

MEDICAL PLASTICS DATA SERVICE

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

www.medicalplasticsindia.com
www.medsourcesia.com

Rajiv Nath
Managing Director,
Hindustan Syringes
& Medical Devices Ltd.



Linchon B. Mehta
Business Development
Manager,
JRD Polymer Pvt Ltd.

• Sterilization of Polymer Healthcare Products

- Sterilization of Single Use Medical Devices: Science Over Myths
- Comparison of Common Sterilization Methods
- Ethylene Oxide Sterilization Validation: A Real-World Scenario
- cGMP-centric Terminal Sterilization using ionizing radiation products
- Medical Polymers and Their Compatibility with Sterilization Methods
- EtO Gas Scrubber with 99 % EtO removal efficiency with all safety measures.
- EtO Health Hazards

• Innovation: Device for Continuous Glucose Monitoring

- **Award:** Mr. Balram Sankaran, Scientist-1, SCTIMST Receives Dr. V. G. Patel New-Age Entrepreneurship Award

- **Meet The Executive :** Mr Linchon B. Mehta, B. D. Manager, JRD Polymer
- **Industry-Academia Collaboration** for Medical Devices Development
- **Global Event:** COMPAMED 2025 – Where Medical Innovation Begins



Balram Sankaran
Scientist, SCTIMST,
Trivandrum



Viral Sheth- M.Sc (Microbiology)
Director- Operation Medreg Consultancy LLP
Director- Medreg Biotox LLP
Principal Consultant- HL Associates



Amit Srivastava
(DGM, ISOMED 2.0, BRIT)



Arun Kumar Tyagi
(TOE, ISOMED 2.0, BRIT)

5th National Two-Day Event On Advances in Medical Polymers & Composites: Shaping the Future of MedTech

Day 1, Dec. 11, 2026 : Seminar; Day 2, Dec. 12, 2026 (Optional) Industry Visits
Venue : Infinity Hall, AMTZ, Visakhapatnam



Ami Polymer
Enabling Healthcare



PURITY STARTS WITH PRECISION

Imapore™ Cartridge Filters-advanced filtration solutions engineered for critical pharmaceutical, biotechnology, and life sciences applications.

In biopharmaceutical manufacturing, every filtration step plays a critical role in protecting product integrity and ensuring process consistency. Imapore™ Cartridge Filters from Ami Polymer Pvt. Ltd. are engineered to deliver exceptional filtration efficiency, reliable performance, and uncompromising quality across a wide range of critical applications.

MEMBRANE TECHNOLOGIES DESIGNED FOR THE RIGHT APPLICATION

PES (polyethersulfone)

Hydrophilic, low protein binding, high flow
Injectables, IV fluids, vaccines, biologics

PTFE (Polytetrafluoroethylene)

Exceptional solvent & chemical resistance
Solvents, aggressive chemicals, air & gas
filtration

PVDF (Polypropylene)

Mechanically robust, steam-sterilizable
Water systems, utility filtration, process
clarification

PVDF (Polyvinylidene Fluoride)

Low extractables, strong chemical resistance
Proteins, diagnostics, mixed-solvent formulations

Glass Fiber (GF)-De th Filters

High dirt-holding capacity Viscous
fluids, fermentation broths, pre-filtration

Syringe Filters

Available in PES, PVDF, PTFE, Nylon, GF & PP.
HPLC/GC, GC labs, R&D, microbiological testing



www.amipolymer.com
media@amipolymer.com

Not only Extruder Manufacturer, but also Extrusion Solution Provider

PS Pipe Extrusion Line



Core Technology

Precision Extrusion System

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

Multi-stage Cooling and Sizing

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

Online Diameter Measurement (with Closed-loop Function)

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

Flexible Adaptability

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

Process Flow

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



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

HIGHRICHJA PRECISION EXTRUSION MACHINERY CO.,LTD

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

Tel: +86-757-86407501

Fax: +86-757-86407500

Website: www.chinahjr.com.cn

E-mail: why@chinahrj.com.cn

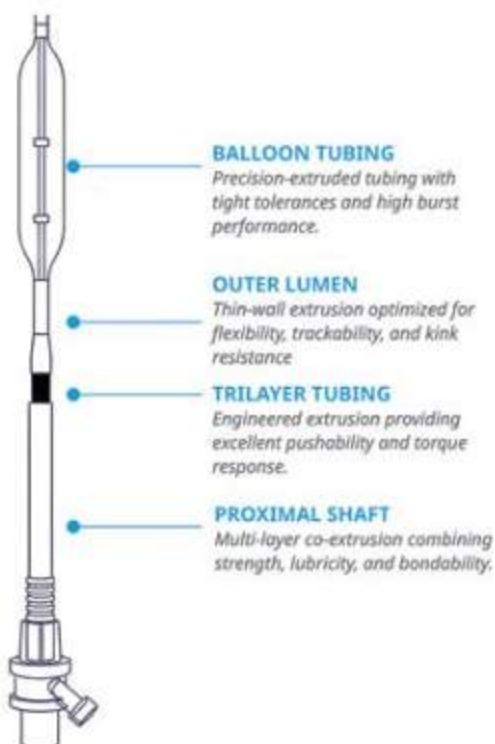
WhatsApp \ Wechat: +0086-13928609286, +0086-13434861212, +0086-13229219297, +0086-13326786657



SUPPORTING CATHETER MANUFACTURERS WITH LOCAL MANUFACTURING, TECHNICAL COLLABORATION, AND RAPID SAMPLING FROM INDIA.

With Lubrizol's new **Medical Extrusion Facility in Chennai**, we can now support PTCA catheter manufacturers with **locally produced catheter components** and development support.

Whether you're accelerating a new program or looking for a trusted component manufacturing partner, Lubrizol combines **local responsiveness with proven medical extrusion expertise**.



- Manufactured in India
- Rapid Sampling
- Support from Concept through Commercialization
- Powered by Lubrizol's global medical capabilities

LOOKING TO ACCELERATE YOUR PTCA PROGRAM?

Our team is ready to discuss your upcoming development and manufacturing requirements.

Reach out to Rajnish.singh@lubrizol.com

A6 Series 90-1000T

Advanced and Intelligent Injection Molding Machine



- 10% energy saving compare to std. Servo machine
- Intelligent weight V/P control
- Standard feature of KEBA controller for all models
- Intelligent clamping force management system



Yizumi Advanced Processing Technology Pvt. Ltd

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

+91-90999 06175

info.india@yizumi.com

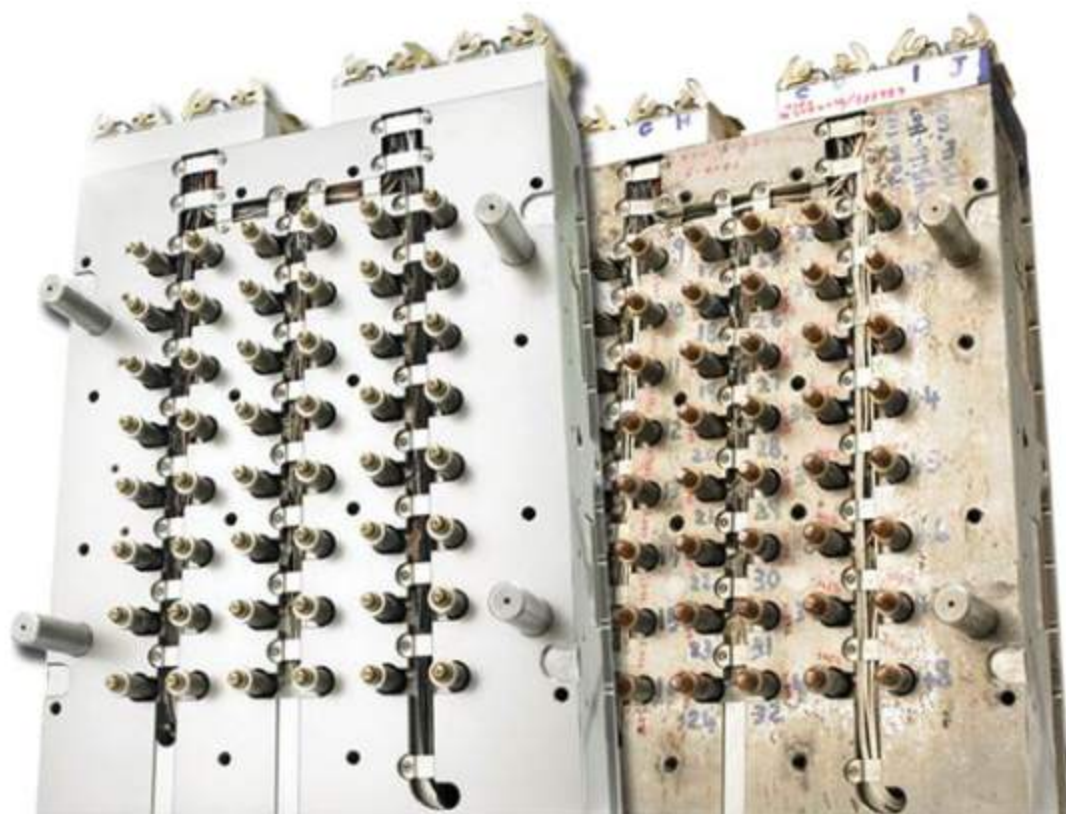
www.yizumi.com





husky.co

GET YOUR HOT RUNNERS BACK TO ORIGINAL PERFORMANCE LEVELS WITH HUSKY'S PLATINUM REFURBISHMENT PROGRAM



Contact us to learn more
about hot runners and controllers

Chennai Office
P-47, VIII Avenue,
Domestic Tariff Area,
Mahindra World City,
Chengalpet - 603 002.

Rajendran Kasi
+919884709703
krajendr@husky.ca

Premium Silicone Tubing Solutions

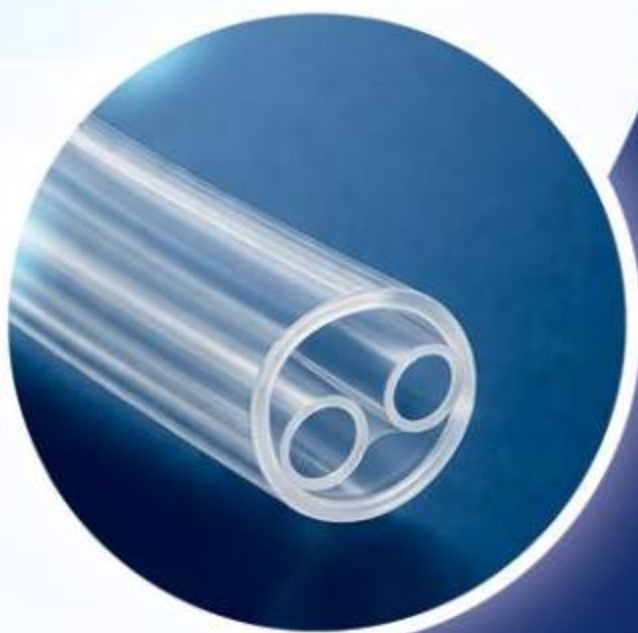
Precision extrusions for diverse medical devices and life science applications

What you can expect:

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

Our Medical & Healthcare Range:

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



Contact us

✉ Email: info@sevitsil.com

☎ Mo.No.: +91-74860 06699
+91-81416 01666

🌐 Website: www.sevitsil.com

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



Scan QR code to
download a catalogue



RIBOSOME RESEARCH CENTRE PVT. LTD.

A Contract Research Organization for cutting-edge biocompatibility testing
MEDICAL DEVICES-ISO 10993-1:2025

COMPREHENSIVE TESTING
REGULATORY SUPPORT
QUALITY-DRIVEN
REPORTING

ONE-STOP SOLUTION FOR ALL BIOCOMPATIBILITY TESTING



CARDIAC STENT

Delivering strength,
flexibility & life-saving
performance



BONE & MUSCLE IMPLANTS

Restoring mobility,
supporting healing,
improving lives



OCULAR IMPLANTS

Enhancing vision with
precision, safety &
clarity



TESTING SERVICES FOR DIFFERENT REGULATORY MARKETS:

USFDA
(510(k))

European Union
CE marks under EU MDR 2017/745

CDSO
(MDR-2017)

01



In Vitro Cytotoxicity Test
ISO 10993-5

02



Genotoxicity Test
Bacterial Reverse Mutation, Micronucleus test,
Chromosomal Aberration test • ISO 10993-3

03



Systemic Toxicity Test
Acute, Sub-acute, Sub-chronic, Chronic Toxicity,
Carcinogenicity, etc. • ISO 10993-11

04



Tests for Irritation
ISO 10993-23

05



Implantation Test
Different routes viz. SC/IM/bone in rodents &
nonrodents • ISO 10993-6

06



Hemocompatibility Testing
Direct/Indirect Hemolysis Test, PTT, Hematology,
Platelet Count, Complement Activation Test etc. •
ISO 10993-4

07



Pyrogen Test
ISO 10993-11

08



Skin Sensitization Test
GPMT & Buehler test • ISO 10993-10

09



Bacterial Endotoxin Test
IP, USP, ISO 11737-3

10



Microbial Limit Test
IP, USP

11



Sterility Test
IP, USP, ISO 11737-2

12



Bioburden Test
USP, ISO 11737-1

13



Ethylene Oxide / Chlorohydrine / Glycol
Residual Analysis • ISO 10993-7

14



Chemical Characterization Testing
ISO 10993-18

15



Toxicological Risk Assessment
ISO 10993-17

16



Biological Evaluation Plan & Report
Preparation of Biological Evaluation Plan &
Biological Evaluation Report

17



Waiver Report
For Biocompatibility Studies



Location:

Ribosome Research Centre Pvt Ltd. Sr. No.
261/1, Block No. 271, Near Dhanvantary
Pharmacy College, Kudsad - 394110,
Taluka: Olpad, Surat, Gujarat, India.

Email Your Inquiries on:

ceo@ribosomeresearch.com
bd3@ribosomeresearch.com
bd2@ribosomeresearch.com
bd5@ribosomeresearch.com

Phone Number:

+91 99041 55567
+91 72111 55605
+91 72111 55601
+91 72111 55604



Because every life matters

ENGEL

Compliance.
Cleanroom.
Validation -
Every cycle



Designed for ISO 7 and GMP-compliant production, ENGEL solutions deliver validated processes, contamination control, and high repeatability for reliable medical manufacturing. Since every cleanroom application is unique, each solution is individually tailored to the product and production requirements. Together with experienced cleanroom partners, ENGEL ensures maximum purity, traceability and confidence in every cycle.

Be precise where it matters most with ENGEL.



