And discussion on fibre optic spectroscopy, deep brain stimulator
- Liked the presentation by a neurosurgeon doctor
- Visit to CIPET was useful since I have not worked or visited a manufacturing company.

Reghuram S
Engineer - HCL Tech, Madurai, India

Decoding Thermoplastic Polyurethane (TPU)

Jennifer Green
Sr. Global Technical Business Development Manager

Jennifer Green is the senior global technical business development manager at Lubrizol, where she specializes in innovative material solutions for medical devices and health care applications. With more than 15 years in the industry, Green has a deep understanding of polymer science and a passion for advancing biocompatible materials like thermoplastic polyurethanes (TPUs) and medical-grade silicones. She collaborates closely with medical device developers to enhance patient outcomes, focusing on sustainability, material performance, and regulatory compliance.

Choosing the Best TPU for Implantable Medical Devices

Thermoplastic polyurethanes (TPUs) are some of the most adaptable materials for medical devices, offering a balance between rigid polymers and elastomers. They're customizable, resistant to wear and can transition from stiffness outside the body to softness inside, which improves patient comfort. They're also great for catheters requiring thin walls, excellent strength and radiopacity.

TPUs are segmented block copolymers made of hard segments, containing isocyanates, and soft segments, containing long-chain alcohols (polyols). By selecting different chemistries for these segments—aliphatic or aromatic isocyanates for hard segments and polyether, polyester, polycarbonate or specialty polyols for soft segments—TPUs can be tailored to specific performance needs. Adjusting the ratio of hard to soft segments enables the creation of materials ranging from soft and flexible, approaching softness of silicones, to stiff and rigid for structural applications.

TPUs can be processed via extrusion, molding and thermal bonding techniques, but their flexibility doesn't stop there. They are also compatible with solvent-based methods and 3D printing, giving manufacturers the tools to produce intricate designs and quickly prototype new devices.

Choosing TPUs: Soft Segments

The starting point for choosing the right TPU is to understand its use case—where in the body it will be located and the length of time it will remain there. This informs the optimal soft segment chemistry for biostability. For example, the choice of soft segment affects resistance to degradation, with polyether soft segment offering better hydrolytic stability than polyester soft segment.

Once this is understood, chemical resistance, strength and fatigue requirements help inform the choice of hard segments. Other factors, such as processing methods and visual criteria, including transparency, also play a role. By answering these questions, manufacturers can narrow down the chemistry to a few promising options for bench testing. It's important to remember that enhancing one characteristic can affect others, so balancing these trade-offs through a structured decision matrix helps in arriving at the best solution.

For instance, material selection for long-term blood-contacting devices must address both physical durability and biological stability. Polyester-based TPUs are usually avoided because of their susceptibility to hydrolytic instability. Polyether-based TPUs provide better hydrolytic resistance but can be vulnerable to oxidative attack on the material surface, which may impact long-term performance depending on the device's design and function. Known for their durability, polycarbonate-based TPUs offer excellent resistance to both hydrolytic and oxidative degradation. At Lubrizol, we continually innovate to extend the implant lifespan of polyurethanes, and in the future, specialty chemistries may offer even greater biostability than what is available today.

Rigid materials demonstrate comparable performance trends. Polyether and polycarbonate-based TPUs offer significantly better durability in long-term blood-contacting applications than polyester-based TPUs. Polyether-based TPUs are the most stable option for devices exposed to low-pH environments such as long-term gastric implants. Polycarbonate-based TPUs, while offering strong oxidative and hydrolytic resistance, may be less suitable to such demands due to their vulnerability to hydrolytic attack in acidic conditions .

Choosing TPUs: Hard Segments

Aromatic and aliphatic TPUs each have their own strengths, giving medical device developers plenty to think about. Aromatic TPUs stand out for their toughness and chemical durability, providing roughly 20% greater tensile strength, fatigue resistance and abrasion resistance compared to their aliphatic counterparts. That said, they can yellow over time because their aromatic ring structure reacts to light, heat or radiation. While this discoloration requires additional design considerations for applications requiring long-term clarity, it doesn't affect their overall performance. In fact, aromatic TPUs are a great choice for devices where strength and durability are the top priorities .

Aliphatic TPUs may be considered in applications where patient comfort and transparency are key, like vascular access and infusion devices. They resist yellowing, which means they stay clear and visually appealing even after extended use . Manufacturers also value their ease of processing when it comes to adding fillers, such as radiopaque materials, making it simpler to meet functional needs.

One of the key advantages of TPUs in medical manufacturing is the versatility in how they can be processed. Techniques like extrusion, molding and thermal bonding make it possible to create thin, flexible, and durable tubing components which can be assembled into complex catheters.

Solvent processing takes advantage of TPU versatility by dissolving the material into a liquid form, allowing for precise shaping and coating. As the solvent evaporates, the TPU remains in its finished shape. This technique is especially useful for creating fine details or thin, consistent coatings that other processes can't easily replicate. It can also be used to incorporate thermally sensitive ingredients that might further enhance the device's performance.

TPUs aren't just versatile—they're a breakthrough material for implantable medical devices. The beauty of TPUs is how easily they can be adapted to fit different applications. OEMs and material manufacturers have an opportunity to work together to fine-tune their chemistry and performance traits to meet the most demanding medical device performance requirements.

Sidebar: Is TPU the Right Material?

When selecting a TPU for your medical device, evaluate the following key factors:

- Application: What is the device's purpose, and what specific functions will it need to perform?
- Materials: How do TPUs compare in terms of performance and compatibility to other materials being evaluated?
- Body contact: Will the device come into contact with blood, tissue or other body fluids?
- Contact duration: For how long must the material perform safely?
- Physical criteria: What are the strength, flexibility and durability needs?
- Chemical criteria: Must the device withstand body fluids or cleaning agents?
- Thermal criteria: Will it be exposed to high or low temperatures during use, sterilization or transportation?
- Sterilization: Is the device intended for single use or will it be reprocessed?
- Processing: Does the material suit the planned processing techniques?
- Visual properties: Does the device require clarity or specific color properties?
- Radiopacity: Is radiopacity necessary for imaging or diagnostic purposes?
- Compliance: Does the material meet the required industry and medical standards?
- Material efficiency: Is the material being evaluated available from the supplier in quantities aligned to your project's scale and budget?

About Lubrizol

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

For more information, visit www.Lubrizol.com

ABC Of Performance Plastics & Their Applications In Food Pharmaceuticals And Medical Devices

Asim Datta
Consultant Faculty, Indian Institute of Packaging & NIPPER
Chandigarh

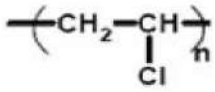
This is in continuation to my last writeup published in MPDS magazine volume 33 (Jan-Feb 2025). Let us explore few more important performance plastics which are in use in the field of Food, Pharmaceutical & Medical devices.

A (Acquaintance)
B (Behaviour)
C (Consumption)

of

PERFORMACE PLASTICS.....Food, Pharmaceuticals & Medical device

Polyvinyl chloride (PVC)

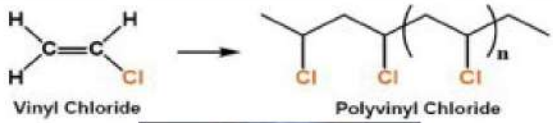


KEY PROPERTIES

- High clarity
- Moderate barrier for gas and moisture
- Hard and rigid.
- Excellent thermoforming property
- Density - 1.35-1.38 gm/cm3

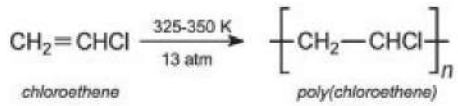
MAJOR PACKAGING APPLICATIONS

- Blister packaging in pharmaceuticals.
- Packaging of meat,cheese
- Medical bag / kit
- Shrink film / sleeve



PVC is produced by polymerization of vinyl chloride monomer (VCM). The main polymerization methods include suspension, emulsion, and bulk (mass) methods.VCM is then sent through a reactor containing a catalyst where polymerization occurs. This process links the vinyl chloride molecules together to form PVC chains. The resulting PVC is a white powder.

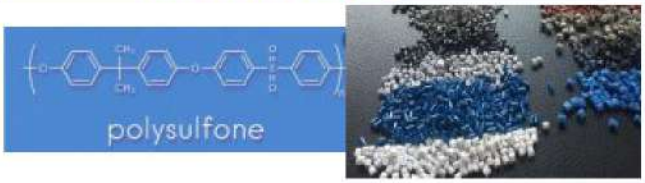
About 80% of production involves suspension polymerization. First, the raw material VCM is pressurized and liquefied, and then fed into the polymerization reactor, which contains water and suspending agents in advance. Next, the initiator is fed into the reactor, and PVC is produced under pressure Pressure (13 atm) at 40 – 60°C.



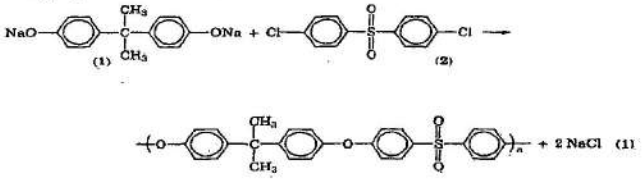
In suspension polymerization an initiator, an organic peroxide is used, which is soluble in chloroethene. After the reaction, excess monomer is removed and the polymer is separated, by centrifuging and drying.