Quality by design



Risk minimisation



Operational excellence



Global standards compliance



Advanced Materials For Next-Generation Auto-Injectors

Celanex® MT® PBT
Hostaform® MT® POM

Celanex® MT® PBT and **Hostaform® MT® POM** deliver the performance required for reliable, patient-centric drug delivery devices. Combining excellent mechanical strength, dimensional stability, low-friction performance, good surface appearance and colorability and PFAS-free* material options, these engineered polymers help enable smooth operation, enhanced durability, and sustainable device designs.



Enhanced durability

Achieved through superior creep resistance, impact performance, and weld-line strength.



Smooth injection operation

Improved low friction for enhanced performance and reduced wear.



Sustainability

Biobased (ECO-B), carbon capture (ECO-C), PFAS-free*, approved grades.

Scan and download
solution showcase



celanese.com



Visit healthcare.celanese.com to learn more
or download our solutions showcase using the QR code.

Learn more about Celanese India's commitment to the medical and pharmaceutical industry.
+91-22-62596200 | EM-Customer-Inquiry-Center-Asia@celanese.com

*containing no intentionally added PFAS

ADVANCED MEDICAL-GRADE POLYMERS

Engineered for Safety. Designed for Performance.

Every Day, Medical Devices Rely on High-Performance Polymers
As healthcare innovation accelerates, manufacturers require materials that are:

**Safer. Stronger. Lighter.
More Reliable. More Sustainable.**

JRD Polymer is your trusted distribution partner, delivering a comprehensive portfolio of medical-grade polymers engineered to meet the highest standards of regulatory compliance, biocompatibility, and performance.

Our Medical Portfolio

PA6 - AKULON® Care

Advanced wound care •
Interventional cardiology devices •
Precision molded components

PBT & PET - ARNITE® Care

Catheters • Inhaler valve systems •
MIS instruments

TPC - ARNITEL® Care

Dialysis tubing • Flexible films •
Breathable healthcare applications

PPA - FORTII® Care

Continuous glucose monitors (CGM) •
Dental implants • Trauma fixation
devices

PA6/66 - NOVAMID® Care

IV fluid bags • Medical barrier films •
Sterile packaging

TPE-S - Franplast® (Medical Grades)

Seals & gaskets • Tubing & fluid handling
• Respiratory & mask components •
Wearable healthcare devices

POM - Kepital / Iupital (Medical Grade)

High-precision parts • Drug delivery
systems • Inhaler components

PMMA

Transparent medical housings •
Diagnostics • Optical components

Medical-Grade Acrylic Copolymers

High-clarity • Impact-resistant •
Healthcare enclosures

ABS Medical Grade + GPPS & HIPS

Device housings • Structural parts •
Disposable components

Polycarbonate (PC) - Medical Grade

Surgical instrument housings •
Oxygenators • IV connectors • Dialysis
components • Transparent reservoirs •
Impact-resistant device enclosures

Key features & compliance

- USP Class VI & USP <87> compliant grades available
- Blood & tissue contact (<24 hours) options
- ISO 10993 aligned materials
- High purity & chemical resistance
- Exceptional dimensional stability
- Sterilization compatible (EtO, Gamma, Steam*)
- PFAS-free solutions available
- Manufactured under ISO 9001 standards
- Full compliance documentation available
- Biocompatibility certificates supported

Address: Office No. 204, B wing, Naman Midtown, Next to One International Center,
Off Senapati Bapat Mart, Prabhadevi (West), Mumbai 400013. **Phone No.:** +91 9323 184 471 / +91 9967 332 111

For enquiries: amol@jrdpolymer.com / jrdoffice@gmail.com / jrdcorporation@gmail.com



rapidfacto software

SOFTWARE FOR MANUFACTURERS



Medical Devices



Automobile

SOFTWARE GENERATES DOCUMENTS AS PER MDR-2017

Book a Free Demo



+91 8708856807

contact@rapidfacto.com

- ✓ Audit Ready
- ✓ Full Traceability
- ✓ Cloud Based
- ✓ Easy to use
- ✓ QMS
- ✓ Inventory
- ✓ Sales, Purchase
- ✓ Resource Planning

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

**BMR
Software**

www.rapidfacto.com

SOFTWARE FOR PRODUCTION, STORE, QA, QC



STAC MoldTech Private Limited

Corporate Profile



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

Manufacturing Facilities & Capabilities Include:

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

Robust Quality Management System

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

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

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

Excellent Customer Support

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

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



STAC MoldTech Private Limited

(Formerly SHANKAR TOOLS AND COMPONENTS)

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

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

CDSCO LICENSE

CDSCO MANUFACTURING LICENSE – MD5, MD9

DOCUMENTS REQUIRED

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

GOVT FEES

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

CDSCO IMPORT LICENSE – MD15

DOCUMENTS REQUIRED

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

GOVT FEES

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

DOCUMENTATION

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

PLANT DESIGN

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

REGULATORY SERVICES

MANUFACTURING LICENSE

IMPORT LICENSE

TEST LICENSE

FACTORY DESIGN

ISO 13485

TECHNICAL FILE

US FDA 510(K)

CE MARKING (MDR, IVDR)

CANADA MDL & MDEL

CLEAN ROOM DESIGN

QMS IMPLEMENTATION

FREE SALE CERTIFICATE





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



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



Decrease
temperature in
injection molding



Excellent
clarity and
aesthetics



Energy
savings



Complies with
GB 15810,
YY0242
standards



Increase in
productivity



Elimination
of voids

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



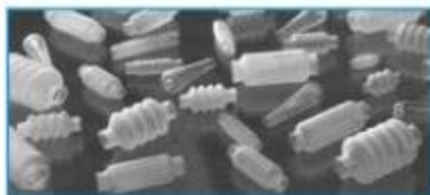
Elastomer Technik



**Your Professional Partner In The
Development & Manufacturing Of
Silicone Products For The
Medical & Pharmaceutical Applications.**

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

Our Range Of Products Includes:



Our Quality & Standards Certificates:

- DIN EN ISO 9001 Quality management
- DIN EN ISO 13485 Quality management for medical devices
- DIN EN ISO 14001 Environmental management
- Cleanroom EG-GMP-guideline Annex 1 cleanroom class D & ISO14644-1 (class 8)

ET Elastomer Technik GmbH:

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

ET Elastomer Technik India Pvt. Ltd.

Plot No.30, GIDC Electronic Park SEZ, Sector - 26,
Gandhinagar - 382 028, Gujarat, India
Phone: +91 97277 63274 Email: admin@elastomer-technik.in



Trust Built on Performance



TOTAL SOLUTION IN PLASTICIZER & POLYMER COMPOUNDS

We, KLJ Polymers & Chemicals Ltd. Delhi, one of the largest manufacturer of Healthcare Polymer Compounds i.e. PVC, TPE and PP compounds for Breath Care, Surgi Care, Storage & Disposables in a single facility having large capacity and expanding with global supply demand.

We care for Clean-Room GMP, Biocompatibilities and Healthcare standards as per USP Class-VI, ISO 10152:2002/ ISO 3826:2013, ISO 10993:2013, IS 10148 & IS 10151, California -65, RoHS, REACH compliances.

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

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

RANGE OF PLASTICIZERS

PHthalates | ADIPATES | TRIMELLITATES | CITRATES | STEARATES | SEBACATES | DI-BENZOATES | TERE-PHTHALATES | BIO PLASTICIZERS | MALEATES | FLAME RETARDANTS | CHLORINATED PARAFFINS | ESBO |

RANGE OF COMPOUNDS

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

COMPOUNDS FOR APPLICATIONS

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

Phthalate Free / REACH Compliant Plasticizers available

Our Application Range:

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

Corporate Office: KLJ Hose, 8A, Shivaji Marg, Najafgarh Road, New Delhi-110 015, India
Tel.: +91 11 41427427/28/29 | Fax: +91 11 25459709 | Email: delhi@kljindia.com

Mumbai: +91 22 61830000, mumbai@kljindia.com | Chennai: +91 44 42383622, chennai@kljindia.com
Kolkata: +91 33 22823851, kolkata@kljindia.com

Plasticizer | Polymer Compound | Petrochemical Trading | Real Estate Development | Chlor Alkali

Shibaura Machine

Sustainable Technology for Future

All Electric Injection Moulding Machine

ELSX^{III} SERIES
S-Concept
30 - 3000T

“

*Next-generation molding machine to achieve
even higher productivity, labor savings, and
environmental friendliness*

”

Medical Component
Moulding

Fast. Precise. Consistent.



Contact Us

shibauramachine.co.in

sales@shibauramachine.co.in

9150021901 / 8925188110

PVC NON-TOXIC MEDICAL TUBE PLANT



Models	TTX-45	TTX-50	TTX-65
Screw Diameter	45mm	50mm	65MM
L/D Ratio	26 : 1	26 : 1	26 : 1
Tube Size Range	1 to 30 mm	1 to 38 mm	5 TO 50 mm
Extruder Motor	5.5 KW	7.5 KW	11.0 KW
Tube Puller Motor	0.75 KW	0.75 KW	0.75 KW
*Output Kg./Hour	20-24	28-32	30-55
Total Connected Load	12.5 KW	14 KW	20.5 KW



PVC NON-TOXIC MEDICAL TUBE PLANT WITH AUTO CUTTER

For making medical use tubes for I V set, scalp vein tubes, Rail tubes, Blood & Urine tubes



C/1, 4410, Phase-4, G.I.D.C. Estate, Road No. 4U, Vatva, B/h Indo-German Tool Room, Ahmedabad - 382445. (Gujarat) INDIA. Phones : 91-79-46014068, 98250 28418, 98980 28418
E-mail : twistew@gmail.com Website : www.twistplasticmachinery.com



L MED™
MADE FOR COMFORT

**ALL SILICONE FOLEY
BALLOON CATHETER**



**PEDIATRIC, ADULT, OPEN TIP, TIP HOLE
& TIEMANN - 2WAY & 3WAY**

LEELAVATHY MEDICAL DEVICES COMPANY

No. 1/122, Paraniptur-Kovur Service Road, Periyapanicherry, Chennai-600128, INDIA

Email Id : sales@lmed.co.in | Web : www.lmed.co.in

Phone: +91 8939480062, 9884399735



ISO 13485 Certified
WHO GMP Certified



**Information Resources For Medical
Technology Industry And Markets**

**MEDICAL PLASTICS
DATA SERVICE**

A Techno-Economic News Magazine For Medical Plastics,
Medical Devices, Diagnostics And Pharma Industry



MEDICAL PLASTICS INDIA

Medical Plastics • Medical Devices • Diagnostics • Pharma
www.medicalplasticsindia.com

www.MEDICAL **PACKAGING** INDIA.com

Medical Devices and Pharmaceuticals
Packaging & Sterilization

www.**medisourceasia**.com

An Authentic Portal Site On Medical Technology
And Markets In Asia

www.indconferences.com



National Conference And Technology Exhibition On
**Indian Medical Devices & Plastics
Disposables/Implants Industry**

Pioneer & The Only Event For Medical Disposables
& Implants Industry In India

CLASSIC COMPUTER SERVICES

B-4, Mandir Apartments, Opp. Jodhpur Char Rasta BRTS Bus Stop, Satellite Road,
Ahmedabad-380 015. Gujarat, INDIA. Mobile : +91 98254 57563 / 98254 57518

E-mail : info@medisourceasia.com • dlpandya@gmail.com • medicalplastics@gmail.com



CUSTOM PVC MEDICAL COMPOUND

For Most Challenging Requirements



**Speciality Medical
Compound**



**Medical
Compound**



**Rigid PVC
Compound**

I Kare USPs

1. I kare has an extensive selection of Medical and General PVC Compounds specially designed for Extrusion, Injection and Blow Moulding.
2. We manufacture products according to exact specifications of customers.
3. Our Medical Compounds designed to meet requirements of sterilisation by ETO, steam, Gamma Radiation
4. Our PVC Compounds are available in both DEHP and NON-DEHP base as per customer's requirement
5. Our variety of Rigid PVC Compounds excels in Gloss, high impact, clarity and yield. Rigid compounds are designed to withstand degradation and discoloration associated with sterilisation.
6. Our Medical PVC Compounds are tested and complies to the global regulatory requirement of ISO 10993 and ISO 3826.

I Kare Compounds Pvt Ltd

📍 Sr No 244/14, Gala No. 1, Vraj Industrial Park, Morai, Vapi, Gujarat Pin 396191
☎ +91 95179 11553, +91 93770 00389 ✉ ikpp10815@gmail.com | care@i-kare.in





The future of healthcare doesn't wait.
Neither should you.

4th WORLD HEALTH INNOVATION FORUM & GLOBAL MEDTECH EXPO 2026



**11-13
DECEMBER 2026**



AMTZ, Visakhapatnam
Kalam Convention Center,
AMTZ Campus



Explore
Innovation in
Healthcare



Create
Public Private
Partnership Platform



Support
Policy-Making
in Healthcare



Impact
Global Health

EXHIBIT AND LAUNCH YOUR PRODUCTS

What are you waiting for?

GRAB YOUR SPACE NOW

Join us. Know more.
Make it happen.



Scan To Register

For Forum Information, Contact Us:

+91 78943 30618 | whif@kiht.in

www.whif.kiht.in

For More Information & Sponsorship Opportunities:

+91-99572 24580

www.whif.kiht.in

Media Partner

**NDTV
Profit**

Lanyard Partner

oritemiz

5th National Two-Day Event On Advances in Medical Polymers & Composites: Shaping the Future of MedTech

Day 1, Dec. 11, 2026 : Seminar, Day 2, Dec. 12, 2026 (Optional) Industry Visits
Venue : Infinity Hall, AMTZ, Visakhapatnam

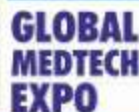
Jointly Organized By



Event Partner



Held In Conjunction With



Supported By



FOCUS

Day 1, Dec. 11, 2026:

- Medical Polymers & Composites
- Emerging processing technologies
- Quality Requirements & Testing
- Standards and Regulations
- Entrepreneurship & Start-up Opportunities
- Recycling & Sustainability

Day 2, Dec. 12, 2026: (Optional)

- Visit to Medical Device Companies, for delegates
- Tour of the world class AMTZ Medical technology park
- Participation in World Health Innovation Forum
- Visit to Global Health Expo Exhibition
- Workshop on Pharma and Medical Device Quality Testing

www.medicalplasticsindia.com
MEDICAL PLASTICS
DATA SERVICE
A Techno-Economic News Magazine for Medical Plastics,
Medical Devices, Diagnostics and Pharma Industry

INTRODUCTION:

The global MedTech industry is among the top sectors in R&D spending, with polymeric materials at the centre of device innovation. The Indian MedTech industry is also expanding rapidly with a CAGR of more than 15% annually. The purpose of this seminar is to explore how **innovations in medical polymers and composites are transforming medical technology**, bridging material science with clinical applications. Discussions on **emerging materials, advanced processing technologies, regulatory pathways, and sustainability imperatives** will inspire strategies that drive innovation, accelerate commercialization, and strengthen India's position in the global MedTech ecosystem.

OBJECTIVES:

- Present the current status of medical polymers and composites in the global MedTech industry
- Discuss breakthroughs in biocompatible, biodegradable, and high performance polymers
- Demonstrate how polymeric materials are transforming patient care, safety, and accessibility
- Review emerging processing technologies — precision moulding, automation, and sustainable alternatives
- Discuss compliance with ISO standards and global regulatory pathways.
- Identify opportunities for start-ups, investment, R&D and market expansion
- **Tour of the world class AMTZ Medical technology park, for delegates**

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

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.



5th National Two-Day Event On Advances in Medical Polymers & Composites: Shaping the Future of MedTech

Day 1, Dec. 11, 2026 : Seminar; Day 2, Dec. 12, 2026 (Optional) Industry Visits
Venue : Infinity Hall, AMTZ, Visakhapatnam

ORGANIZERS



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

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



**Indian Plastics Institute (IPI)
- Medical Plastics Division**

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. IPI has set up a medical plastics vertical to support medical device industry in strengthening India's position in the global MedTech ecosystem

Event Partner



Andhra Medical Technology Zone (AMTZ)

Andhra Pradesh Medical Technology Zone is one of world's largest medical technology manufacturing cluster with over 100 companies working on research, development and production of life saving medical devices.

AMTZ includes Common Manufacturing Facilities & Common Scientific Facilities that with specialized laboratories, warehousing, and testing centers such as the Center for Electromagnetic Compatibility and Safety Testing, Center for Biomaterial Testing, Center for 3-D Printing, Centers for Lasers, MRI Super Conducting Magnets, Gamma Irradiation Centre, Mold & Machining Centre, and many other industrial service centers.

Concurrent Events



**World Health
Innovation Forum**

World Health Innovation Forum - Event Presentation & Global MedTech Expo

The World Health Innovation Forum provides an unparalleled opportunity for companies to connect with a global community of health innovators, leaders, and policymakers. It includes:

**GLOBAL
MEDTECH
EXPO**

- Networking with Global Leaders: Engage with top leaders in medical and manufacturing sectors, round tables, and open forums, student paper competition, public-private collaborations.
- Scientific Sessions and Round Tables: Participate in in-depth scientific discussions
- Paper Presentation: Encourage young & ignited minds talent through a dedicated Public-Private Partnership Policies: Gain insights into policies shaping
- Engagement with Policymakers: Connect with policymakers and health innovation agencies to influence the future of health.
- Expo Area: Discover new technologies and innovative solutions in the expo area

CONTACTS

SPE INDIA - D L Pandya, Vice President, SPE India Medical Plastics Division,
E-Mail: dipandya@gmail.com, admin@speindia.org/medicalplastics@gmail.com,
M: 9825457563/9825457518
Rajiv Sanghavi, SPE India International Councilor, rsanghavi@speindia.org,
M: 9619140918/9820088050

Address: Society Of Plastics Engineers India
B 315-B 316, Damji Shamji Corporate Square, Laxmi Nagar, Ghatkopar East,
Mumbai 400 075. Website: www.speindia.org

INDIAN PLASTICS INSTITUTE

30, Sarvodaya, Industrial Estate, 1st Floor, Near Paper Box Factory,
Off Mahakali Caves Road, Andheri East, Mumbai - 400093. Sandeep Shinde,
Secretary General, GC, IPI. Phone: +91 22 66950347, M.: 7738919439,
Email: indianplasticsinstitute@iplindia.org

Download Registration Form



Table of Contents

Vol. 34 No. 5 September-October 2026



27

COVER STORY

Sterilisation of Polymer Healthcare Products

A variety of general considerations of sterilisation must be made to achieve sterility without adversely affecting product and material quality. A comparative analysis for various sterilizations methods is given.



28

Sterilization of Single Use Medical Devices: Science Over Myths

Rajiv Nath Managing Director, Hindustan Syringes & Medical Devices Ltd.

Catheters to blood collection tubes and dialyzers—must reach patients sterile and functionally intact. Sterilisation is not a contest between superior technologies or a cost cutting exercise. It is an engineering decision shaped by material science, packaging behavior, and device design.



33

Ethylene Oxide Sterilization Validation: A Real-World Scenario

Viral Sheth- M. Sc (Microbiology), Director- Operation Medreg Consultancy LLP Director- Medreg Biotex LLP Principal Consultant- HL Associates

Ethylene oxide (EtO) Sterilization requires a validated and controlled process addressing sterilization performance, microbiological control, packaging compatibility, residual Ethylene oxide and chlorohydrin, aeration, and routine monitoring.



36

cGMP-centric Terminal Sterilization using ionizing radiation products – An Overview

Arun Kumar, (To/E, ISOMED 2.0, BRIT) & **Amit Srivastava** (DGM, ISOMED 2.0, BRIT)

Terminal gamma sterilization of single-use disposable medical products is a critical process in Which sterility assurance, product quality, traceability, and regulatory compliance must be consistently maintained throughout the complete product lifecycle. A cGMP- centric approach provides a systematic framework for controlling the process from material receipt and inspection through storage, irradiation, post- processing, release, and final dispatch.



39

MEET THE EXECUTIVE

Linchon B. Mehta, Business Development Manager., JRD Polymer Pvt Ltd.

The Company supplies carefully selected polymers grades supported by appropriate technical documentation, biocompatibility information, and sterilization data. Our medical polymer covers several polymer families, allowing us to address a broad range of requirements across the medical device industry. Working in Business Development, has allowed him to apply technical understanding to customer requirements.



42

AWARD

Balram Sankaran, Scientist-, SCTIMST Receives Dr. V. G. Patel New-Age Entrepreneurship Award

Instituted by the Entrepreneurship Development Institute of India (EDII), Ahmedabad, this award commemorates legacy of Dr. V. G. Patel, Padmasree Awardee, who pioneered entrepreneurship education in the country. With over 20 years of experience in research, technology transfer and commercialization, Mr. Sankaran has played a key role in facilitating the commercialization of 50+ medical devices to MSMEs and startups. He also helped establish TIMED, a Technology Business Incubator focused on medical devices and biomaterials.



43

INNOVATION

Device for Continuous Health Information Monitoring.

The Device Systems are designed to support people Who want to take a more proactive approach to managing their health. Its continuous glucose monitoring technology provides ongoing glucose insights helping users understand how their bodies respond to food, exercise, medication and everyday routines.

44

An implantable, continuous renal replacement device

Holly is surgically placed inside the body, stays connected to blood vessels in the pelvis, and keeps filtering waste continuously like a normal kidney.

Table of Contents

Vol. 34 No. 5 September-October 2026



45

INDUSTRY INSTITUTE LINKAGE

Industry-Academia Collaboration for Medical Devices Development

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

The diversity of technology is the main reason justifying industry-academia collaboration for a new medical device development. A well-structured academic-industry may accelerate a new device development.

47

AiMeD & REGULATORY UPDATES

- Medical Testing Parts May Get 100% Funding
- NITI Eyes Policy Support to Boost Medical, Dental Device Production
- Govt Eases Loan Licence Requirement For 'Outsourced' Sterilisation Of Medical Gear

51

INDUSTRY NEWS

- Healthium & Romsons Lead Race to Buy BL Lifesciences
- Gujarat's Medical Device Park
- Lubrizol And Polyhose Inaugurate Advanced Medical Tubing Facility In Chennai

COMPAMED



54

COMING EVENTS

Global Event

COMPAMED 2026: Where medical innovation begins

COMPAMED focuses on materials, components, technologies and services for the development and manufacture of medical devices. MEDICA showcases medical products, systems and solutions for use in hospitals and medical practices. Together, they cover the entire spectrum from technological development and manufacturing, through quality assurance, regulation and market access, to practical application in healthcare.

National Event

Advance in Medical Polymer & Composites: Shaping the Future of Medtech Including Industry Visits
Dec 11-12, 2026@ AMTZ, Visakhapatnam.

55

EVENT REPORTS

- Medical Fair India 2026, Mumbai
- Medical Manufacturing India 2026, Mumbai

59

PRODUCT GALLERY

EtO Gas Scrubber with 99 % EtO removal efficiency with all safety measures.

The counter current packed tower type scrubber makes EtO scrubber most efficient for removal of EtO. The basic design of the scrubber, channels the gas flow upwards through a packed bed while the scrubbing liquid flows downward by gravity over the packing.

- EtO Health Hazards

25

DID YOU KNOW?

About Medical Polymers and Their Compatibility with Sterilization Methods

Medical polymers have different levels of compatibility with common sterilization methods depending on their thermal, chemical, and radiation resistance.

29

FAST FACTS

Sterilisation choices must follow science, not myths

Sterilisation must follow engineering logic, not convenience or cost.

Flashback

MEDICAL PLASTICS DATA SERVICE

Select Article Index

Sept.- Oct. 2023

COVER STORY

- **Medical Plastics Knowledge Pavilion** The theme Pavilion is conceptualized by "Plastivision India 2023" in association with "MEDICAL PLASTICS DATA SERVICE", a Techno-Economic News Magazine for Medical Plastics, Medical Devices, Pharmaceuticals, Diagnostics & Healthcare Industry...
- **Evolution Of Polymers As Catheter Tubing Materials** The catheter and tubing market can be classified based on the technicalities of usage and is then further divided into distinct anatomical application areas, each with its own set of property criteria...(Sept-Oct 2023)

MANUFACTURING

- **Reciprocal Die Assembly Streamlines Medical Tubing Extrusion** A reciprocal extrusion die assembly for medical wound-drain tubing developed by Guill Tool is an alternative to traditional tip and die assemblies...
- **Filler-Sealer Machine for Single-Dose Plastic Vials** In addition to the enhanced sterility afforded by fully automatic mechanisms, the machine does not require preheating with hot air, significantly mitigating any risk of compromising the filled product. (Sept-Oct 2023)

MANUFACTURING

Medical Device Translation And Compliance Dr. Manoj Komath, Scientist G, Biomedical Technology Wing, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum The design and development process of a medical device is basically a translation activity of converting the requirements of an unmet need into a physical product. To ensure consistent translation, a set of policies and practices could be adopted, known as the 'medical device design controls'. Good design controls help...(Sept-Oct 2023)

QUALITY

Materiovigilance programme of India and its reporting tools

Mr. V. Hari Haran, Senior Materiovigilance Associate, Materiovigilance programme of India (MvPI), Indian pharmacopoeia Commission (IPC) Posted in National Institute of Mental Health and Neurosciences (NIMHANS), Bengaluru. (Ministry of Health & Family Welfare) Govt of India

Mrs Abirami N Materiovigilance associate Materiovigilance programme of India Indian pharmacopoeia commission Ghaziabad The Ministry of Health and Family Welfare, Government of India, approved and commenced the Materiovigilance Programme of India (MvPI) in the country. (Sept-Oct 2023)

Did You Know?



Medical Polymers and Their Compatibility with Sterilization Methods

Medical polymers have different levels of compatibility with common sterilization methods depending on their thermal, chemical, and radiation resistance.

Common Medical Polymers and Sterilization Compatibility

• PEEK (Polyether Ether Ketone)

- Compatible with: Steam Autoclave (121°C–134°C), Hydrogen Peroxide Gas Plasma, Ethylene Oxide (EtO), Gamma/E-beam Radiation.
- Notes: High resistance to thermal and mechanical degradation; minimal dimensional change.

• PSU (Polyphenylsulfone)

- Compatible with: Repeated Steam Autoclaving, Hydrogen Peroxide Gas Plasma, EtO.
- Notes: Withstands hundreds of autoclave cycles without losing toughness.

• PEI (Polyetherimide)

- Compatible with: Steam Autoclave, Hydrogen Peroxide Gas Plasma, EtO.
- Notes: Retains high dimensional stability and structural integrity under heat.

• Silicone

- Compatible with: Steam Autoclave, EtO, Chemical Sterilants.
- Notes: Limited compatibility with high-dose gamma/radiation sterilization.

• PTFE / FEP (Fluoropolymers)

- Compatible with: Steam Autoclave, EtO.
- Notes: Excellent chemical resistance; poor-to-moderate tolerance for gamma irradiation.

• Polypropylene (PP) / Polyolefins (HDPE)

- Compatible with: Ethylene Oxide (EtO).
- Notes: Limited or variable performance with high-heat steam or high-dose gamma radiation.

• PVC (Polyvinyl Chloride)

- Compatible with: Ethylene Oxide (EtO).
- Notes: Poor compatibility with steam and gamma radiation due to embrittlement or degradation.

• PLA (Polylactic Acid / Biodegradable Polymers)

- Compatible with: Selective low-temperature or gas methods.
- Notes: Prone to minor dimensional shrinkage (approx. 0.8%) or molecular weight reduction under certain gas or radiation cycles.

In a Nutshell....



"Precision in medical device manufacturing isn't just about technology.

It's about having proven expertise across multiple quality standards and certifications."

- Michael Froeman, JD,
OcutrxTech.com

EDITOR

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

ASST. EDITOR

MIHIR VYAS

EDITORIAL ADVISORY BOARD

Mr. C. BALAGOPAL

Director - Enter Technologies Pvt. Ltd.

Chairman - Mobilexion Technologies Pvt. Ltd.
Trivandrum

Dr. A.V. RAMANI

Group Sr. Vice President (R&D), The TTK Group

Dr. Vinny Sastry

President, Winovia LLC, U.S.A.

Dr. SUJOY K. GUHA

B.Tech.(Hon), M.Tech., M.S., Ph.D., M.B.B.S.
IIT, Kharagpur

Dr. G. S. BHUVANESHWAR

Consultant, Medical Devices - Design, development,
testing and quality management.

Adjunct Professor, Dept. of Engineering Design,
Indian Institute of Technology, Madras.

Dr. AJAY D. PADSALGIKAR, Ph.D.

Senior Principal Scientist DSM Biomedical in Exton
Pennsylvania, USA

Dr. K. Sivakumar,

M.Pharm, Ph.D

Dr. Amit Dave,

M. Pharm, MBA, Former CEO/Vice President Export
- Zydus Cadila/Clarix Lifesciences

PUBLISHED BY :

Classic Computer Services

B-4, Mandir Apartment, Opp. Jodhpur Char Rasta

BRTS Bus Stop, Ahmedabad-15, India

Phone : 98254 57598 (10am to 2pm), 98254 57563

E-mail: info@medicalplasticsindia.com

Website : www.medicalplasticsindia.com

Reg. No. GUJ-ENG-00446/23/ALL/TC/94 dt. 3/8/94

DESIGNED AND PRINTED BY :

Image Virtual Creation, Ahmedabad-54

Ph:098795 55948

Notice: Every precaution is taken to ensure accuracy of content. However, the publishers cannot accept responsibility for the correctness of the information supplied or advertised or for any opinion expressed herein.