PVC is used for many life-saving and healthcare products like

- Blood and plasma transfusion sets
- Catheters and cannula
- Blood bags
- intravenous solution giving sets
- Surgical and examination gloves
- Mattress and bedding covers
- Blister packs for pharmaceutical solid dosage medicines



Polysulfones are a family of high performance amorphous thermoplastics. These polymers are known for their toughness and stability at high temperatures. Aromatic polysulfones can be produced by the polycondensation reaction of bisphenol salts with 4,4-dichlorodiphenyl sulfone (4,4-DCDPS) Reactions are carried out in high- boiling polar solvents like dimethyl sulfoxide (DMSO), and N-methyl pyrrolidone (NMP) at temperatures ranging from 130 to 160°C



Polysulfone polymer is known for its unique properties like:

- Transparency
- Sterilizability.
- High impact resistance
- Chemical resistance .
- Flame retardancy & and good electrical properties (Good Insulator)
- High creep resistance and thermal stability
- Biocompatibility

Implantable polysulfone port

Examples of medical devices that use polysulfones are : Implants, surgical instruments, and diagnostic equipment like MRI machines, CT scanners, X-ray machines,Medical fittings and connectors

Polysulfone Membrane Blood Dialyzer

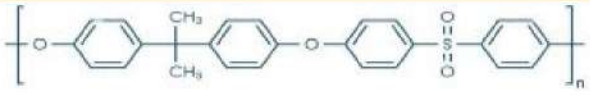
Polysulfone Surgical Storage Containers

Polycondensation reaction

Aromatic polysulfones can be produced by the reaction of bisphenol salts with 4,4- dichlorodiphenyl sulfone (4,4-DCDPS) (Figure 8.2). Reactions typically are conducted in high-boiling polar solvents like sulfolane, dimethyl sulfoxide (DMSO), and N-methyl pyrrolidone (NMP) at temperatures ranging from 100 to 250°C This reaction involves diphenoxide and bis(4-chlorophenyl)sulfone (DCDPS). The diphenoxide is produced in situ from a diphenol and sodium hydroxide. The polymerization is carried out in a polar, aprotic solvent, such as dimethyl sulfoxide, at 130–160°C

Polysulfone is used in medical devices, such as synthetic membranes, hemodialysis, blood circulation, and implant materials

The bisphenol monomers and a salt forming agent react to form bisphenolate. The bisphenolate and 4,4'-dihalodiphenyl sulfone undergo polycondensation to produce polysulfone.

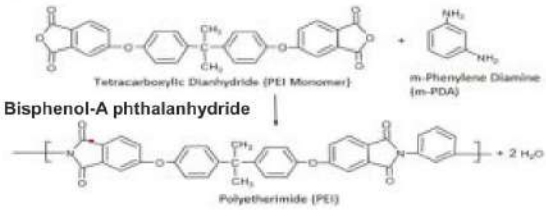


polysulfone

POLYETHERIMIDE (PEI): AN UNIQUE & RELIABLE POLYMER FOR MEDICAL DEVICES

Polyetherimide(PEI) is an amorphous, transparent engineering thermoplastic. The unique polymer offers an exceptional combination of high heat resistance, flame retardancy, and chemical resistance. PEI can maintain its mechanical strength & dimensional stability across a wide range of temperatures. PEI is also sterilizable through autoclaving, radiation, chemical methods therefore it is very useful and a favoured option for medical devices.

PEIs are made through a polycondensation reaction, which is a reaction consisting of two or more monomers, each containing one or more functional groups, which in this case are a dianhydride and a diamine,



Synthesis of PEI between bisphenol-A phthalanhydride and a diamine PEI is used in many medical devices

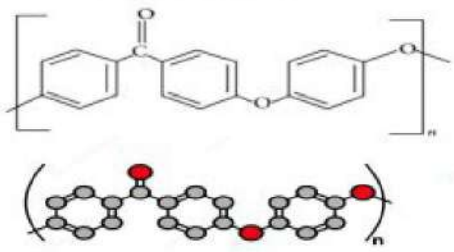
- Surgical instruments like the handles, forceps, and retractors of surgical instruments.
- Implantable devices like orthopedic implants, cardiovascular devices, and dental implants.
- Diagnostic equipment like blood analyzers, imaging devices, and diagnostic reagent containers.
- Medical tubing due to its strength characteristics, thinner walls, and larger inner diameter requirements

surgical devices made from medical grades PEI maintain properties after repeated autoclave cycles.

Polyetherimide (PEI) Compression Spring

PEEK (Polyether ether ketone) Plastic

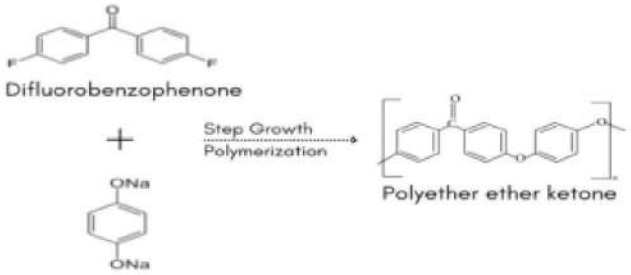
Chemical Structure



PEEK

PEEK belongs to polyaryletherketone (PAEK) family of polymers.

PEEK Plastic Polymerization



Disodium Hydroquinone

Polyetheretherketone (PEEK) is a high-performance polymer that is produced through a step-growth polymerization process: 4,4'-difluorobenzophenone is reacted with the disodium salt of hydroquinone in a polar aprotic solvent, such as diphenyl sulfone.The sodium phenoxide attacks the fluorine atoms in the difluorobenzophenone, forming ether linkages and longer polymer chains.

PEEK is a semicrystalline polymer with a rigid aromatic backbone that gives it a high glass transition and melting temperature. It has excellent mechanical properties and chemical resistance, and can be used conveniently at temperatures up to 240°C

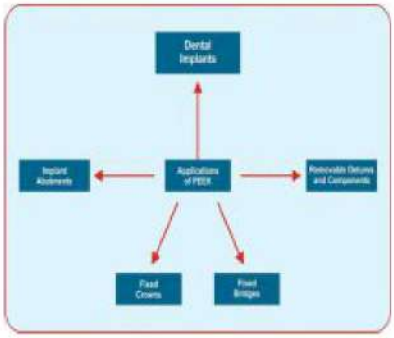
PEEK® is an organic thermoplastic polymer that offers excellent mechanical and chemical resistance properties because of its chemical make-up. PEEK® is short for polyether ether ketone, which means it's a member of the polyaryletherketone family. These polymers are notable for their phenylene rings and oxygen bridges, which result in resilience, durability and strength.

Many medical device manufacturers now use PEEK® as a way to improve the biocompatibility of load bearing implants. PEEK® is increasingly becoming the new standard biomaterial across a range of medical, orthopedic, and dental applications.

Polyetheretherketone (PEEK) is a thermoplastic polymer with many uses, including: Medical implants. Polyetheretherketone provides cost-effective, innovative parts with excellent wear, heat, electrical and chemical resistance. Its applications in healthcare industry mainly in the area of dental instruments, endoscopes and dialyzers.

PEEK polymers maintains outstanding mechanical strength, excellent stress cracking resistance and hydrolytic stability in the presence of hot water, steam, solvents and chemicals. This plastic offers improved biocompatibility of load bearing implants.PEEK is used in medical implants like bone replacement materials, screws, and plates for spinal surgeries and cranial implants. PEEK is biocompatible and has a modulus of elasticity similar to bone.

High Precision, PEEK, Thermoplastic Medical Spinal Implant Component

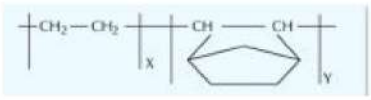


Polyetheretherketone (PEEK) in dentistry.

PEEK has been established as a biocompatible material, meaning it is safe for use in vivo (within the living body). Extensive research has shown that PEEK exhibits no signs of cytotoxicity, genotoxicity, or immunogenicity. Studies spanning more than 20 years have demonstrated its effectiveness in various applications, including spinal fusion cages, orthopedic implants, and dental devices.

COC (Cyclic olefin copolymer)

It is an amorphous transparent copolymer possessing a cyclic olefin structure.



KEY PROPERTIES

- Low Density
- Highly transparent
- Good water vapour resistant
- Very good acid and alkali resistant
- Density –1.02 gm/cm3

MAJOR PACKAGING APPLICATIONS

- Blister packaging material
- COC Vials replace the glass vials.
- Co-extruded film & laminates used for food & pharmaceutical packaging
- Pre filled syringes.
  Cyclic olefin copolymer (COC) is a plastic material that is widely used in medical devices and packaging applications due to its unique properties COC is used in a variety of medical devices, including:
- Laboratory and diagnostic devices: Syringes, vials, ampoules, cuvettes, microtiter plates, test tubes, petri dishes, and pipettes
- Needleless injectors, injector pens, and inhalers: COC is used in the development of drug- delivery systems
- Blister packs: COC is ideally suitable for the production of blister packs due to its good thermoformability

cOC is a good choice for medical devices because of its:

- Clarity: COC is highly transparent and clear, which ensures accurate results in assays
- Biocompatibility: COC is biocompatible with the tissues and proteins used in assays
- Heat resistance: COC can withstand high temperatures during the manufacturing process and sterilization through autoclaving
- Chemical resistance: COC is resistant to solvents like alcohol
- Sterilization compatibility: Most COC grades can undergo sterilization by gamma radiation, steam, or ethylene oxide
- Low water absorption: COC has a low water absorption value of less than 0.01% Norbornene or norbornylene or norcamphene is a highly strained bridged cyclic hydrocarbon. It is a white solid with a pungent sour odor.

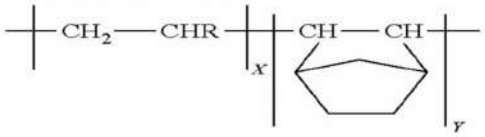
The molecule consists of a cyclohexene ring with a methylene bridge between carbons 1 and 4. The molecule carries a double bond which induces significant ring strain and significant reactivity.

Ethylene/norbornene content within cyclic olefin copolymer (COC) is well known to affect the chemical and physical properties of the copolymer, such as the glass transition temperature (Tg) and transparency.

Materials

TOPAS® COC is manufactured by TOPAS Advanced Polymers GmbH and sold by Polyplastics in the Americas, Japan and Asia Pacific.

TOPAS COC

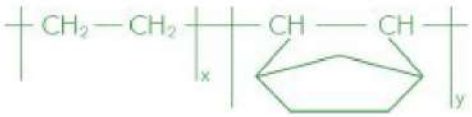


TOPAS® COC (cyclic olefin copolymer) is a glass-clear and extremely pure plastic for healthcare, packaging, and electronics applications. From insulin delivery, to food contact films, TOPAS® COC is the high-performance material of choice.

The broad global regulatory compliance of TOPAS® COC can make your next development a simpler task.

TOPAS® COC is manufactured by TOPAS Advanced Polymers GmbH and sold by Polyplastics in the Americas, Japan and Asia Pacific.

Raw ingredients and production method

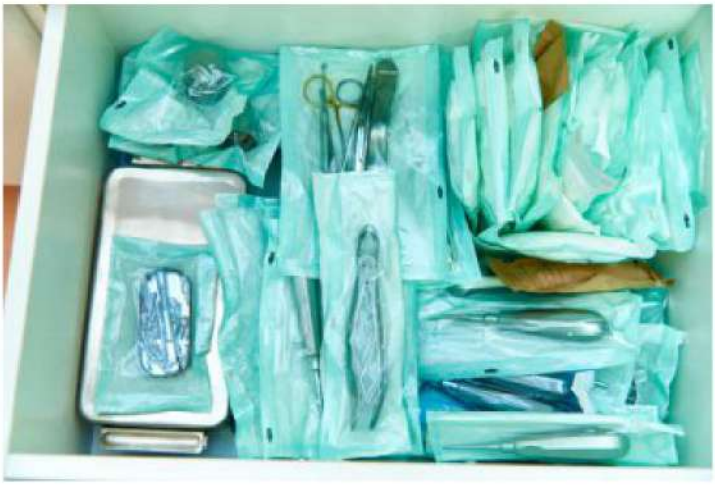


TOPAS® COC is a cyclo olefin copolymer (COC) copolymerized from norbornene and ethylene using a metallocene catalyst. Comonomer content determines the glass transition temperature, so TOPAS® COC grades with high cyclic olefin content have higher heat resistance.

Precision Begins at the Mold: The Next Leap for India's MedTech Industry

Dr. Teja Maganti
CEO, Medi. Mold Design and Fabrication Association (AMTZ)

India is racing ahead in medical device innovation—but behind every life-saving plastic component lies a silent enabler that rarely makes headlines: the mold. While startups and manufacturers focus on design and materials, the lack of local, high-precision tooling continues to delay launches, inflate costs, and stifle scale. Why are we still importing the very tools that define our MedTech future? If India wants to lead in affordable, world-class healthcare manufacturing, it must start thinking not just about making in India—but about molding in India. Because in medical plastics, precision doesn't start on the shop floor—it starts inside the toolroom.



India's MedTech sector is experiencing an exciting phase of growth. With rising domestic demand, favorable regulatory reforms, and a surge in homegrown innovation, the country is quickly becoming a hotspot for medical device manufacturing. From diagnostic kits to surgical disposables and implants, there is an increasing appetite for high-quality, affordable solutions that can serve both Indian and global markets. But beneath every device made of plastic—be it a nasal cannula, a lancet, or a diagnostic cartridge—there lies an often-unseen but absolutely essential element: the mold.

Tooling remains one of the least talked-about yet most influential factors in the success of any medical plastic product. It is the mold that determines whether a part will meet dimensional tolerances, whether it can be replicated over thousands of cycles, and whether it will pass stringent regulatory checks. While polymer selection, injection molding precision, and process control are all critical, they mean little without the right tooling. Unfortunately, in India, most high-precision medical molds are still imported. Despite our ambitions of becoming self-reliant in MedTech, we are heavily dependent on tooling ecosystems in East Asia and Europe—an issue that not only delays development timelines but also adds significant cost, complicates compliance, and compromises IP control.

This reliance on foreign tooling creates several layers of challenges. For instance, a startup developing a novel diagnostic cartridge may find itself stuck in a 12-week wait cycle for an overseas tool. Clinical trials get delayed. Minor design changes require an entirely new loop of communication and fabrication. Documentation from foreign vendors may not match Indian regulatory requirements, and the cost of each mold—especially in foreign currency—can severely stretch early-stage budgets. More critically, with IP shared across borders and without local accountability for design iterations, innovation becomes sluggish and risk-prone. In an industry that thrives on speed, accuracy, and clinical readiness, such delays are no longer acceptable.

The medical plastics industry must begin to see tooling not as a purchase order but as strategic infrastructure. It's not just a matter of producing a few molded parts; it's about enabling a system that can evolve quickly, comply rigorously, and manufacture consistently. A poor mold doesn't just create a defective part—it creates regulatory exposure, clinical setbacks, and financial strain. This is especially important for the types of devices where India hopes to lead—high-volume, low-margin consumables like syringes, cartridges, swabs, and connectors that require millions of consistent units with minimal scope for error.

The solution lies in building local, specialized tooling capabilities that are tailored to the medical industry. India needs a network of precision tool rooms located within medical manufacturing clusters—facilities that understand not just how to cut steel, but how to validate molds for ISO 13485 compliance, traceability, and performance under cleanroom production conditions. These tool rooms must be integrated into the broader ecosystem of device manufacturing—situated near sterilization units, quality labs,

molding shops, and regulatory cells. Only then can tooling become part of the innovation cycle, not a barrier to it.

What's promising is that this change has already begun, albeit in a limited but encouraging manner. Some manufacturing clusters—most notably Andhra Pradesh MedTech Zone (AMTZ) in Visakhapatnam—have started housing dedicated tooling and precision manufacturing facilities such as Medi Mold, which provide ISO-certified infrastructure, CNC and EDM capabilities, and shared access to molding, 3D printing, and quality control systems. Such centers are empowering MedTech startups to drastically cut lead times, retain IP, and validate products without being at the mercy of overseas vendors. This model of co-locating design, tooling, validation, and regulatory infrastructure represents a scalable, national opportunity that must now be replicated across emerging MedTech hubs.

In a few documented cases, companies that were initially reliant on imported molds transitioned to local suppliers and managed to reduce their development time by nearly 70% and costs by up to 40%. Others have begun to combine traditional tooling with additive manufacturing, using 3D-printed inserts or conformal cooling channels to accelerate prototype iteration and improve final part performance. These examples demonstrate that India already has the capability—it now needs greater coordination and investment to scale that success.

While 3D printing won't replace tooling for high-volume medical plastic parts anytime soon, it is quickly becoming an important partner in the process. Hybrid tooling strategies—where 3D-printed components are used alongside machined parts—allow for faster design cycles and more complex geometries, especially for pilot runs and limited editions. This fusion of subtractive and additive manufacturing is enabling a new wave of flexibility in tooling that India must leverage if it hopes to lead in responsive, scalable medical manufacturing.

For the plastics industry, this shift requires a new mindset. Tool makers must begin to specialize in medical device standards, understanding not only geometric precision but also the documentation, validation, and lifecycle expectations of regulated markets. At the same time, device manufacturers must bring tooling into the conversation much earlier. Instead of treating the mold as the final step before mass production, it must be integrated into the earliest phases of product design. The earlier tooling engineers are involved, the fewer surprises, delays, and redesigns occur downstream.