From the Editor's Desk



Sterilization of Polymer Healthcare Products

Sterilization is not a singular problem nor discipline, but an interfacial area of investigation of materials, biology, chemistry, product design development, manufacturing, environmental control, biocompatibility, microbiology, engineering, material/drug safety, mathematics, manufacturing, R&D, and quality and product/package design, particularly in a new era of device/drug combinations.

The focus in this issue is to differentiate and integrate various aspects of sterilization to healthcare products and polymer materials.

As rightly mentioned in his very analytical article by Mr. Rajiv Nath, Managing Director, Hindustan Syringes & Medical Devices Ltd, **"Sterilization Choices must follow Science, not myths. It must follow engineering logic, not convenience or cost"**.

Another well researched article by Mr. Viral Sheth, Director-Operation, Medreg Consultancy LLP highlights "A Real-World Scenario" on Validation for Ethylene Oxide Sterilization. - an important sterilization modality for medical devices particularly for heat and moisture sensitive products.

One more important research-based by Mr. Amit Srivastava and Mr. Arun Kumar ISOMED and BRIT, Mumbai explains terminal gamma sterilization of single-use disposable medical products as a critical process in which sterility assurance, product quality, traceability, and regulatory compliance must be consistently maintained throughout the complete product lifecycle. A cGMP- centric approach provides a systematic framework for controlling the process from material receipt and inspection through storage, irradiation, post- processing, release, and final dispatch.

Under "Did You Know" column, compatibility of commonly used Medical Polymers with different methods is given.

Manufacturers and suppliers of Medical Polymers immensely contribute to the growth of domestic medical device manufacturing industry. Under 'Meet the Executive' column, Mr. Linchon Mehta, Business Development Manager, JRD Polymer Pvt Ltd shares how working in Business Development has allowed him to apply technical understanding in the process of supplying carefully selected medical polymer grades to address a broad range of requirements across the medical device industry.

We Congratulate Mr. Balram Sankaran, Scientist, SCTIMST for winning Dr V.G. Patel New-Age Entrepreneurship Award, instituted by Entrepreneurship Development Institute of India (EDII). Mr. Sankaran has played a key role in facilitating the commercialisation of 50+ medical devices to MSMEs and startups. He also helped establish TIMED, a Technology Business Incubator focused on medical devices and biomaterials. TIMED has nurtured 100+ deep-tech healthcare startups and innovators and facilitated 25+ patents, contributing to the growth of entrepreneurship at the intersection of healthcare, technology and innovation.

This issue highlights Innovation regarding a Device for continuous health information monitoring for people who want to take a more proactive approach to managing their health.

Another equally important column in this issue is on "Industry Institute Linkage". As explained by Mr Amit Shah, a large array of medical devices with a wide variety of technologies involved clearly calls for Industry-Academia Collaboration for Medical Devices Development. He explains most popular models being used.

As always, this issue covers Industry, Association & Regulatory News, Event Highlights and more.

D.L. Pandya

Sterilisation of Polymer Healthcare Products

The focus in this issue is to differentiate and integrate various aspects of sterilisation to healthcare products and polymer materials. To sterilise is one thing, but to sterilise healthcare products and then polymeric materials without adversely affecting their end use with the user extends the scope of sterilisation, with a special focus on traditional considerations with new opportunities.

All sterilisation methods have their limitations. But all sterilising methods have one thing in common; they must remove or destroy all micro-organisms, if sterilisation is to be true to its definition.

Sterilisation is not a singular problem nor discipline, but an interfacial area of investigation of materials, biology, chemistry, product design development, manufacturing, environmental control, biocompatibility, microbiology, engineering, material/drug safety, mathematics, manufacturing, R&D, and quality and product/package design, particularly in a new era of device/drug combinations. It requires a multidisciplinary effort.

A variety of general considerations of sterilisation must be made to achieve sterility without adversely affecting product and

material quality. The control of sterilisation must begin with the design of the product and the process.

The sterilisation process cannot be considered alone from product development, rather, it is interrelated to product design, equipment, polymers, materials, bioburden to be sterilised, and product to be released. Sterilisation and product design and materials are parallel considerations.

Sterilisation, healthcare product and polymeric materials are not without complications and solutions. There are several commercial sterilisation methods that cannot inactivate all viable entities.

There is a need to sterilise new drug/device combination products coming into to market. In producing these combinations, manufacturers may use a combination of approaches and processes from physical, chemical, radiation, and plasma agents.

"Sterilisation of Polymer Healthcare Products by Wayne Rogers".

Comparison of Common Sterilization Methods

Sterilization Characteristic	Steam	Dry heat	Ethylene oxide (EtO)	Gamma radiation	Electron beam (e-beam)
Process type	Batch	Batch	Batch	Batch	Continuous
Post-sterilization testing for Sterility Assurance Level (SAL)	Parametric release; biological indicators	Parametric release; biological indicators	Parametric release; biological indicators	Dosimetric release	Dosimetric release
Post-sterilization treatment	Need to dry the product	None	Need to aerate product remove residues	None	None
Penetration	Requires vapor permeable packaging. Surface penetration	Good Penetration	Requires gas-permeable packaging; high pressure, temperatures for improved penetration	Excellent penetration	Near complete penetration, need dosimeters; low penetration in high density materials
Safety	Almost no safety concerns	Almost no safety concerns	Considered a mutagen/carcinogen; need to remove residual absorbed EtO	Minimal concern; environmentally safe; non-toxic (need protection from radiation)	Almost no safety concern
Reliability	Excellent	Good	Good	Excellent	Excellent
Turnaround	Slow	Slow	Slow	Fast	Fast
Process Parameter Controls	Temperature, Pressure, vacuum, relative humidity, time	Temperature, pressure vacuum, time	Temperature, pressure vacuum, relative humidity, gas conc., time	Time	Time
Material constraints	Heat resistant and hydrolysis resistant materials only	Heat resistant materials only	Polymers that do not absorb or degrade with EtO	Radiation stable polymers; complex parts and kits not effectively sterilized	e-Beam stable polymers; low-density materials only
Relative cost Advantages	Inexpensive Simple process, widely used, excellent for reusable devices, excellent for heat-stable liquid	Relatively inexpensive Relatively simple process	High capital investment Well characterized, good for kits, combination products, parametric release	High capital investment Simple, fast, excellent penetration, dose uniformity	High capital investment Simple, fast, less material degradation
Disadvantage	Comparatively high temperatures, generally not appropriate for single-use devices and large lots	High temperatures, limited use	Relatively complex process; some limits to penetration; need to remove EtO residuals	Limited applicability to kits and complex designs/products; no drug/combination products; material degradation	Limited penetration, poor on high-density products, dosimetric release is not very uniform affected by part configuration



Rajiv Nath

Managing Director,
Hindustan Syringes & Medical
Devices Ltd.

Abstract: Sterilisation choices must follow science, not myths

Quote: Sterilisation must follow engineering logic, not convenience or cost.

Why Sterilisation Choice Matters

Single use medical devices—from syringes and catheters to blood collection tubes and dialysers—must reach patients sterile and functionally intact. Sterilisation is not a contest between “superior” technologies or a cost cutting exercise. It is an engineering decision shaped by material science, packaging behaviour, and device design.

Start with the Device, Not the Technology

Industrial sterilisation relies mainly on:

- Ethylene Oxide (EO/EtO)
- Gamma Irradiation
- Electron Beam (E Beam)
- Steam Autoclaving

Each interacts differently with polymers, adhesives, coatings, electronics, and packaging. The correct choice depends on:

- Material chemistry
- Bond lines and coatings
- Dimensional tolerances
- Packaging configuration
- Sterilant penetration needs
- Intended patient contact and functional performance

Sterilisation of Single Use Medical Devices: Science Over Myths

Understanding these parameters helps clinicians and procurement teams evaluate suppliers scientifically and avoid myths that compromise patient safety.

Ethylene Oxide (EO): For Complex, Heat Sensitive Devices

EO remains essential for mainstream disposables such as **catheters, syringes, scalp vein sets, lumened devices, and electronics**. It penetrates packaging and hard to reach surfaces **without heat or moisture**, making it ideal for sensitive polymers.

In breathable ribbon packed or blister packed syringes, validated packaging and seal integrity allow EO to reach internal surfaces. Controlled humidity, temperature, gas concentration, exposure time, and aeration ensure sterility and safe residue levels under **ISO 11135** and **ISO 10993 7**.

EO is indispensable for polymer based devices that cannot tolerate radiation or steam.

Gamma Irradiation: Deep Penetration for Suitable Materials

Gamma irradiation provides terminal sterilisation in sealed packaging and is ideal for:

- **Carbon steel surgical blades** — aluminium foil packaging prevents corrosion; moist heat cannot penetrate effectively.
- **Blood collection tubes** — rubber closures block sterilant gases; additives must remain stable.
- **Dialysers** — dense configurations require deep, uniform penetration.

Gamma avoids moisture and chemical residues and allows sterilisation after final packaging. However, radiation can alter colour, flexibility, or tensile strength in certain polymers, making **dose mapping, ageing studies, and packaging validation** essential.

E Beam: Fast and Efficient — Within Limits

E beam sterilisation is rapid and suited for **high throughput, lower density devices**. Its limited penetration depth means geometry, product density, and carton size must be validated. It is unsuitable for dense loads, large cartons, or complex assemblies requiring uniform dose delivery.

Steam Autoclaving: Reliable for Heat Stable Devices

Steam remains the gold standard for **metal instruments, glassware, moisture stable components**, and for resterilising reusable medical devices. It is unsuitable for most polymer based disposables, which may deform, absorb moisture, or lose functional integrity under high heat.

Dispelling the Myth of “Superiority”

No sterilisation method is universally superior. Each has strengths and limitations. The correct choice depends on:

- Device construction
- Packaging behaviour
- Clinical performance requirements
- Shelf life ageing characteristics

Sterilisation must be treated as a core design parameter, not an afterthought or cost driven decision.

Why HMD's Approach Deserves Confidence

HMD's sterilisation strategy is driven by engineering led selection, not assumptions. Across product lines—including syringes, blades, scalpels, catheters, and blood collection devices—HMD validates each method for:

- Material compatibility
- Packaging behaviour
- Penetration or dose uniformity
- Long term ageing performance
- SAL 10⁻⁶
- Compliance with global standards

HMD revalidates whenever materials, suppliers, or load configurations change, ensuring consistency across millions of units. For procurement managers, this means predictable

performance, fewer recalls, and confidence in an engineered sterilisation process.

A Message to India's Medical Community

As India's medical device sector grows, clinicians and procurement teams should insist on **science based sterilisation**. Key questions include:

- Is the method validated for the specific material and packaging?
- Are ageing, dose, and bioburden controls documented?
- Does the manufacturer revalidate after changes and follow global standards?

Manufacturers that treat sterilisation as engineering better protect clinicians and patients.

Conclusion

Sterilisation is a **patient safety decision built into device design**. When aligned with material science and packaging engineering, it delivers sterile, reliable, clinically trusted devices.

HMD reflects this through **science based selection, rigorous validation, and a sustained commitment to patient safety**.

FAST FACTS

Sterilisation choices must follow science, not myths

Sterilisation must follow engineering logic, not convenience or cost.

rapidfacto

Medical Device QMS Software

Always be ready for ISO & CDSCO Audits?

✓ INDIAN MDR ✓ ISO 13485 ✓ 21 CFR Part 11

8708856807

rapidfacto.com

: Attention :

MEDICAL PRODUCTS MANUFACTURERS

FOR

**Surgical Peelable & Tearable Pouches,
Lids & Reels For Sterilized
Medical Disposables & Devices**

Contact :

Surgi Pack India Pvt. Ltd.

PLANT : J/49, MIDC Tarapur Indi. Area, Boisar, Taluka : Palghar,
Thane - 401 506 India. ☐ Tel. No. : 93245 51325

OFFICE : 102, Pran Kutir, Ram Lane, Off. S. V. Road, Kandivali (West),
Mumbai - 400 067 India.

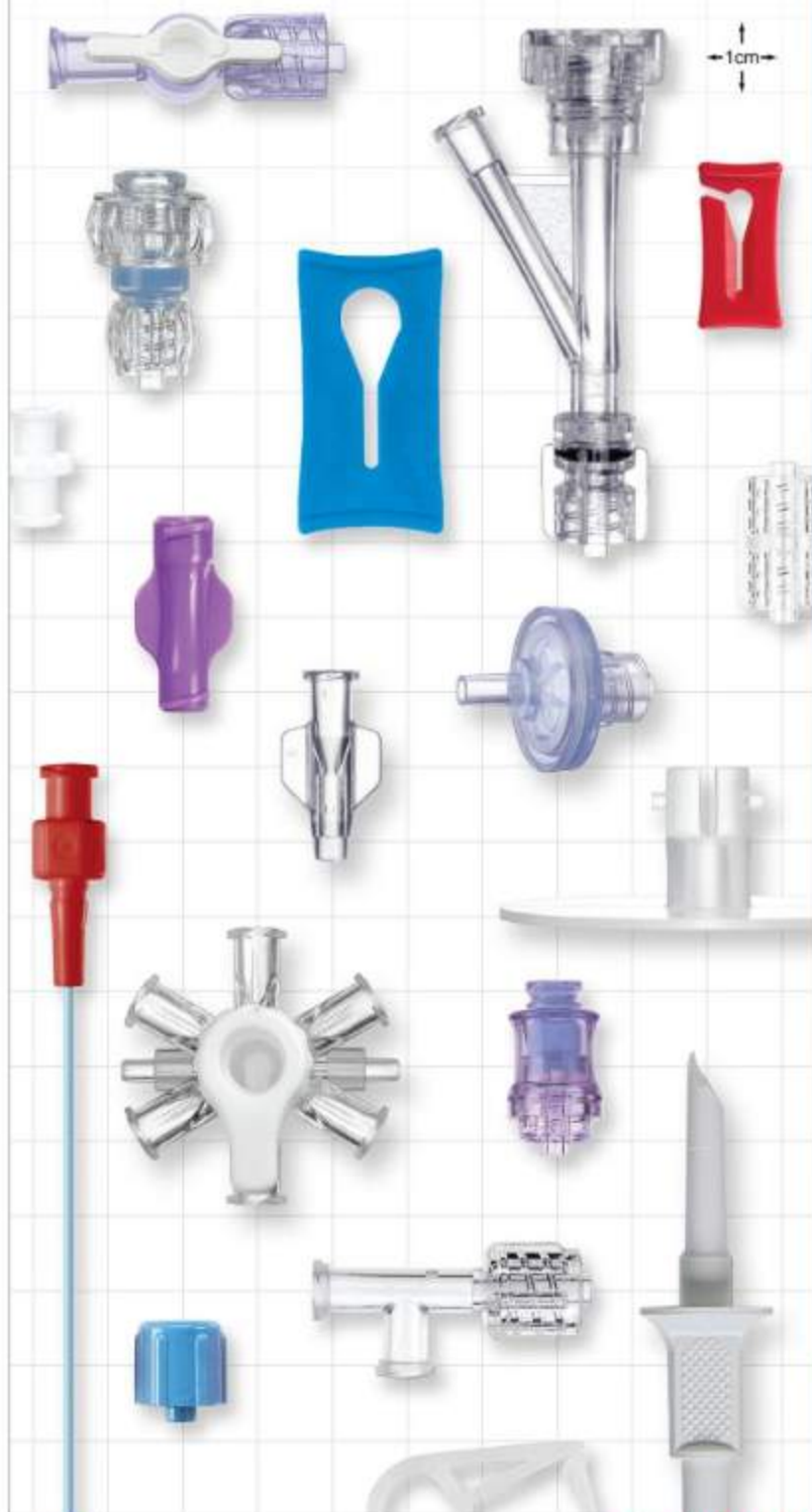
Contact Person :

BIRJU TANNA (CEO)
Cell : +91 98199 70333

E-mail : birju.t@surgipackindia.com ☐ Sales@surgipackindia.com

QOSINA

Thousands of Stock Components



For nearly 45 years,

Qosina has been a trusted partner to medical device engineers, providing thousands of in-stock components and innovative solutions to meet the industry's evolving needs. Qosina delivers high-quality components and practical support.

Serving diverse applications, Qosina's extensive product portfolio includes over 5,000 components across 25+ categories. With same-day shipping, flexible order quantities, and an ISO 8 Class 100,000 cleanroom for repackaging, Qosina ensures timely, customized solutions that meet your project's unique demands.

Whether you're in the design or development phase, Qosina is here to support you with practical, reliable solutions at every step.

Log on to qosina.com today to see our full product offering.

International Exhibition & Conference ON Medical Materials & Devices



ASM Geodesic Dome Cleveland

MMD-2026

Medical Materials & Devices
December 16 to 18, 2026

Co-located with



Organised By



Supported by



Date : December 16 to 18, 2026

Venue : CIDCO Exhibition Centre, Navi Mumbai

Organised by

ASM International India Chapter

Tel : 90828 13522

Emails : sudhakar Bonde : sudhakar@subodhlabs.net

Suhas Sabnis : metsolcon@yahoo.co.in | India Chapter : asmindia79@gmail.com

Exhibition Organiser

M/s Orange Marcom Services Pvt. Ltd.

Tel : Pankaj : 93542 28024 ; Rajnish Sinha : 98104 19110

Email : pankal@orangemarcom.in,

rahnish@orangemarcom.in

Media Partner

www.medicalplasticsindia.com

**MEDICAL PLASTICS
DATA SERVICE**

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



**Safe.
Reliable.
Compliant.**

Built for the Long Term.

REVA CHEM FAB INDIA

Trusted Partner in
ETO Sterilization Systems

ETO STERILIZATION SYSTEM

FOR MEDICAL DEVICE
MANUFACTURERS



100% Customised Solutions

Chamber sizes and design tailored to your plant, product and packaging requirements.



Advanced Automation

PLC Based Systems with HMI/IPC and Scada operations with 100% fail safe features.



Regulatory Compliance

Designed to meet ISO 11135, EN550, 21 CFR Part 11, MDR and more.



Complete System Supply

Design, Manufacturing, Installation, Commissioning, & Validation



BUILT ON
60+ YEARS
OF ENGINEERING HERITAGE

From our legacy of innovation Since 1967 (Panchal Industrial Engineering) to today's advanced ETO Systems, **REVA CHEM FAB INDIA** combines experience with modern technology to deliver high-quality, customised solutions for the medical device industry.

APPLICABLE DESIGN CODES / STANDARDS



ISO 11135
ETO sterilization
processes



EN 550
Design and
construction
requirements



21 CFR Part 11
For electronic
records and
process control



ISO 9001:2015
Quality Management System
Certified by TUV NORD

+91 9326 133 299

info@revachemfab.com

www.revachemfab.com

Head Office:
Mumbai, Maharashtra

Manufacturing Unit 1:
Vapi, Gujarat



Ethylene Oxide Sterilization Validation: A Real-World Scenario

Viral Sheth- M.Sc (Microbiology)

Director- Operation Medreg Consultancy LLP

Director- Medreg Biotex LLP

Principal Consultant- HL Associates

1. INTRODUCTION :

Sterilization is an essential part of medical device and In vitro diagnostic medical devices manufacturing and reprocessing, as effective microbial control is necessary for ensuring safety and reduce the risk of infection. **Ethylene oxide (EtO) sterilization** is widely used as a low-temperature sterilization method, particularly for devices that are sensitive to heat and moisture. EtO gas can penetrate the device and its packaging and inactivate microorganisms by reacting with essential cellular components, including proteins and genetic material. This makes EtO particularly suitable for complex and heat-sensitive medical devices where conventional high-temperature sterilization methods may affect material properties or device performance [1][2].

2. ETHYLENE OXIDE: CHARACTERISTICS AND SAFETY CONSIDERATIONS

Ethylene oxide (EtO) was discovered in the late 1850s and first used as a sterilant in the 1940s. Ethylene oxide is a man-made, colourless, and flammable gas with a sweet Odor. Its chemical formula is C_2H_4O . Commercially Available in Cartridge form generally 100% and cylinder form with mixture of CO_2 gas i.e. 90:10, 80:20, 70:30, 20:80, 10:90). Boiling Point: $10.7^\circ C$. Flammable Limits: Lower 3% (30,000ppm) - Upper 100%. Detectable Odour: After 500 -750 ppm exposure. Ignition Temperature in Air: $428.9^\circ C$. In Absence of Air: $571.1^\circ C$. Solubility in Water: Completely Soluble. It is heavier than air [1][2].

As per guidelines from explosives Dept. Petroleum and Explosive Organization (PESO), Cylinders should always be stored: Vertically, In a well-ventilated area, Under shade, Below $30^\circ C$.

Exposure Limits Breakdown:

- **Permanent Exposure Limit (PEL):** 8-hour TWA: 1 part per million (1 ppm)
- **Short-Term Excursion Limit (STEL):** 5 ppm (over a 15-minute period)
- **Action Level:** 0.5 ppm (8-hour TWA) to trigger monitoring and medical surveillance [3]

3. SAFETY CHALLENGES OF EtO STERILIZATION [4]

- Toxic and carcinogenic nature of EtO requires stringent occupational safety and exposure controls.
- Residual Ethylene oxide and ethylene chlorohydrin (ECH) must be controlled to established acceptable limits before

device release.

- Flammability requires specialized equipment, ventilation and facility safety controls.
- Environmental emissions require appropriate emission-control systems and compliance with environmental requirements.
- Process sensitivity to critical parameters, including Ethylene oxide concentration, temperature, relative humidity and exposure time, requires comprehensive process validation and routine monitoring.
- Device and packaging compatibility.
- Complex device geometries and lumens require specific consideration to demonstrate adequate EtO penetration and microbial inactivation.
- Sterilization-cycle variability associated with product configuration, load arrangement and material characteristics requires defined and validated worst-case conditions.
- Facility and infrastructure requirements for storage, sterilization, aeration, ventilation and emission control increase the operational complexity of the sterilization process.

4. REGULATORY AND STANDARDS FRAMEWORK FOR EtO STERILIZATION:

Ethylene oxide (EtO) sterilization of devices requires a validated and controlled process capable of consistently achieving the specified Sterility Assurance Level (SAL). SAL 10^{-6} corresponds to a probability of no more than one non-sterile unit in one million sterilized units and is the commonly specified SAL for medical devices requiring a high level of sterility assurance, while SAL 10^{-3} corresponds to no more than one non-sterile unit in one thousand sterilized units. ANSI/AAMI ST67:2019 provides requirements and guidance for establishing the appropriate SAL for products labelled sterile [5].

The principal standard for EtO sterilization, ISO 11135:2014/A1:2018, specifies requirements for the development, validation and routine control of the sterilization process, including industrial and healthcare-facility applications [6].

Regulatory requirements across major medical-device markets are aligned with the need for validated sterilization:

- In the European Union, Regulation (EU) 2017/745 (MDR), Annex I, Section 11.5, requires devices labelled as sterile to be sterilized using appropriate, validated methods [7].

- In the United States, FDA recognizes ISO 11135 for EtO sterilization and identifies ISO 10993-7 for the evaluation and control of residual EtO and ethylene chlorohydrin (ECH) [6,8,9]; and
- In India, CDSCO and applicable BIS requirements provide the regulatory framework for medical-device sterilization, with IS/ISO 11135 providing the applicable requirements for EtO sterilization [10,11].
- Supporting standards, including ISO 11737-1/-2 for microbiological methods, ISO 11607-1/-2 for sterile barrier systems and packaging validation, and ISO 14937 for general sterilization-process requirements, complement the EtO validation strategy [12,13].

In addition to these principal regulatory requirements and the primary EtO sterilization standard, supporting standards and technical reports are mentioned below.

Table 1: Additional supporting standards

Standard / Guidance	Main purpose
ISO 11139:2018/ Amd 1:2024	Sterilization of health care products - Vocabulary of terms used in sterilization and related equipment and process standards

Table 2. Comparison of EtO Sterilization Requirements in Medical Device Manufacturing and Healthcare Institutions

Aspect	Manufacturer Self-Sterilization	Healthcare Industry Institutional Sterilization
Application	Sterilization during device manufacturing	Sterilization before/after device use
Responsible party	Device/IVD manufacturer	Healthcare institution
Main regulatory framework	MDR/IVDR applies to the device and manufacturing process	MDR may apply to relevant EtO cartridge/device configuration
EtO itself	Not independently MDR/IVDR-conformity assessed merely because it is used in manufacturing	May fall within MDR depending on its intended purpose/configuration
Sterilization process	Part of manufacturer's QMS and device conformity assessment	Controlled according to predetermined conditions applicable to healthcare use
Process validation	Required as part of manufacturing/QMS	Appropriate validated / defined conditions required
ISO 11135	Applicable where relevant to the manufacturing EtO process	Applicable where relevant to the sterilization process
Ancillary requirements	Yes - equipment, utilities, safety, monitoring, validation, etc.	Yes - together with applicable regulatory requirements
Technical documentation	Included in manufacturer's technical documentation	Documentation/records according to applicable healthcare/regulatory requirements

6. EtO STERILIZATION MARKET OVERVIEW

EtO remains highly important because of its broad material compatibility, especially for heat and moisture sensitive medical devices. FDA states that other modalities cannot currently replace EtO for many devices. U.S. Food and Drug Administration

EtO is hazardous and emissions from commercial sterilization facilities are receiving increased regulatory attention, particularly in the U.S. US EPA

EtO Sterilization Equipment Market [15]

The global EtO sterilization equipment market was valued at USD 1.81 billion in 2025 and is projected to reach USD 3.13 billion by 2034, at a 6.2% CAGR.

The Segment and end-user distribution of the EtO sterilization equipment market in 2025 is presented in the following charts.

Standard / Guidance	Main purpose
AAMI TIR14:2016	Contract sterilization using ethylene oxide
AAMI TIR15:2016/ (R)2024	Physical aspects of EO sterilization.
AAMI TIR16:2017/ (R)2020	Microbiological aspects of EO sterilization.
AAMI TIR17:2024	Compatibility of materials subjected to sterilization
AAMI TIR28:2016/ (R)2020	Product adoption and process equivalence for ethylene oxide sterilization

5. COMPARISON OF EtO STERILIZATION IN MEDICAL DEVICE MANUFACTURING AND HEALTHCARE FACILITIES

The regulatory requirements for EtO sterilization differ depending on whether the process is performed as part of medical device manufacturing or within a healthcare institution for device processing [14]. The following table summarizes the key differences:

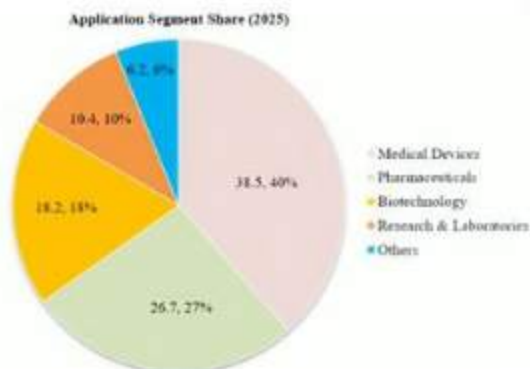


Figure 1. Segment distribution of the global EtO sterilization equipment market, 2025.

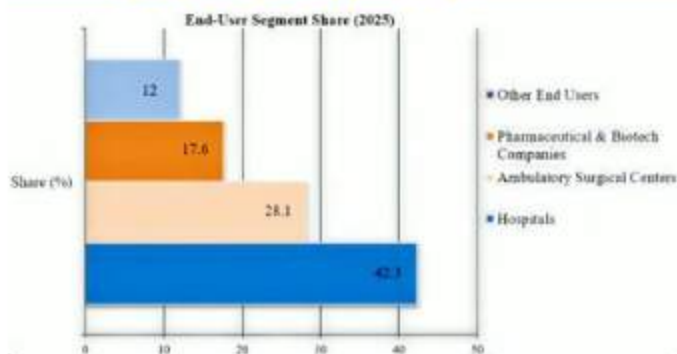


Figure 2. End-user segment distribution of the global EtO sterilization equipment market, 2025.

EtO Sterilization Services Market [16]

The global EtO sterilization services market is projected to expand significantly, driven by increasing demand for sterilized medical products and the growing need for effective infection-control solutions.

The following charts illustrate the market size and forecast, together with the regional distribution of the global EtO sterilization services market.