This transformation also demands policy support. Government schemes such as the Assistance to Medical Device Clusters for Common Facilities (AMD-CF) have created a model worth scaling. Incentivizing the development of certified tool rooms—especially in states with emerging MedTech hubs—can go a long way in creating the foundational infrastructure required for self-reliant manufacturing. Similarly, skill development programs focused on mold design, CAM programming, and metrology for MedTech applications will be critical in bridging the capability gap.

What India must avoid is the illusion of self-reliance. Manufacturing a product locally using imported molds is not self-reliance. It is dependency wrapped in domestic packaging. True sovereignty in MedTech manufacturing means owning the entire value chain—from design to tooling to production to compliance. And tooling, though hidden, is a central pillar of that sovereignty. Without it, we're simply assembling someone else's vision.

If India wants to be the world's supplier of affordable, high-quality medical devices, it must become the world's supplier of medical-grade tooling—at least for itself. It must create infrastructure that allows every startup to prototype and iterate without delay, every MSME to scale with confidence, and every multinational to look at India not just as a market, but as a manufacturing partner.

The future of medical plastics won't be written only in polymer grades and processing speeds. It will be determined by how well we build and control our molds. It will depend on how many engineers are trained not just in design, but in DFM (Design for Manufacturability). It will be shaped by how quickly we can move from CAD to cavity to clinic. In this future, those who control the mold will control the market.

India has the talent. It now has a growing policy framework and a demonstrated appetite for localized manufacturing. What's needed is a shift in how we think about tooling—not as a purchase but as a platform. Not as an input but as an infrastructure. The challenge is large, but the opportunity is larger.

We can continue to depend on imported tools, waiting months to test our ideas and paying heavily for delays and redesigns. Or we can invest, as an industry and as a country, in the capacity to mold our future—literally and figuratively. If we choose the latter, we don't just become makers of medical products. We become makers of possibility.

Let us stop outsourcing agility. Let us stop exporting control. Let us build India's medical plastics leadership—from the mold up.

FAST FACTS

The medical plastic injection mold sector faces a critical shortage of engineers and technicians proficient in advanced CAD/CAM Systems, CNC programming and mold analysis , constraining production and innovation.

Recent Updates to ISO/FDIS 10993-1:2025 and Their Implications for Medical Device Manufacturers

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Introduction

ISO 10993-1 has long stood as the cornerstone of international guidance for the biological evaluation of medical devices. From its inception in 1992, the standard provided a unified framework that allowed regulators, manufacturers, and test laboratories across the globe to converge on a common language and methodology for assessing the biocompatibility of materials and finished devices. Its central purpose has always been to ensure that medical devices do not pose unacceptable biological risks to patients when used as intended. Over time, this standard has evolved in response to new technologies, fresh scientific insights, changing regulatory landscapes, and a growing ethical commitment to reduce animal testing. Major revisions were published in 2003, 2009, and 2018, each reflecting shifts in both science and policy. The upcoming revision, ISO/FDIS 10993-1:2025, represents not only an incremental update but a substantial restructuring of the standard. It introduces tighter integration with ISO 14971, a redefinition of exposure durations, new device categorization rules, and more explicit expectations regarding chemical characterization and toxicological risk assessment. For manufacturers, these changes mean more than academic adjustments; they represent tangible regulatory obligations, with significant consequences for timelines, testing strategies, and market access. This article examines the technical updates in detail, explains their implications, and provides practical insights into how manufacturers can adapt.

Development of FDIS 10993-1

Like all ISO standards, ISO 10993-1 passes through a series of clearly defined developmental stages. It begins as a working draft (WD), progresses to a committee draft (CD), is circulated as a draft international standard (DIS), and finally reaches the Final Draft International Standard (FDIS). At the FDIS stage, only editorial refinements are possible, since the technical content has already been agreed upon by consensus. ISO/TC 194, Working Group 8, is responsible for this part of the series and has drawn upon decades of collective expertise from regulators, academics, test laboratories, and device manufacturers. The motivations for the 2025 revision are multifaceted. One major driver is the need for harmonization with ISO 14971, which governs risk management of medical devices. The two standards increasingly overlap, and discrepancies between their definitions or processes have led to confusion in the past. Another driver is the steady advancement of scientific tools, particularly in the areas of chemical characterization and mechanistic toxicology. The ability to identify and assess extractables and leachables has grown considerably in the past decade, making it possible to substitute or supplement biological testing with detailed toxicological risk assessments. Furthermore, global regulatory requirements have intensified, particularly under the EU MDR, which places far greater emphasis on justification of safety through structured evidence. The US FDA has also pressed manufacturers to rely on chemical characterization as a primary tool, especially to reduce animal use. These scientific and regulatory forces, coupled with the ethical imperative of the 3Rs (replacement, reduction, and refinement of animal testing), have shaped a document that is more demanding but also better aligned with current expectations.

Major Updates in ISO/FDIS 10993-1:2025

Among the many updates introduced in the 2025 revision, several stand out for their immediate impact on manufacturers. The title itself has changed, shifting from 'evaluation and testing within a risk management process' to 'requirements and general principles for the evaluation of biological safety within a risk management process.' This is more than semantics; it signals a movement away from checklist-driven testing towards a holistic framework in which biological safety must be established as part of a broader, risk-based decision-making process. The standard now requires explicit consideration of reasonably foreseeable misuse. Examples include devices being used for longer than intended, applied at a different anatomical location, or used by populations not originally targeted by the manufacturer. This expectation aligns directly with ISO 14971, which has long required consideration of misuse scenarios as part of risk management. Another critical change is the redefinition of exposure duration. Previously, cumulative hours or minutes of use determined whether a device was categorized as limited, prolonged, or long-term. The 2025 version instead counts calendar days of contact. Thus, a device used intermittently for short periods across many days will be up-classified compared to its previous designation. Device categorization has also been reorganized. The older distinction between surface-contact, external-communicating, and implant devices has been replaced by four categories: contact with intact skin, contact with intact mucosa, contact with breached or compromised tissue or internal tissues, and contact with circulating blood. Annex A has been substantially rewritten. The former single table of endpoints has been replaced with four separate tables describing biological effects to be considered. The emphasis is no longer on ticking boxes but on conducting a genuine risk-based assessment. These biological effects include systemic toxicity, local tissue effects, genotoxicity, carcinogenicity, and hemocompatibility,

along with reproductive or developmental toxicity, immunotoxicity, or neurotoxicity where relevant. The clear message is that manufacturers can no longer rely on prescriptive test lists; they must demonstrate, through evidence and justification, that all relevant risks have been identified and addressed.

Comparison with ISO 10993-1:2018

The differences between the 2018 edition and the 2025 FDIS are striking. The 2018 document contained eighty-one mandatory 'shall' statements, but it also offered one hundred and twenty-four advisory 'should' statements, giving manufacturers considerable interpretive flexibility. The 2025 revision has increased the number of mandatory requirements to one hundred and thirty while reducing the number of advisory statements to just thirty-six. This signals a shift towards a more prescriptive standard with fewer areas left to discretion. The number of definitions has expanded from fourteen to forty-three, many of which align with ISO 14971, ensuring that biological evaluation and risk management speak the same language. Another visible change is the increased emphasis on life cycle thinking. Whereas the 2018 version tended to focus on pre-market evaluation, the 2025 revision emphasizes that biological safety must be monitored and reassessed throughout the total product lifecycle, including post-market surveillance. The net effect is to raise the bar for compliance, making it more difficult for manufacturers to rely on legacy data or minimal justifications. Instead, they must produce structured, well-documented Biological Evaluation Plans and Biological Evaluation Reports that integrate fully with their risk management systems.

Regulatory Perspectives

The regulatory consequences of ISO/FDIS 10993-1:2025 are profound. Within the European Union, harmonization with the Medical Device Regulation is expected soon after publication, meaning that compliance will be obligatory for CE marking. Notified Bodies will scrutinize BEPs and BERs for alignment with the new requirements, and gaps are unlikely to be tolerated. In the United States, while the FDA may not formally endorse every aspect of the revision, it has already emphasized the importance of chemical characterization and toxicological risk assessment in its biocompatibility guidance documents. Manufacturers seeking FDA approval will need to reconcile the revised ISO requirements with specific FDA expectations, but in most cases the alignment will be beneficial rather than contradictory. Other global jurisdictions, from Japan to Brazil, tend to follow ISO standards closely, meaning that the 2025 version will soon become a global reference point. For multinational manufacturers, the practical reality is that compliance with ISO 10993-1:2025 will be essential for maintaining global market access.

Practical Implications for Manufacturers

The practical implications for manufacturers are extensive. For new devices, the expectation is that a comprehensive biological evaluation plan and report will be prepared from the outset, aligned with ISO 14971 and capable of withstanding scrutiny by regulators. Exposure duration must be carefully calculated according to the new rules, and classification into one of the four contact categories must be justified. This will inevitably lead to more devices being up-classified, requiring assessments for systemic toxicity, genotoxicity, and even carcinogenicity. Chemical characterization and toxicological risk assessment will assume a central role in these evaluations, enabling manufacturers to address multiple endpoints simultaneously and minimize animal use. For existing devices, the challenge will be conducting gap analyses that identify where current data fall short of the new requirements. In many cases, previously approved devices may suddenly require additional data generation, either through chemical characterization, toxicological assessment, or new biological testing. These requirements will extend timelines and increase costs, making early planning essential. For companies with large portfolios of legacy devices, prioritization strategies will be necessary to ensure that the most commercially critical products are addressed first. Across the board, manufacturers must recognize that these changes are not optional; they represent the new baseline for regulatory acceptability.