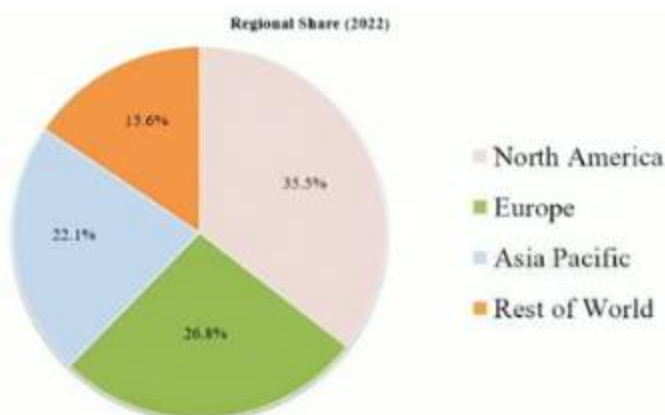


Figure 3. Regional distribution of the global EtO sterilization services market, 2022.

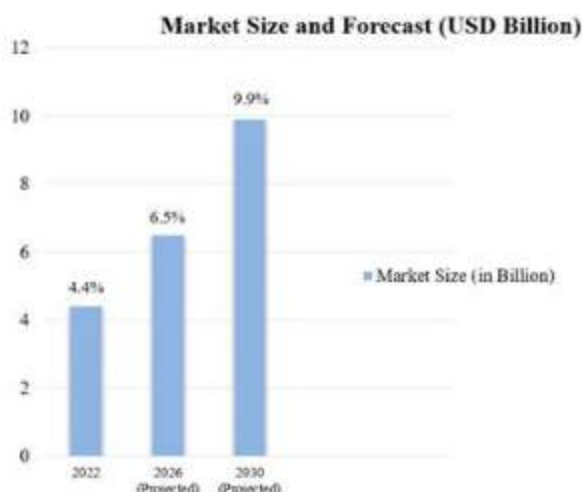


Figure 4. Global EtO sterilization services market size and forecast, 2022–2030 (USD billion).

7. SELECTING AN EtO STERILIZATION SYSTEM AND MANUFACTURER:

Selecting an EtO sterilization system requires consideration of more than the equipment itself. The sterilizer should be suitable for the type and configuration of products, material compatibility, packaging system, required sterilization cycle, facility layout, operator safety, aeration requirements, process monitoring, and validation needs. These factors should be evaluated to ensure that the selected system can consistently achieve the required sterilization performance without adversely affecting the product or its packaging.

Selection of the manufacturer is equally important. Key considerations include quality certifications and regulatory compliance, technical expertise, customization capability, installation and commissioning support, validation assistance, and after-sales service. The manufacturer should demonstrate experience in the design, installation, validation, maintenance, and servicing of EtO sterilization systems. Adequate operator training, preventive maintenance, technical support, and availability of spare parts should also be considered to ensure reliable operation throughout the equipment lifecycle.

8. CONCLUSION

Ethylene oxide (EtO) sterilization remains an important sterilization modality for medical devices and in vitro diagnostic medical devices, particularly for heat- and moisture-sensitive products. Its effective application requires a validated and controlled process addressing sterilization performance, microbiological control, packaging compatibility, residual Ethylene oxide and chlorohydrin, aeration, and routine monitoring. ISO 11135 provides the principal framework for the development, validation, and routine control of EtO sterilization, supported by complementary standards for sterility assurance, bioburden, residuals, packaging, and material compatibility. The differences between manufacturer-controlled and healthcare-facility sterilization also require appropriate consideration of regulatory responsibilities, process controls, documentation, and safety requirements. As safety and environmental considerations continue to influence EtO use, selection and implementation of sterilization systems should consider process capability, validation, safety and emission controls, product compatibility, operator training, maintenance, and lifecycle support to ensure consistent sterilization performance, patient safety, and regulatory compliance.

rapidfacto

Medical Device QMS Software

Always be ready for ISO & CDSCO Audits?

✓ INDIAN MDR ✓ ISO 13485 ✓ 21 CFR Part 11

8708856807

rapidfacto.com



Amit Srivastava
(DGM, ISOMED 2.0, BRIT),



Arun Kumar Tyagi
(TO/E, ISOMED 2.0, BRIT),

cGMP-centric Terminal Sterilization using ionising radiation products – An Overview

Abstract

Terminal gamma sterilization of single-use disposable Medical products is a critical process in which sterility assurance, product quality, traceability, and regulatory compliance must be consistently maintained throughout the complete product lifecycle. A cGMP-centric approach provides a systematic framework for controlling the process from material receipt and inspection through storage, irradiation, post-processing, release, and final dispatch. At the ISOMED 2.0 facility of BRIT, Department of Atomic Energy, Government of India (A land based stationary gamma radiation processing facility), effective sterilization depends on validated irradiation processes, controlled loading configurations, reliable digitally controlled automatic Ceric-Cerous dosimetry, calibrated monitoring equipment, and documented evidence demonstrating that the required radiation dose has been consistently delivered. Integrating ISO 13485, ISO 9001, ISO 14001, and ISO 45001 strengthens this cGMP framework by incorporating product quality, process control, environmental responsibility, and occupational health and safety into a unified management system. Risk management, change control, deviation investigation, root-cause analysis, CAPA, equipment qualification, process validation, personnel competence, and internal audits provide mechanisms to maintain the facility's validated condition and drive continual improvement. Hence, cGMP-centric terminal gamma sterilization is an integrated, evidence-based, and continuously controlled system designed to ensure that every medical plastic product processed at ISOMED 2.0 receives the intended treatment. Based on the cGMP centric framework, ISOMED 2.0 has established its own niche in the contemporary radiation processing sector. The unique international certifications training and service introduced by ISOMED 2.0 in 2018 on ISO11137 (Sterilization of health care products- Radiation) bears the testimony for the relevance and significance of cGMP in terminal sterilization.

The terminal gamma sterilisation of single-use disposable medical plastic products involves not only subjecting the product to ionising radiation but also the consistent delivery of a validated and controlled sterilisation process together with the preservation of product quality, packaging integrity and traceability. The reliability of the sterilised product is based on the defined controls which are put in place before irradiation, during processing and after irradiation. A cGMP-focused approach forms the basis of such control, and the sterilisation process must be validated and operated within defined and controlled parameters.

The single-use disposable medical plastic products received are subjected for checking in order to detect any damaged packaging, wrong labelling, discrepancies in quantity or any other conditions which could have an effect on sterilization processing. Once the material has met the acceptance criteria defined, it should move on to the next stage. The traceability system must set up a clear link between the customer, the product, the batch number, the quantity received, the storage location, the loading configuration, the irradiation cycle, the dosimetry information, the processing date, the processing status, the release decision and the dispatch details. In ISOMED 2.0 [Fig.1], the irradiation cycle's identity, the processing parameters and the dose results should be kept as part of the batch records.



Fig.1

The single-use disposable medical plastic products can be affected by temperature, humidity, sunlight, contamination, physical damage and incorrect handling. Storage areas must therefore be kept under review in accordance with the specified product and customer requirements. [Fig. 2] In routine, Good Irradiation Practice include housekeeping, pest control, environmental monitoring and protection against physical damage. The storage system should also have adequate controls to stop unauthorised movements or accidental dispatch of unreleased material.



Fig. 2

The effectiveness of gamma sterilization is based on the control of the radiation dose absorbed. It is therefore necessary for the sterilisation process to operate within a dose range that has been established and validated for the specific product, its packaging configuration. In order to understand how the dose is distributed within the irradiation load and to identify the positions that correspond to the minimum and maximum dose levels, dose mapping and validation studies are carried out. In ISOMED 2.0, routine processing shows that the validated loading configuration and process conditions remain unchanged. Dosimetry supplies the objective proof that the required dose has been given. The dosimetry system itself must be properly controlled, calibrated or verified where appropriate, should be traceable to recognised standards and have to be protected against any conditions which could affect its reliability.

Digital dosimetry measurement systems which have a minimal transmittal error (developed by ISOMED), [Fig. 3] must be used when determining the sterilisation dose and should be subject to calibration and verification. This rule also extends to weighing systems, temperature and humidity measuring devices, monitoring instruments and all other equipment which can affect product quality or process decisions. The calibration records should include the equipment identification, its calibration status, the due date, the acceptance criteria, the results, and the actions taken whenever the equipment is found to be outside the specified requirements.

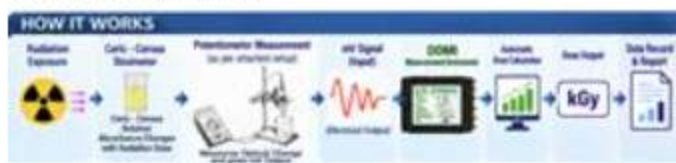


Fig. 3

The scientific foundation for showing that the sterilisation process is capable of yielding consistent results is provided by equipment qualification and process validation. When carrying out qualification, account should be taken of the irradiator, the equipment and the monitoring systems, and process validation should produce documented evidence that the defined process is able to consistently achieve the desired sterilisation result when operated within the specified and defined parameters.

Validated loading patterns, product density, packaging materials, process parameters, dosimetry systems, equipment or software should not be altered carelessly. Instead, any such changes must be assessed by means of a formal change-control system in order to judge their possible effect on validated status, product quality, regulatory compliance, occupational safety and

environmental performance. The formal change-control procedure should specify the proposed change, the reason for the change, the documents and processes which will be affected, the risk assessment, the validation requirements, the training requirements, the regulatory implications and the approval responsibilities together with the implementation plan.

Just as deviation management must be regarded as a basic element of the quality system, a deviation can result from equipment failure, an unexpected dose result, an incorrect loading arrangement, damaged packaging, a documentation error, a calibration failure, a power interruption, non-compliance with procedures, or any other kind of departure from an established procedure or specified requirement. The first thing to do should be to contain the situation and protect the affected product. The deviation must then be recorded, investigated and assessed on a risk-based basis. The root-cause analysis has to tell the difference between a single instance of human error and a weakness in the overall process. Where necessary, corrective and preventive action should be carried out via the CAPA system. The connection between deviation, root-cause analysis, CAPA and change control is especially important. A deviation can point to a weakness in a process; the investigation might lead to the identification of the root cause; CAPA then specify the corrective or preventive actions; and the implementation of these actions might call for formal change control, extra validation or staff training. Closing a deviation should therefore not just involve filling in the paperwork. The organization must determine if the action taken was effective and whether other similar risks occur elsewhere in the process. This kind of integrated approach promotes continuous improvement while keeping the sterilization operation in its validated state.

Risk management needs to be incorporated at every stage of the entire material sterilization lifecycle. When the materials are received, stored, handled, irradiated, go through post-processing, are released and are dispatched, potential risks should be assessed. The 5-Why and 1-How risk-management methods can be used to identify the possible failure modes together with their causes, consequences and the existing controls. Special care must be paid to any risks which might affect sterility assurance, product identity, and the integrity of the packaging, dose delivery, traceability or the release decisions. Risk management also has to consider the occupational hazards connected with irradiation facilities, material handling, electrical systems, mechanical equipment, chemicals and emergency situations.

The product-quality aspect of sterilization for medical devices as specified by ISO 13485 places particular emphasis on process control, risk-based thinking, traceability, and documentation, the competence of personnel, the infrastructure and the monitoring of processes. ISO 9001, on the other hand, offers a more general quality-management framework which stresses a process approach, meeting customer requirements, organizational controls, continual improvement and decision-making based on evidence. In the ISOMED 2.0 facility, these principles are combined rather than being managed as separate systems. A single process map, a set of procedures, records, audit procedures, training systems, corrective actions and management reviews can be established in such a way as to meet the relevant requirements of both standards while still keeping a firm focus on the safety of medical products and on customer requirements.

The operational framework is supplemented by ISO 14001 in relation to the environmental aspect. Since gamma sterilization requires energy, infrastructure, maintenance resources and the use of associated consumables, waste generation, resource consumption, electrical energy use, maintenance activities,

packaging waste, chemical use and emergency situations must all be dealt with within the environmental management system. Environmental objectives should be set up and operational controls should be put in place in order to reduce significant environmental impacts. Environmental compliance should be incorporated into regular operational planning rather than being regarded as a separate activity disconnected from production.

ISO 45001 also provides a systematic method for dealing with occupational health and safety. The gamma irradiation facility has hazards which demand careful engineering, administrative and operational controls. Radiation safety is essential and is backed by suitable shielding, interlocks, access controls, monitoring systems, emergency provisions and qualified personnel. Nevertheless, occupational safety includes more than just radiation; manual handling of medical products, the movement of pallets, mechanical equipment, electrical systems, slips and falls, maintenance work, the use of chemicals and activities carried out by contractors all have to be considered. Employees should get the proper training, use the necessary personal protective equipment and understand the emergency procedures.

Another feature which is common to both cGMP and the ISO standards is that personnel should be competent. Those employees and contractors whose activities may have an effect on the quality or safety of a product must be properly qualified and trained. Training should be tailored to the individual's job duties and should include the relevant standard operating procedures, the principles of GMP, safety requirements, the operation of equipment, documentation practices, the reporting of deviations, emergency response measures and the applicable regulatory requirements. Where it is appropriate, the effectiveness of the training should be assessed. Authorization to carry out critical activities must be based on proven competence and not just on having attended a training course. Based on the cGMP centric framework, ISOMED 2.0 has established its own niche in the contemporary radiation processing sector. The unique international certifications training and service introduced by ISOMED 2.0 in 2018 on ISO11137 (Sterilization of health care products-Radiation) bears the testimony for the relevance and significance of cGMP in terminal sterilization. As on today, ISOMED 2.0 has trained over 75 healthcare industry professionals from India and south east Asia.

The evidence that the facility is working as it should be consists of the documentation and the assurance of data integrity. All SOPs, work instructions, forms, equipment records, calibration certificates, maintenance records, batch-processing records, dosimetry records, environmental records, training records, deviation reports, CAPA records and change-control documents must be under control and readily retrievable. The entries have to be attributable, legible, made at the time they refer to (contemporaneous), original or otherwise properly controlled copies, accurate and safeguarded against unauthorised alteration. Electronic systems need to have appropriate access control, backup and data-protection measures. Reliable and traceable objective evidence is required to support the quality of the sterilisation process.

Before the product has been released, the batch records in should be checked against the established acceptance criteria. The purpose of this check should be to confirm required dose was obtained and that the relevant equipment was in a calibrated condition, that the applicable deviations have been evaluated, that the necessary documentation has been completed and that there is no unresolved issue which could have an adverse effect on the quality of the product. Release should thus be a quality decision that is carefully controlled rather than an automatic administrative action.

Dispatch is the last stage in the ISOMED 2.0 material lifecycle and maintain the same degree of control that was exercised at the time of receipt and processing. The identity and amount of the product should be checked against the relevant documentation and the customer's requirements. Only material that has been released should be dispatched. The dispatch records have to keep traceability with respect to the relevant batch and processing documentation. This allows the facility to deal effectively with customer enquiries, complaints, investigations and any possible recalls. Since a full record of the lifecycle is kept, an auditor or investigator should be able to trace a product from the time it was received through to inspection, storage, irradiation, release and dispatch.

Internal audits offer a vital means of determining if the system in place is actually working. They should look not only at whether the necessary documents exist but also at whether the staff adhere to the approved procedures, the findings of the audits should be subject to a risk assessment and then dealt with by taking the appropriate corrective actions. Management review must consider the quality objectives, customer feedback, deviations, CAPA, the results of the audits, process performance, the resources needed, environmental performance, occupational-health-and-safety performance and the opportunities for improvement.

The final aim of cGMP-based terminal sterilization goes beyond mere regulatory compliance or simply passing an audit; it is to make sure that single-use disposable medical plastic products handled at ISOMED 2.0 is given the right treatment under controlled and validated conditions, remains identifiable throughout its entire lifecycle, is protected against being mixed up or damaged, and is only released when there is adequate documented evidence showing that it conforms to the relevant requirements. If the principles of cGMP are applied to all stages involved—including receipt, inspection, storage, sterilization, post-processing and dispatch—and if quality, environmental and occupational-health-and-safety controls are incorporated into the same process structure, then terminal gamma sterilization becomes a controlled, traceable and continuously improving system for processing medical products one that can support product safety and customer confidence.

Conclusion:

The precipitating needs of the contemporary world for technology driven quality eco system provides an impetus for the risk sensitive terminal sterilisation practices for the healthcare products. In Indian context, over 43 radiation processing facilities operating across length and breadth of the country as of now, have rapidly acclimatised to this needs of the hour. This has substantially proved to be a trusted torch bearer in the ambitious journey of the nation in transformation to self-reliance in quality healthcare for the common mass.

rapidfacto

Medical Device QMS Software

Always be ready for ISO & CDSCO Audits?

✓ INDIAN MDR ✓ ISO 13485 ✓ 21 CFR Part 11

8708856807

rapidfacto.com



Linchon B. Mehta

Business Development Manager,
JRD Polymer Pvt Ltd.

We recognized that medical device manufacturers' need more than conventional engineering plastics. They require carefully selected grades supported by appropriate technical documentation, biocompatibility information, and sterilization compatibility data.

Our medical polymer portfolio covers several polymer families, allowing us to address a broad range of requirements across the medical device industry.

Our journey has been built on quality, reliable supply, and long-term customer relationships.

**MP
DS**

Your company, JRD Polymer, has long experience in the distribution of chemicals and plastics. Could you give us a brief history of your company's journey in the field of distribution?

LBM

JRD Polymer is part of the Doshi Group, whose legacy dates back to 1945. Established as an independent business unit in 1980, we have grown from chemical distribution into chemicals, plastics, engineering polymers, and specialty materials.

Our journey has been built on quality, reliable supply, and long-term customer relationships. Today, we connect global manufacturers with Indian industries, providing the right materials to meet their needs, including specialized sectors like medical devices.

**MP
DS**

When and how did your company enter the medical polymers business?

LBM

As the Indian medical device industry continues to develop, we see increasing demand for high-performance materials that offer reliable processing, consistent quality, and application-specific performance.

We recognized that medical device manufacturers need more than conventional engineering plastics. They require carefully selected grades supported by appropriate technical documentation, biocompatibility information, and sterilization compatibility data.

This led us to develop a dedicated focus on medical-grade polymer solutions. We are building relationships with specialized material manufacturers and introducing grades suited to applications such as drug delivery systems, diagnostic devices, infusion components, surgical instrument housings, and wearable medical devices.

Our objective is to help Indian medical device manufacturers access advanced materials from established global suppliers while receiving responsive local commercial and technical support.

**MP
DS**

Could you throw some more light on your company's "Medical portfolio"?

LBM

Our medical polymer portfolio covers several polymer families, allowing us to address a broad range of requirements across the medical device industry.

The portfolio includes the following material categories:

- * **Polyacetal (POM):** Medical-grade grades offering dimensional stability, stiffness, low friction, and wear resistance. These can be considered for precision components in insulin pens, inhalers, infusion systems, and other drug delivery devices, subject to grade-specific suitability.
- * **Polycarbonate (PC):** Suitable grades can offer transparency, impact resistance, and dimensional stability for diagnostic equipment, medical housings, and selected fluid-handling components.
- * **Thermoplastic copolyester elastomers (TPC):** Materials such as Arnitel® can provide flexibility, softness, durability, and over moulding opportunities for selected wearable healthcare devices and patient-monitoring applications.
- * **Polyamide (PA) and polybutylene terephthalate (PBT):** Engineering materials that may be suitable for selected structural components, housings, connectors, and precision-moulded parts.
- * **Polythiazide (PPA):** A high-performance engineering polymer known for its strength, stiffness, heat resistance, and dimensional stability. Depending on the grade, it can be considered for precision-moulded components, connectors, and structural parts in medical and diagnostic equipment.

- * **Polyphenylene Sulphide (PPS):** A high-performance polymer offering excellent thermal stability, chemical resistance, and dimensional stability. Selected grades may be suitable for precision components and parts used in medical and diagnostic equipment where resistance to heat and demanding chemical environments is important.
- * **Polyethylene terephthalate (PET), HIPS, polymethyl methacrylate (PMMA), and ABS:** Selected grades can address requirements involving clarity, stiffness, thermal performance, surface quality, and dimensional stability in appropriate medical or diagnostic applications.

An important distinction is that not every grade within a polymer family is suitable for medical use. We focus on identifying grades specifically intended for the proposed application.

MP
DS

How does your company support the medical device industry regarding regulatory norms for the materials supplied? What other customer support activities do you undertake?

LBM

Regulatory and technical support is an essential part of medical polymer distribution. The choice of raw material can influence product safety, performance, validation, and ultimately the manufacturer's ability to meet applicable regulatory requirements.

At JRD Polymers, our approach is to facilitate access to the relevant documentation available from the material manufacturer. Depending on the grade, this may include technical data sheets and safety data sheets.

We work with customers on:

- **Material selection:** Identifying suitable grades based on mechanical, thermal, chemical, and processing requirements.
- **Technical coordination:** Connecting customers with the material manufacturer's technical experts when more detailed application support is needed.
- **Processing guidance:** Helping customers understand the recommended processing window and material-handling requirements.
- **Supply-chain reliability:** Supporting consistent sourcing, product identification, traceability, and continuity of supply.
- **Application development:** Working with device manufacturers and moulders during material evaluation and new-product development.

It is important to emphasize that regulatory compliance is a shared responsibility. We support customers with material information, but the medical device manufacturer remains responsible for validating the finished device, its manufacturing process, its sterilization cycle, and its regulatory compliance.

MP
DS

Could you share information about your company's expansion plans and new materials to be introduced for the benefit of the Indian medical device industry?

LBM

Our broader direction is to strengthen our presence in high-value and application-specific polymer segments, with medical devices being an important area of opportunity.

India has considerable potential to expand its domestic manufacturing capabilities in medical devices,

diagnostics, drug delivery, and healthcare technologies. As these sectors grow, manufacturers will need access to specialized materials that meet increasingly demanding requirements for performance, consistency, and documentation.

We intend to continue broadening our medical polymer offering in line with customer requirements and the capabilities of our international material partners. Areas of interest include precision-moulding materials, medical-grade elastomers for wearable devices, engineering polymers for drug delivery systems, and materials for diagnostic and healthcare equipment.

Early involvement in material selection can help customers evaluate alternatives before committing to tooling and validation.

Our expansion strategy is not simply about adding more products. It is about developing a more application-focused portfolio, improving access to technical expertise, and ensuring that customers receive dependable support throughout the material selection process.

Specific launches and timelines will depend on supplier arrangements, market demand, and the completion of the necessary commercial and technical evaluations.

MP
DS

Could you briefly describe your personal professional journey in the polymer industry?

LBM

My professional journey has been closely connected with polymers, materials, and their applications across different industrial sectors. My academic background in polymer engineering and materials science has helped me understand how polymer chemistry, structure, processing, and properties influence the performance of a finished component.

Working in business development has allowed me to apply that technical understanding to real customer requirements. I have learned that successful material selection involves much more than comparing datasheets or prices. It requires understanding the customer's application, manufacturing process, performance expectations, and long-term business objectives.

In my role at JRD Polymers, I focus on developing customer relationships, identifying new business opportunities, coordinating with material suppliers, and helping customers evaluate polymer solutions for their applications.

The medical device sector is particularly interesting because it brings together materials science, precision engineering, quality systems, and patient safety. It demands a disciplined and collaborative approach, and I find that challenge professionally rewarding.

I believe that continuous learning, technical curiosity, and the ability to build trust between suppliers and customers are essential to succeeding in this industry.

MP
DS

How do you view the global medical polymers market and the Indian market?

LBM

The global medical polymers market is evolving alongside advances in healthcare technology, diagnostics, minimally invasive procedures, drug delivery, and wearable medical devices.

Manufacturers increasingly seek materials that combine

Meet the Executive

mechanical performance with properties such as transparency, flexibility, chemical resistance, dimensional stability, and compatibility with the intended sterilization method. There is also growing interest in lightweight designs, component integration, precision moulding, and materials that enable more compact and user-friendly devices.

India presents a particularly promising opportunity. The country has a growing medical device manufacturing ecosystem, a large healthcare market, and increasing interest in strengthening domestic manufacturing and reducing dependence on imported finished devices and components.

At the same time, Indian manufacturers face challenges involving material availability, development costs, access to specialized technical support, validation requirements, and competition in global markets.

I believe that access to the right medical-grade polymers, combined with strong technical partnerships, can help Indian manufacturers develop products that are competitive internationally.

For distributors such as JRD Polymers, the opportunity lies in bridging the gap between global material technology and local manufacturing needs. By improving access to specialized grades and helping customers understand their application-specific requirements, we can contribute to the development of a stronger domestic medical device industry.

MP
DS

Based on your experience in business development,

 **MORRISONS**
LIFECARE PVT. LTD.



Manufacturer of

SURGICAL DISPOSABLE & MEDICAL DEVICES

with state-of-art manufacturing & maintaining International Standards

CE ISO G.M.P

MORRISONS' caters to the needs of:

Urology | Anaesthesia | Surgery | Gynaec & Obst. | Orthopedics

No:3 Anna Street, Padikuppam, Chennai - 600 107, India.
Ph: 91 - 44 - 26155047 / 26156047, Telefax: 91 - 44 - 26154047
email@morrisonslifecare.com

www.morrisonslifecare.com

how would you differentiate the medical polymers market from the non-medical market, particularly regarding customer support requirements?

LBM

The fundamental difference is the level of responsibility associated with the final application.

In conventional industrial applications, material selection is generally driven by factors such as cost, mechanical performance, processing efficiency, durability, and productivity. Quality and safety remain important, but the qualification process depends on the particular industry and application.

In medical applications, these requirements are accompanied by additional considerations relating to patient safety, biological interactions, regulatory documentation, traceability, and validation of the finished device.

For example, a polymer that performs well in an industrial component cannot automatically be considered suitable for a medical device. The material must be evaluated against the intended use, the nature and duration of patient contact, the manufacturing process, and the applicable sterilization method.

Linchon B. Mehta is a Polymer Engineering professional with 8 years of experience spanning business development, application development, product development and customer management in the polymer industry. He currently serves as Business Development Manager at JRD Polymer Pvt. Ltd., Mumbai, where he works with OEMs, Tier 1 suppliers and moulders to develop new applications and business opportunities.

Previously, he worked with LyondellBasell (Mumbai) and DSM Engineering Materials (Pune) focusing on customer solutions, market-driven product development and commercialisation of engineering polymer applications.

Academically, Linchon holds an MTech in Polymer Engineering & Technology from the Institute of Chemical Technology (ICT), Mumbai. He completed his B.E. in Polymer Engineering from Maharashtra Institute of Technology, Pune, securing First Rank (Gold Medallist). He has published more than 8 research papers in peer-review scientific journals.

rapidfacto

Medical Device QMS Software

Always be ready for ISO & CDSCO Audits?

✓ INDIAN MDR ✓ ISO 13485 ✓ 21 CFR Part 11

8708856807

rapidfacto.com

Balram Sankaran, Scientist-, SCTIMST, Trivandrum Receives Dr. V. G. Patel National Award 2026 in the New-Age Entrepreneurship Category.



Recognising his distinguished contribution to new-age entrepreneurship, the Dr. V. G. Patel National Award 2026 recognises Mr. Balram Sankaran, Scientist-G (Senior Grade), Sree Chitra Tirunal Institute for Medical Sciences & Technology, Trivandrum, as the Winner in the New-Age Entrepreneurship Category.

With over 20 years of experience in research, technology transfer and commercialisation, Mr. Sankaran has played a key role in facilitating the commercialisation of 50+ medical devices to MSMEs and startups. He also helped establish TIMED, a Technology Business Incubator focused on medical devices and biomaterials.

Under his mentorship, TIMED has nurtured 100+ deep-tech healthcare startups and innovators and facilitated 25+ patents, contributing to the growth of entrepreneurship at the intersection of healthcare, technology and innovation.

This year, the prestigious award received 532 applications from 302 institutions across 18 countries, including 25 Indian states. It recognises the outstanding contribution of trainers, educators and mentors in promoting innovation and entrepreneurship.

About V G Patel Award

Instituted by the Entrepreneurship Development Institute of India (EDII), Ahmedabad, this award commemorates legacy of Dr. V. G. Patel, Padmasree Awardee, who pioneered entrepreneurship education in the country. The award recognizes the outstanding contributions of trainers, educators, and mentors who are shaping India's entrepreneurial ecosystem by inspiring, guiding, and nurturing the next generation of entrepreneurs and startups. The award includes a citation and a cash prize of ₹1,00,000 in each of three categories namely, Traditional/Conventional Entrepreneurship, New Age Entrepreneurship (startups) and Social Entrepreneurship.

The selection process is a comprehensive three-tier evaluation mechanism, with an initial screening, an in-depth assessment by a high-level Award Committee, and a personal interaction with shortlisted candidates.