Case Scenarios

The impact of the new classification rules can be illustrated through concrete case examples. Consider a dental device intended for daily use for one hour across a period of ten days. Under the 2018 version, the cumulative exposure of ten hours would have placed it in the category of limited exposure. Under the 2025 FDIS, however, the same device is categorized as prolonged exposure because the number of calendar days is counted rather than the number of hours. This reclassification triggers additional requirements for systemic toxicity and genotoxicity assessment. Another example is a catheter intended for mucosal contact over several weeks. Under the previous standard, it may have required limited testing. Under the new version, it falls into the prolonged mucosal contact category, necessitating genotoxicity evaluation and potentially carcinogenicity assessment. Similarly, extracorporeal blood-contact devices, even when used intermittently, may now fall into categories requiring hemocompatibility, genotoxicity, and systemic toxicity assessments. These examples demonstrate how the revised definitions of duration and categorization have real and immediate consequences for product development and market access.

Combination Products

Combination products, which include drug-device or biologic-device systems, face particularly complex challenges under the new framework. Manufacturers of these products must navigate overlapping and sometimes conflicting requirements from multiple standards and regulatory guidelines. For instance, device components must be assessed under ISO 10993-1, -17, and -18, while the drug components are subject to USP 1663 and 1664, ICH Q3C, Q3D, and M7. Extractables and leachables testing becomes doubly demanding, as it must address both device-related and drug-related expectations. Toxicological risk assessment must reconcile different approaches to uncertainty factors and acceptable daily exposures. The only practical strategy for manufacturers is to plan early, integrate testing strategies, and maintain open lines of communication with regulators. In many cases, pre-submission meetings with agencies such as the FDA will be essential to ensure that testing plans are acceptable. The regulatory pathway for combination products is already complex, and ISO/FDIS 10993-1:2025 adds another layer of requirements that manufacturers must be ready to meet.

Implementation Timelines

Publication of ISO/FDIS 10993-1:2025 is expected before the end of the year, with harmonization under the European MDR to follow shortly thereafter. Manufacturers cannot afford to wait until harmonization is formally announced. By the time that occurs, regulators and notified bodies will already expect to see evidence of compliance with the new framework. The FDA will likely incorporate elements selectively into its own guidance, but the trend towards greater reliance on chemical characterization and toxicological risk assessment is already evident in the United States. In practice, this means that manufacturers must begin

preparing now. Gap analyses, internal training, updated standard operating procedures, and revised biological evaluation plans and reports are all required. Failure to act proactively risks delays in regulatory approval, market withdrawal of legacy devices, and reputational damage.

Conclusion and Recommendations

ISO/FDIS 10993-1:2025 represents a significant turning point in the regulation of biological safety for medical devices. It redefines fundamental concepts such as exposure duration, reclassifies devices into new categories, strengthens alignment with ISO 14971, and emphasizes life cycle safety. It requires manufacturers to adopt more rigorous, structured, and risk-based approaches to biological evaluation. The implications are substantial: increased testing requirements, higher costs, longer timelines, and more complex documentation. At the same time, there are opportunities to improve efficiency, reduce animal testing, and enhance patient safety by embracing chemical characterization and toxicological risk assessment. The message for manufacturers is clear: adaptation is not optional. Companies that act early, invest in updating their processes, and engage proactively with regulators will be best positioned to thrive in the new environment.

How MDR Laboratories Can Help

MDR Laboratories is uniquely positioned to support manufacturers in adapting to the requirements of ISO/FDIS 10993-1:2025. With decades of experience in genetic toxicology, regulatory toxicology, and biocompatibility, the laboratory has built a strong reputation for delivering comprehensive and regulatorily robust Biological Evaluation Plans (BEPs), Biological Evaluation Reports (BERs), and Toxicological Risk Assessments (TRAs). The team combines deep scientific expertise with state-of-the-art analytical capabilities in chemical characterization to address even the most complex regulatory challenges. Operating under ISO/IEC 17025 accreditation and OECD-GLP compliance, MDR ensures that every report and dataset it produces meets the highest standards of reliability and international acceptance.

MDR's approach begins with detailed gap analyses of existing data packages, identifying precisely where updates are needed to bring devices in line with the 2025 FDIS requirements. The laboratory then develops tailored BEPs and BERs that integrate seamlessly with ISO 14971 risk management principles, while its in-house toxicologists prepare TRAs that withstand scrutiny from both Notified Bodies and the FDA. By leveraging advanced chemical analysis platforms, MDR minimizes unnecessary in vivo testing and provides clear, evidence-based justifications that accelerate approvals. Beyond testing and documentation, MDR offers training, regulatory strategy, and dossier preparation to give clients a competitive advantage.

In an era of heightened regulatory expectations and evolving standards, MDR Laboratories acts as a trusted partner, helping manufacturers navigate complexity with confidence. By delivering authoritative BEPs, BERs, TRAs, and chemical characterization reports, MDR ensures smoother regulatory pathways, reduced risk, and faster market access for medical devices worldwide.

Indian Medical Device Industry

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

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

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Global Medical Elastomer Market

The Medical Elastomer Market is witnessing strong growth driven by demand for flexible, durable, and biocompatible materials in medical devices, implants, and packaging. Rising healthcare advancements and minimally invasive procedures further boost adoption. Key players such as DuPont, BASF, SABIC, Dow, and Celanese are focusing on innovation and sustainability to meet evolving industry needs.

The medical elastomer market is expected to grow at a CAGR of 8.3% to reach USD 14.27 billion by 2029 from USD 9.57 billion in 2024 as per a recent report by "MarketsandMarkets™"

The medical elastomer market is driven by the growing demand of medical devices fuelled by expansion of healthcare technologies. Medical devices such as surgical instruments and diagnostic tools need components which are durable, flexible and biocompatible.

The medical elastomers offer these properties. Additionally, the increased elderly population across the globe is enhancing the demand for devices such as catheters, syringes, and prosthetics where medical elastomers are crucial in order to ensure patient comfort and improved performance. Furthermore, the advancement in wearable medical devices and remote monitoring systems is also driving the demand for medical elastomers as such materials offering durable and comfortable designs. The globally risen healthcare expenditure as well as the continuous innovation and R&D is further increasing the demand for medical elastomers.

"Thermoplastic Elastomers are the fastest growing type in the medical elastomer market during the forecast period, in terms of value."

Thermoplastic elastomers are the fastest growing type of the medical elastomer. These elastomers are combination of unique properties such as elasticity, durability, and processability. Unlike traditional elastomers these can be processed like plastics along with retention of rubberlike properties. This makes them compatible for various medical applications. Their versatility increases their utility in various applications in the healthcare sector. These elastomers can be used to manufacture catheters, medical tubing, syringes, and wearable devices. In addition to this, they provide superior biocompatibility and sterilizability complying with strict healthcare regulations. Moreover, the increasing requirement for lightweight, flexible, and low-cost materials and R&D and innovations in TPE formulations are added factors driving the demand for thermoplastic elastomers in the medical elastomer market.

"Catheters accounts second largest market share of medical elastomer market by application during the forecast period, in terms of value."

The catheters sector account the second largest market share in medical elastomer market due to their vital critical role in medical procedures such as urology, cardiology, and drug delivery. Medical elastomers offer the flexibility, biocompatibility, and durability required by catheter to ensure efficient performance resulting into patient safety and comfort. The increasing prevalence of chronic diseases like cardiovascular disorders and diabetes are resulting into rising demand for catheters for minimally invasive procedures. Moreover, ongoing innovations such as antimicrobial elastomers are further enhancing utility of the catheters in healthcare industry. This segment remains one of the key growth drivers within the medical elastomer market, which is increasingly growing due to demands in healthcare.

"MarketsandMarkets™ has been recognized as one of **America's best management consulting firms by Forbes,** as per their recent report.

https://www.theglobeandmail.com/investing/markets/markets-news/GetNews/34817282/medical-elastomer-market-size-sales-volume-price-growth-rate-analysis-report-20252029-expert-review/

Single-Use Plastics In Healthcare : Circularity And Decarbonisation Strategies

A new report from global sustainability consultancies Eunomia and Systemiq highlights the healthcare sector's use of single-use plastics, which drive up costs, waste, and greenhouse gas (GHG) emissions.

Among the regions analyzed, the U.S. and Canada generated the most healthcare plastics waste, together producing 1.2 million metric tons of single-use healthcare plastics waste, 4.3 million metric tons of CO e emissions, and costs to health systems as high as $29 billion in 2023 alone.

"This report presents the strongest evidence yet to galvanize the global healthcare community into urgent action on plastic waste," says Pallavi Madakasira, managing consultant at Eunomia. "It offers a common set of priority interventions and a data-driven roadmap to accelerate progress. Most importantly, it shows that safe, proven, and cost-saving solutions are already within reach."

The report, A Prescription for Change: Rethinking plastics use in healthcare to reduce waste, greenhouse gas emissions and costs, quantifies the environmental and financial impacts of single-use plastics across seven high-volume product categories: gloves, fluid bags and tubing, rigid devices, rigid device packaging, PPE, wipes, and pharmaceutical packaging.

"Healthcare has become overly dependent on disposable plastics, locking hospitals into rising costs and increasing greenhouse gas emissions," says Yoni Shiran, partner and plastics lead at Systemiq. "By redesigning products and procurement around circular economy principles, we can protect patients, protect budgets, and build resilience against future shocks."

The report highlights five practical, evidence-based circular economy strategies that U.S. hospitals and suppliers can scale today:

- Refuse and reduce unnecessary use (e.g. overuse of gloves).
- Reuse safe, durable alternatives such as gowns, trays, and masks.
- Substitute with paper-based or compostable materials where safe.
- Improve recycling through better design and segregation.
- Procure low-GHG emissions plastics from biobased or Carbon Capture and Storage (CCS)- derived sources.

If scaled across the system, these interventions could, by 2040, cut single-use plastics waste in North America by 54 percent, reduce GHG emissions by 58 percent, and deliver almost $8 billion in annual savings (a 21 percent reduction) compared to a business-as-usual scenario. If no action is taken, costs could go up to $37 billion per year by 2040.

Realizing this "high-ambition scenario" will require decisive and coordinated action from all system actors, including regulators and policymakers, who have sometimes exempted healthcare

plastics from past policies.

"Protecting patient health is non-negotiable — but many plastics pose their own risks," says Will Clark, international supply chain transformation director at Health Care Without Harm, a global non-governmental organization that provided a health sector perspective on the findings. "This report shows we can safely reduce or replace plastics, cut costs and environmental harm, and still deliver high-quality care."

More details @ https://eunomia.eco/reports/a-prescription-for-change/

FAST FACTS

Medical Device Quality Management System (QMS)

Establishing a quality management system (QMS) is often seen as a burden—or at least a fairly high hurdle for medical device startups to get over.

The truth is that your QMS is a vital part of your organization's success. And while it is a regulatory requirement, it may not be as difficult to build as you think.

Exploring International Markets For Medical Devices - A Strategic Perspective

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

We have been discussing the international markets for medical Devices with a focus on the export opportunity for more than two years now. The ultimate objective is to facilitate and support medical device exports from India. We have covered almost all the major markets of Asia and Latin America by now. This time, we would like to give a slightly different perspective with an overview of what has been covered so far.

How to select a market for the Export plan - Market scanning

The most studied and recommended model for market selection is **the GE McKinsey Matrix for Market Scanning** (also known as The Market Attractiveness-Competitive Strength Matrix). The readers are encouraged to read about this conceptual framework, as sufficient material about this model is available on the internet. However, a quick summary here will help.

This Matrix is a strategic planning tool used for evaluating various markets and then selecting or prioritising a specific market. The matrix assesses market attractiveness in the form of potential and matches the same with the company's competitive strength in a particular market. The classical use is for different market segments, but with some modifications, we will use the same model for countries (geographical segments).

The following dimensions are used in this matrix –
- Market size
- Market growth rate
- Loyalty or switching rate, and ultimately
- Strength of the competition

These parameters are finally matched with the strengths of the decision-making company.

The original matrix is fairly complex, but we will simplify the concept for our quick use. The data on these parameters, when compared, gives an objective selection method of a country (meaning a geographical segment).

Let us take an example of some LATAM countries and understand the concept in more detail. Based on the recent articles, the reader will recollect the following data

for the market size –

	Market size bn USD	Growth	Import	Major Buyers
Smaller Markets				
Argentina	1.4	5%	65%	Public hospitals
Colombia	1.5	3%	65%	Public hospitals
Large Markets				
Brazil	12	2.5%	50%	Public + Pvt hospitals
Mexico	15	8%	Net export	Public + Pvt hospitals

All these countries have the Latin languages (Spanish or Portuguese), all are almost equally far from India, and all have similar political systems (Socialism). So these factors being equal ("ceteris paribus"), we can overlook those parameters, making the comparison easier.

Argentina and Colombia are both smaller markets. If we are to decide between them and select only one, we can see that market size is almost same, both are public hospital-oriented markets and both have equal import dependence. So

Highlights

- The Market Attractiveness-Competitive Strength Matrix is a good objective model for market selection.
- A company needs to decide its own criteria for selection.
- A clear contract documentation is highly recommended.

these factors are the same for the Market Attractiveness-Competitive Strength Matrix discussed above. Growth rate-wise, Argentina is better (5% vs 3%).

For larger markets, a comparison between Brazil and Mexico will show that Mexico is better for market size as well as growth. Market style (public tenders) is the same. Competition may be higher since there are local manufacturers. In other words, for an exporter, if the product manufactured can compete on price and quality against local manufacturers, Mexico is a better choice.

Market selection based on the Regulatory aspect

If we compare the Regulatory classification of Brazil and Mexico, Brazil follows a risk level-based classification with four classes –

- Class I – low risk
- Class II – medium risk
- Class III – high risk
- Class IV – maximum risk

Mexico, on the other hand, has three classes, and the classification is ambiguous. Also, hard copies of the documents are generally required. So, an exporting company's capability on Regulatory aspects becomes important here as complexity is more in Mexico.

A comparison between Argentina and Colombia will show that both are at par for Regulatory rules.

Contractual arrangements

Over and above these factors taken form the model discussed, one factor which cannot be overlooked is the local partner. To find the right local partner, a company needs sufficient efforts, some access (the local Indian embassy, for example, can help), clear legal & contractual understanding (documentation), and luck. Since the local partner handles an Indian company's regulatory affairs, the right people (or a Regulatory consultant) should be accessible with the local partner. The contract must include mutual exclusivity, registration transferability (even by paying registration costs if applicable), due diligence clause, and an exit clause.

The last words

Economic and political factors also play a role in selection in the international scenario. In the cases discussed here, Colombia is much stable compared to Argentina. On the other side, both Brazil and Mexico are fairly stable and predictable markets.

An ultimate decision will depend on the Selection Criteria, the Company's regulatory, financial and market access capability. It may also be useful to use one country's registration or documentation for a similar country, without much additional investment.

In this article series, we will eventually cover a similar summary for the Asian and African markets, which will give a similar strategic perspective of those markets to the readers.

AiMED
Association of Indian Medical Device Industry

AiMeD & Regulatory Updates

AiMeD Welcomes Government's GST Rate Cut and MRP Implementation Relief for Medical Devices

New Delhi, 13 September 2025: The Association of Indian Medical Device Industry (AiMeD) has welcomed the timely directions issued by the Department of Pharmaceuticals (DoP), National Pharmaceutical Pricing Authority (NPPA) and the Central Drugs Standard Control Organisation (CDSCO) to ensure smooth implementation of the revised GST rates on drugs, formulations, and medical devices, effective from 22nd September 2025.

The Office Memorandum issued by DoP–NPPA clarifies that while manufacturers and marketers are required to revise Maximum Retail Prices (MRPs) to reflect reduced GST, recalling or re-labelling of existing stock already released in the market will not be mandatory, provided price compliance is ensured at the retailer level. CDSCO has further permitted the use of stickering on medical devices (Class C and D) within three months to reflect revised MRPs, thereby easing operational challenges for importers and manufacturers.

Commenting on the development, Mr. Rajiv Nath, Forum Coordinator, AiMeD, stated:

"This is a timely and pragmatic step by the Government that addresses an important operational challenge faced by retailers, manufacturers, importers, and distributors whenever GST rates are revised. The provision ensures compliance, consumer transparency, and prevents wastage of packaging material while also safeguarding the industry against undue stock losses. We appreciate that the Government has struck the right balance between protecting consumer interests and supporting industry ease of doing business."

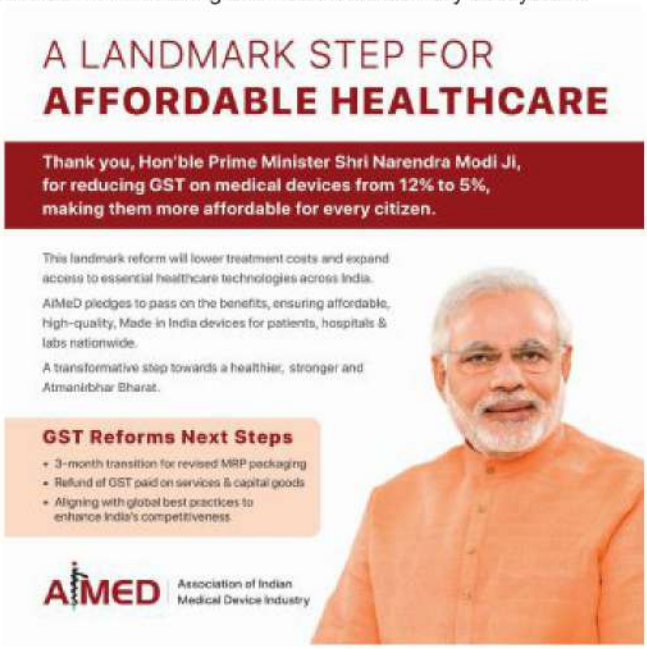
He further added:

"The allowance to use existing packaging material by DoCA till 31st December 2025 is a cost-saving very welcome measure that will benefit MSMEs and reduce unnecessary waste. We urge all industry members as well as our channel partners and stakeholders to strictly comply with the guidelines and issue prompt public notifications to ensure transparency and consumer trust."

"We await clarification for applicability for Class A & B medical devices as well as on pre-printed flexible packaging stocks with prior MRP for small packs of disposable medical devices like needles where online over-printing may be a challenge."

"We also await decision on GST reforms of refund on GST paid on services and on capital expenditure as is available in many countries globally so that reduction of prices is possible to be globally competitive, as the purpose of GST was to tax value addition at each step of the supply chain and not cause working capital stress to manufacturers or traders."

AiMeD reiterated its commitment to extend full cooperation to the Government for ensuring smooth transition of revised GST rates, safeguarding patient interests, and strengthening India's medical device manufacturing and healthcare delivery ecosystem.



NPPA Directs Drug Makers To Reduce Medicine Prices Following GST Rate Cut

NPPA has directed pharmaceutical and medical device companies to cut MRPs in line with recent GST reductions, effective 22 September. The move aims to pass tax relief directly to consumers and reduce healthcare costs.

New Delhi: The National Pharmaceutical Pricing Authority (NPPA) on Friday issued a directive to all drug and medical device manufacturers, directing them to immediately reduce the maximum retail price (MRP) of their products.

This move comes as a response to the government's decision to rationalize goods and services tax (GST) rates on drugs and formulations, a recommendation made during the 56th meeting of the GST Council.

The NPPA's action, effective 22 September, aims to ensure that the benefits of the GST reduction are passed directly to the public.

In an official memorandum on Friday, the NPPA laid out clear instructions for the pharmaceutical industry.

It said that all manufacturers and marketing companies must revise the maximum retail price of their drugs and medical devices to reflect the new GST rates.

While the NPPA communication does not specify penalties for non-compliance, it has the authority to monitor prices of drugs and medical devices and can take corrective action. Non-compliance with NPPA's price notifications can lead to prosecution under the Essential Commodities Act, 1955, which may result in imprisonment and fines.

To ensure this is implemented smoothly, they are required to issue a revised or supplementary price list to dealers, retailers, state drug controllers, and the government.

"The NPPA's directive is of immense importance to the public. By mandating the revision of MRPs, the authority is ensuring that the GST rate reduction translates into lower prices for consumers, making essential medicines and medical devices more affordable and accessible. This decision is of benefit for patients across the country, as it directly impacts their out-of-pocket healthcare expenses," an official familiar with the matter said.

Communication push

The regulator has also emphasized the need for widespread communication to ensure the public is aware of these changes. Manufacturers and marketing companies are instructed to use all possible channels, including electronic, print, and social media, to inform dealers, retailers, and consumers about the reduced GST rates and the corresponding revised MRPs.

Industry associations have also been asked to release advertisements in national and vernacular newspapers to ensure compliance.

The decision holds great significance for both the government and the pharmaceutical industry's stakeholders.

For the government, it demonstrates a commitment to consumer welfare and health equity, leveraging fiscal policy to reduce the financial burden of healthcare on citizens. For the industry, the NPPA has provided guidance on how to manage the transition.

The memorandum clarifies that recalling or re-labelling existing stock released before 22 September, is not mandatory if companies can ensure price compliance at the retail level.

Industry response

However, companies that wish to re-label their stock may do so in a phased manner to prevent any market shortages of essential drugs and devices, it said.

"This is a timely and pragmatic step by the government that addresses an important operational challenge faced by retailers, manufacturers, importers, and distributors whenever GST rates are revised. The provision ensures compliance, consumer transparency, and prevents wastage of packaging material while also safeguarding the industry against undue stock losses. We appreciate that the government has struck the right balance between protecting consumer interests and supporting industry ease of doing business," said Rajiv Nath, forum coordinator, AiMeD (Association of Indian Medical Devices Industry).

Nath reiterated the industry's commitment to working with the government to smooth GST transition support and strengthen India's medical device manufacturing and healthcare delivery ecosystem.

Earlier this month, Mint reported that the GST council had announced a complete removal of GST, from 12% to nil, on 33 life-saving drugs used for severe conditions like cancer and rare diseases.

Additionally, three other vital life-saving drugs have also been made tax-exempt, down from a 5% GST rate.

Furthermore, the tax benefits extend to a broad spectrum of healthcare products.

GST on all other drugs and medicines has been reduced from 12% to a more affordable 5%.

Similarly, a wide array of medical devices and supplies, including surgical equipment, dental apparatus, diagnostic kits, and common items like glucometers and bandages, will now attract a GST rate of just 5%, a significant drop from the previous 12% and 18% rates.

India-UK Trade Deal: Med Device Firms Cautious About Country Of Origin

Bilateral trade in pharmaceuticals and medical devices is set to receive a boost post the UK-India Free Trade Agreement (FTA), according to industry veterans.

India's imports of medical devices from the UK grew by 36 percent to Rs 2,295 crore in FY24, while exports to the UK increased by 13 percent to Rs 1,015 crore. Rajiv Nath, Chairman and MD of Hindustan Syringes and Medical Devices (HMD)—one of the top three disposable syringe makers in the world—and the forum coordinator of the medical devices industry body Association of Indian Medical Device Industry (AiMeD), believes that bilateral trade will rise on both sides post the FTA. "Our top exports to the UK were contact lenses, diagnostic reagents, surgical instruments, and PPE kits, while our major imports were oxygen therapy equipment like ventilators, X-ray equipment, diagnostic testing reagents, and IVD analysis instruments. Mostly, small and mid-sized manufacturers export through distributors in niche markets," Nath said.

"Previously, medical devices imported into the UK were duty-free, so tariff restrictions were not an issue, but regulatory approval costs and time were a challenge. We sought recognition of Indian CDSCO regulatory approval or QCI's voluntary Indian certification for medical devices to fast-track regulatory approval by the UK MHRA and address non-tariff barriers faced by Indian exporters, and we look forward to an update on this," Nath added.

Regarding imports into India, AiMeD has emphasized the need for strict monitoring and verification of Rules of Origin to prevent misuse of the FTA through the potential routing of third-country products as purportedly UK-made goods. "We welcome UK-made medical products into India via this FTA," he added. Import duties levied by India were mostly at 7.5 percent, which, post-FTA, are expected to come down in a phased manner. The industry is, however, awaiting the fine print.

As part of this agreement, import duties on MedTech products will be reduced from approximately 15 percent to around 3 percent, significantly lowering costs and improving access to advanced medical technologies, said Pavan Choudary, Chairman of the Medical Technology Association of India (MTaI).

For pharmaceutical exports, the UK is already an important and growing market. Companies like Torrent Pharmaceuticals, Dr Reddy's Laboratories, and Aurobindo have a presence in the UK. "With India's pharmaceutical exports to the UK reaching $914 million in FY24, the agreement strengthens supply chains,

enhances access to affordable medicines, and drives Foreign Direct Investment (FDI). This partnership paves the way for collaborations in bulk drug imports, CDMO, and joint research, empowering India's competitive edge and promoting global partnerships," said Namit Joshi, Chairman of the Pharmaceutical Exports Promotion Council.

Sudarshan Jain, Secretary General of the Indian Pharmaceutical Alliance, noted that the pharma sector will have opportunities to supply affordable and quality-assured medicine, contributing to better patient care in the UK. "We are awaiting further details to identify specific areas where these opportunities can be effectively leveraged," Jain said.

https://www.business-standard.com/economy/news/trade-boost-med-device-players-cautious-country-origin-125072401618_1.html

FAST FACTS

"Countries worldwide now look to India not only as a market, but as a leader in healthcare innovation"

- Shri Amit Agrawal,
Secretary, Department of Pharmaceuticals

"Medical Plastics Data Service" to be the Knowledge Partner for Skill Development Certificate Course for Plastics in Medical and Healthcare Industry by AIPMA's AMTEC

From let to right : Dr Ashutosh Gor, Mr D L Pandya, Mr Arvind Mehta and Mr Ajit Gupte during the meeting held on September 5, 2025

Plastics play a major role in the manufacturing of Medical Devices including Medical Disposables, Medical Equipment, Diagnostics, Hygiene products as well as Pharmaceutical Packaging. These sectors are growing at more than 15 % annually. The sector is considered sun rise sector and supported by State and central Governments under "Make-in-India' program.

Understanding of Medical Plastics Materials, their processing, productivity, quality and regulatory requirements will help the candidates to perform effectively and help them develop careers successfully with relatively high potential for earning and growth. This is a unique and only such skill development course for Indian Medical Disposables and healthcare industry.

"MEDICAL PLASTICS DATA SERVICE", THE BIMONTHLY MAGAZINE BEING PUBLISHED FOR LAST 33 YEARS, WILL BE SUPORTING AIPMA'S AMTEC AS KNOWLEDGE PARTNER FOR A 70 HOURS' OFF-LINE SKILL DEVELOPMENT COURSE FOR CURRENT AND POTENTIAL EMPLOYEES OF MEDICAL and HEALTHCARE INDUSTRY.

ABOUT AIPMA'S AMTEC

Established by the All India Plastics Manufacturers Association (AIPMA), a pioneering industry body founded in 1945. the Arvind Mehta Technology & Entrepreneurship Centre (AMTEC), represents a bold step toward bridging the gap between academic theory and industry practice. Backed by nearly eight decades of AIPMA's leadership in driving policy, innovation, and sustainability, AMTEC is purpose-built to shape future-ready professionals.

AIPMA'S AMTEC offers expert-led programs focused on advanced design, manufacturing, automation, and sustainable practices. Through real-world simulations, hands-on training, and global collaborations, our curriculum ensures that students, entrepreneurs, and professionals alike are equipped with practical skills that meet global industry standards.

From product design and prototyping to full-scale production and market readiness, AMTEC provides end-to-end support. With state-of-the-art technology, research facilities, and a future-forward mindset, we are proud to play a key role in driving self-reliance, growth, and innovation within the Indian plastics sector and beyond.

India Set To Drive Affordable Innovative Healthcare Solutions :

Shri Amit Agrawal Union, Secretary, Department of Pharmaceuticals

Government policies and competitive industry driving India's MedTech sector for sustained double-digit growth.

India making major strides towards self-reliance in high end medical devices

Shri Amit Agrawal, Secretary, Department of Pharmaceuticals, highlighted India's transformation into an emerging hub for medical technology at the 17th CII Global MedTech Summit, themed "Innovating for a Healthier Future – Advancing MedTech for Global Impact: Make in India, Make for the World", in New Delhi.

Addressing medical technology stakeholders at its opening plenary, Shri Agrawal stated that with India being home to the world's largest population and a rapidly growing economy, the domestic demand for affordable and innovative healthcare solutions is set to grow sustainably at double-digit rates of growth over the coming decades. He emphasized that the MedTech sector's core mission must remain cantered on patient well-being and on developing high-quality, cost-effective medical devices for both domestic and global markets.

Shri Agrawal noted that, post-COVID, India has successfully

crossed a significant milestone in domestic manufacturing of advanced equipment, including MRI and CT scan machines, mammography units, ventilators, stents, heart valves, dialysis machines and a range of implant devices. He stated: "Products that seemed impossible for local production a decade ago are now manufactured in India, demonstrating the country's growing capabilities and innovation ecosystem."

Highlighting Government's support for the sector, the Secretary referred to the three upcoming dedicated medical device parks expected to be functional in the coming year, support planned for their continued infrastructure upgrade and the Production Linked Incentive (PLI) Scheme for Medical Devices as major policy steps propelling the industry forward. Shri Agrawal called for deep collaboration among innovators, entrepreneurs and investors to accelerate the journey of new ideas from laboratory to market, thereby strengthening India's global competitiveness.

Expanding medical device park facilities, targeted policy initiatives like the PLI scheme and the Marginal Investment Scheme for backward integration, and the soon-to-be launched ₹5,000 crore Promotion of Research and Innovation in Pharma MedTech Sector (PRIP) Scheme would result in enhancing Indian MedTech sector's cost - competitiveness and production efficiency, deepening of the domestic value chain and creation of a strong innovation ecosystem. The Secretary said that these will enable India to not only meet its own requirements but also offer affordable innovative healthcare solutions to the global North and South alike.

"Countries worldwide now look to India not only as a market, but as a leader in healthcare innovation. We must believe in our own capabilities and intensify industry-government partnership to realize the full potential of the MedTech sector," said Shri Agrawal. He stated that with ongoing economic reforms and international trade agreements, the sector will generate millions of new jobs while helping ensure accessible, high-quality healthcare for all.

He concluded by inviting all stakeholders to contribute to shaping India's MedTech vision and called for collaborative and concerted efforts across the value chain — in partnership with all stakeholders — to realize India's vision of Viksit Bharat 2047.

(Ref : Posted On: 30 AUG 2025 9:17AM by PIB Delhi)

Press Release

QOSINA
Thousands of Stock Components

Qosina Debuts Interactive Vending Machines for Engineering Samples

Qosina, a global supplier of OEM single-use components to the medical and pharmaceutical industries, is rolling out a new way to sample: vending machines stocked with medical device components.

With instant availability and an engaging format, the vending machines—nicknamed Qosina Qubes—turn sampling into a hands-on experience that encourages discovery and innovation.

Companies will soon be able to request a machine for their own offices or labs, putting Qosina's thousands of components within arm's reach for rapid prototyping and exploration.

"Engineers love solving problems but often face delays in getting the right part they need when they need it," said Lee Pochter, CEO of Qosina. "In addition to our traditional sampling options, the Qosina Qubes provide instant access—no forms, no delays—with the simple push of a button. Equal parts functional and engaging, they make discovery faster and easier, so engineers can focus on driving their next breakthrough."

The new vending solution will launch at MEDevice Boston (September 30–October 1, 2025) and ISPE (October 1, 2025), giving attendees a first look at the interactive concept. Following the trade show debut, the machines will be introduced at M2D2, an incubator in the Boston area, and at additional customer locations, expanding access for engineers and innovators.

For more information, or to learn how to bring a Qosina vending machine to your workplace, visit https://bit.ly/qosinaqube-vendingmachines.

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.

Contact : 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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- ☐ Medical Device Manufacturer
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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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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.

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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

ORGANIZERS

Society Of Plastics Engineers (SPE) INDIA Medical Plastics Division

SPE , founded in 1942, with 60000 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.

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.

WHO SHOULD PARTICIPATE?

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

CONTACTS :

SPE INDIA - D L Pandya , Vice President , SPE India Medical Plastics Division, E-Mail : dlpandya@gmail.com / medicalplastics@gmail.com, M : 9825457563
Rajiv Sanghavi, SPE India International Councilor, rsanghavi@speindia.org , M : 9619140918 / 9820088050
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PREVIOUS EVENT REPORT

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EMERGING TRENDS, INNOVATIONS AND OPPORTUNITIES IN PLASTICS/POLYMERS FOR MEDICAL DEVICES AND HEALTHCARE

Jan 20, 2023 Seminar, Jan 21, 2023 Industry Visit (Optional and Limited Participation); 9.30 AM onwards; Venue : Hotel Appolo Dimora, Thiruvananthapuram

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Supporting Organizations

- Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST)
- Association of Indian Medical Industry (AiMeD)
- Kerala Startup Mission
- Terumo Penpol Pvt. Ltd.
- Rajiv Gandhi Centre for Biotechnology (RGCB)
- Indian Institute of Science Education & Research
- Kerala Life Sciences Industries Parks Pvt. Ltd. (KLIP)
- Kerala Medical Technology Consortium
- Kerala Plastics Manufacturers Association (KPMA)*
- HLL Life Care
- CSIR – National Institute for Interdisciplinary Science and Technology (NIIST)

HIGHLIGHTS

Day 1 Seminar	Day 2, Visit To Industry, Testing & Research Facility
Expert Presentations / Panel Discussions covering : • General Overview and Business Opportunities. • Introduction to Polymers & Plastics for Medical Applications • Developments & Opportunities in Medical Polymers • Medical Plastics Processing, Design & Development, Quality, Testing, Recycling	**Visit to Following Two Organizations** 1. **Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST).** - Including : Biomedical Technology Wing Testing Laboratories, Prototype Development Centre, TiMeD (Technology Business Incubator). 2. **HLL Lifecare Limited Center of Excellence R & D.**

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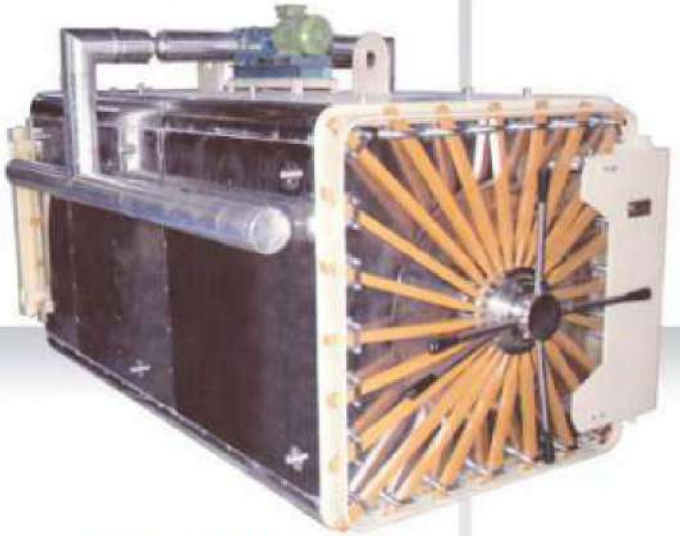

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