About SCTIMST-Timed

SCTIMST TIMed is India's pioneering Technology Business Incubator focused exclusively on supporting the medical devices and biomaterials sector. It was established in 2015 by the Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST) in Thiruvananthapuram, Kerala with the funding and support of the Department of Science & Technology (DST),

Government of India. TIMed connects innovators with clinical experts, investors and government grants like NIDHI and BIRAC BIG apart from need based services and mentoring. Over 100 startups, innovators and entrepreneurs developing innovative medical devices across country have been nurtured and supported by TIMed. Some of the successful startups include Waferchips Techno solutions Pvt Ltd, Sascan Meditech Pvt Ltd, ByLin Medicals, Evelabs Technologies, Alicorn Medicals Pvt Ltd. For further information www.timed.org.in Email: timed@sctimst.ac.in



**JIMIT MEDICO
SURGICALS PVT. LTD.**

AN ISO 13485 : 2016 & CE CERTIFIED COMPANY

Manufacturers & Exporters of Disposable Medical Devices

Infusion Set, Blood Administration Set,
IV Cannula, Urine Bag, Catheters, Gloves,
HIV KITS, Ophthalmic KITS, Ophthalmic Knives
(Blades), Cap, Mask, Gown, Drapes, Bandages,
Dressings etc.

Specialized in Handling Large Quantity & OEM / Contract Manufacturing

Factory : 16, Ranchodnagar, Near Vinzol Railway,
Crossing, Vatva, Ahmedabad-382445, INDIA

Tele : +91 89055 70200, +91 88492 38712.

E-mail: info@jimitsurgicals.com • Web: www.jimitsurgicals.com

Device for Continuous Glucose Monitoring

Tracky is the med-tech brand of Drstore Healthcare Services India, focused on making health monitoring more connected, accessible and easier to understand. The brand develops smart medical devices and digital health solutions, with a particular focus on metabolic health and helping people better understand the factors that influence their everyday wellbeing.

At the centre of Tracky's approach is the idea that health data becomes more useful when it is viewed as a whole rather than as individual numbers. Through its connected platform, Tracky brings together important health information such as glucose levels, nutrition, medication, physical activity, sleep, blood pressure and body composition. This allows users to see how different aspects of their lifestyle may be connected and gives them a clearer picture of their overall health.

Tracky's solutions are designed to support people who want to take a more proactive approach to managing their health. Its continuous glucose monitoring technology provides ongoing glucose insights helping users understand how their bodies respond to food, exercise, medication and everyday routines. By providing trends and patterns rather than relying only on occasional readings, the platform aims to make health information easier to understand and use in daily life.

The brand also focuses on creating a connected experience for healthcare professionals, families and caregivers. Through available health reports and insights, doctors can access relevant information during consultations and follow-ups, while family members and caregivers can stay informed remotely when required. This connected approach is intended to make health monitoring more convenient while supporting better-informed conversations between individuals and healthcare professionals.

Tracky is also incorporating technology such as AI-powered health assistance, Bluetooth connectivity and digital integrations into its platform. These features are designed to make collecting

and accessing health information simpler while helping users engage with their data in a more meaningful way.

With its focus on metabolic health Tracky aims to move beyond standalone monitoring devices towards a broader connected health ecosystem. The company's larger vision is to bring different health signals together so that glucose, activity, sleep, heart rate and other indicators can eventually be understood in relation to one another.

Through its combination of medical devices, digital technology and connected health data, Tracky is working towards making health monitoring more convenient and helping individuals and healthcare professionals develop a more complete understanding of health.



Alpha Medicare and Devices Pvt. Ltd.

(taking care...Since 1984)

Manufacturers & Exporters of Disposable Medical Devices

ISO 13485 : 2016 & CE CERTIFIED COMPANY

Our Product Range :

• Infusion Set • Blood Transfusion Set • Measured Volume Burette Set • Alpha Foley's Balloon Catheters • Scalp Vein Sets (Blister Pack) • Urine Bags • Uromasure Urine Bags • Mucus Extractors • Cord Clamp (Blister Pack) • Guedel Airway • Three Way Stop Cocks • Extension Tubes with 3 way Stop cock • High pressure Monitoring Tubes • Feeding Tubes • All kinds of Catheters • Closed Wound Suction Unit • Yankaur Suction Set • A.D. Kit Sets • Water Sealed Drainage Bags • Other Diagnostic Products like Urine Culture Bottles Screw Type [30ml. 45ml. & 60ml.] • Petri Dish (55mm & 90mm)

- Class 10000 Assembly [Clean Room]
- In house Imported Injection Molding Machines
- Latest E.T.O. Sterilization Facilities
- Own Govt. certified laboratory to perform Chemical, Physico Chemical, Sterility & Micro Biological Tests.
- Exporting our products to almost more than 23 countries.

Contact:

Mr. Sohil Saiyed (Director)
(M) 9638979798

97, Alpha Estate, Near Abad Estate, Opp. Kashiram Textile, Narol, Ahmedabad 382 405. [GUJ] INDIA
phone: +91-79-29700601/29700832 • Office Mobile: +91- 9638979798
Website: www.alphamedicare.com • E-mail: contact@alphamedicare.com

NEW PRODUCTS

- "Alpha-Flow" I.V. Cannula
- Oxygen / Nebulizer Mask
- Nasal Oxy Set (Twin Bore)
- I.V. Flow Regulators
- Spinal Needles
- Gauze Swabs
- "Med-Exer" Spirometer (Three Balls)
- "Alpha Superfix" (Cannula Fixator)
- Surgical Paper Tape



ISO 13485 : 2016



Holly, An Implantable, Continuous Renal Replacement Device To Make Dialysis Simpler and more convenient

Nephrodite, a medical device company dedicated to creating a better alternative to dialysis has developed developing Holly, an implantable, continuous renal replacement device designed to restore freedom, function and independence in people living with end-stage kidney disease. Founded by board-certified urologists Nikhil L. Shah, DO, MPH, and Hiep T. Nguyen, MD, the company combines deep clinical expertise with engineering innovation to deliver a true renal replacement platform. Headquartered in Atlanta, Georgia, Nephrodite is backed by leading investors and supported by a robust intellectual property portfolio.

"Holly is surgically placed inside the body, stays connected to blood vessels in the pelvis, and keeps filtering waste continuously like a normal kidney" says Dr Shah, unlike current dialysis sessions that filter waste and excess fluids from the blood only 2-3 times a week.

Dr KS Nayak, director of nephrology at Gleneagles Fortis Hospital, Hyderabad and lead medical advisor, Nephrodite India, says the technology could greatly improve quality of life, especially in India. "During the day, no one will even know the patient has a device implanted. They can work, travel and carry on with normal life, connecting to a bedside machine for water removal only when convenient, usually at night. It can serve as a bridge to kidney transplants or even become a destination therapy for many".

India bears one of the world's largest kidney disease burdens, with more than 2 lakh new patients being diagnosed with end-stage kidney disease (ESKD) every year. But only 6-10% of them undergo dialysis and barely 1% gets new kidneys. For those on dialysis, repeated needle pricks and frequent hospital visits can be quite exhaustive.

Holly was named a 'breakthrough device' by the US FDA in 2025 after encouraging animal studies (in living sheep) that showed it could safely replace kidney function over several days. FDA has also given the nod for human trials. The prototype has been perfected for over a decade, and is now in its preclinical phase. An animal study is expected in 2027 before human trials begin in India. The device is already being manufactured in Kochi, Bengaluru and Mumbai. Dr Nayak says it is currently the only medical device with a proven track record of providing a solution for ESKD.

Dr Sree Bhushan Raju, head of nephrology at Nizam's Institute of



HOW IT WORKS

- Implanted surgically, connected to blood vessels in pelvis permanently
- Mimicks kidney by filtering waste, excess fluid from blood continuously
- External dialysate tube connects device to compact bedside unit for 8 odd hours every day (preferably overnight) to drain excess fluid
- Doesn't need repeated needle punctures, unlike conventional dialysis
- Once disconnected from bedside unit, it operates invisibly, letting patients work, travel, and go about daily life as usual

Medical Sciences, Hyderabad says that while earlier concepts involved bulky, wearable systems that were difficult to use, newer designs are smaller, lighter and more practical. "These implantable kidney systems have the potential to make dialysis simpler and more convenient, giving kidney failure patients more freedom. Manufacturing the device in India could reduce costs and improve access," he says.

India was chosen for its engineering, manufacturing and clinical research capabilities. "Our goal is to develop a scalable artificial kidney that can reduce dependence on dialysis centres and improve access to kidney replacement therapy worldwide," says Dr Shah.

References :

01 <https://nephrodite.com/newsroom/nephrodites-holly-implantable-continuous-dialysis-system-awarded-selection-into-fdas-tap-to-accelerate-development-and-patient-access/>
02 "Times of India < Ahmedabad", Aug. 12, 2026, P. 8.



**ISO 9001:2015
Certified Company**

S. Nath & Co.

Excellence in Quality

**Manufacturer & Exporter of
Surgical Disposable Products since 1980**

IDEAL®

FINESTER®

- Infusion Set
- Blood Administration Set
- Urine Collection Bag
- Mucus Extractor
- Umbilical Cord Clamp
- Scalp Vein Set
- Measure Volume Set
- Microdrip Set
- Tubes & Catheters
- Specimen Containers

Address:

S.Nath & Co.

B.N. Estate, Near Uttam Dairy, Sukhramnagar,
Ahmedabad-380021, Gujarat, India.

Contact No: 9825360531

Website: www.snathco.com • E-mail: snathco@hotmail.com



MEDICAL PLASTICS INDIA

Medical Plastics • Medical Devices • Diagnostics • Pharma
www.medicalplasticsindia.com



Industry-Academia Collaboration For Medical Devices Development

Dr. Amit Dave

M. Pharm, MBA

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

Dr Amit Dave, a member of the Editorial Advisory Board of our Magazine and a regular contributor to our Magazine, has been conferred a PhD in Management after completing his three-and-a-half-year research journey. On behalf of all the readers of our Magazine, we congratulate him on this achievement.

The subject of his PhD was R&D models and Industry-Academia collaborations for the Indian medical devices sector. Needless to say, these are both highly relevant subjects for our readers.

He will share his knowledge and findings on Industry-Academia collaborations for the medtech field in a series of articles. Once this subject is covered, we will resume our articles on international market strategies, based on his more than 25 years of experience exploring markets across the world.

COLLABORATIONS MAKE IMPOSSIBLE POSSIBLE

Very aptly said. This phrase was the title of one research paper. As learned readers know, there are multiple possibilities for collaborations in the medical device industry – collaborations with academia for research, collaborations with incubation centres, collaborations through an industry cluster, collaborations with a government agency, and so on. We plan to cover many such collaborations for a better perspective of possibilities in a series of articles.

The first set of articles will focus on Industry-Academia Collaborations.

Industry-Academia Collaborations – Why

A large array of medical devices (close to 20000 types!), a wide variety of technologies involved, and a limited exploration in some fields by the Industry, clearly call for collaborative efforts. A new Medical Device development probably requires the highest number of diversified technologies like biomaterials of a very wide range, electricals, electronics, electromagnetics, chemicals, biochemicals, mechanics, moulding technologies, metallurgy, optics, fluidics, computer programming...to name a few. Over and above this, ergonomics and design science for convenience and efficiency of usage are expected for a new device. Compare this with pharma product development. Though new molecule development demands highly complex and much more difficult chemical and pharmacological evaluation processes, a copy pharma product development is fairly simpler (but not easy). A copy medical device development, on the other hand, needs a large array of processes and needs "horizontal"

processes, unlike many other fields needing "vertical" or deeper exploration of selected but limited technology fields. This is where universities and academicians can be of help to medical device companies for development.

To summarise, this diversity of technology is the main reason justifying industry-academia collaboration for a new medical device development. Academic institutions and universities grow through discovery and innovation, while technology-oriented companies are normally driven by fixed and pre-set processes. A well-structured academic-industry collaboration may accelerate a new device development. On the other hand, Academic institutes discovering novel technology solutions benefit by joining hands with industry experts, making faster commercialisation and acceptance of discoveries of academic teams. WHO, in its document, also requests member countries to formulate the right national strategies for collaborating between teams and people for new technology development.

One interesting situation to be quoted here also highlights limited market size estimates, calling for academic institutes to take up development of new products. Unless there is a large market size, an industry house will not be interested in developing a product. For pacemakers, initial market surveys revealed a total market size of about 1000 pieces only, which would not be attractive for a large medical device corporation. The role of a university can be important in such situations. The story took a turn, however, when, at a later stage, the market was found to be very large, with 200,000 units for the United States only (and this became a great turning point for Medtronic to enter the field).

Most popular models for Industry – Academia collaborations

The three most common models for such collaborations are **Sponsorship, Technology Transfer, and Consulting arrangement**. These are explained below in more detail.

Sponsorship model

This is the most common model where a sponsor company



enters into a contract with a college or university, and such a formal contract details an arrangement where the sponsor company funds the innovation. Timelines with milestones, deliverables, IP ownership and methods of interaction are also well-defined through a negotiated contract signed by both sides.

Technology Transfer

For a ready technology which is developed by a university, this arrangement is more suitable. As the product is ready, the method of transferring the manufacturing technology is detailed in a contract with corresponding fees. Ownership or transferability of IP and troubleshooting during implementation, along with protocol testing, are also covered in a contract.

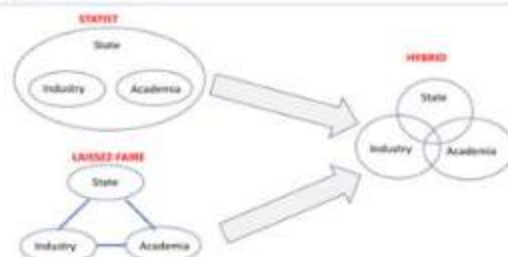
Consulting arrangement

This is generally entered into between a company and a faculty member or an academician, where this academician is an individual. This academician is a consultant for a specific time period or for a specific project. A personal equation with a specialist academician plays an important role here.

Sponsorship model, which is the most commonly used, allows a company to set and negotiate the terms, including the time frame, much better. On the other hand, technology transfer offers a ready technology, sometimes at a higher price. The most flexible and personalised model is consulting.

Triple Helix Model to facilitate Collaborations

Triple Helix model



Triple Helix Model is a highly discussed collaboration model. The model says that the three parties involved, namely governments, universities and industry, can have three states of interaction:

- Statist state (where state policies control the remaining two parties)
- Laissez-faire (all three work on their own without being concerned about the other two)
- Hybrid state (an ideal state, where each one hand-holds the other two)

The model highlights mutual consideration, openness, and flexibility for both industry and academia.

SEC GLOBaL

Align Energize...

Unlock Growth & Stay Compliant with Compliance for Growth

- End-to-end compliance solutions for businesses of all sizes
- Expert guidance on legal, regulatory, and statutory requirements
- Customised support to help your business expand smoothly and securely
- Stay updated with the latest compliance changes and avoid penalties
- Access to industry specialists with extensive experience in Indian and global markets
- Affordable and transparent pricing-no hidden costs
- Seamless onboarding with personalised service tailored to your needs
- Focus on your core business while we manage your compliance headaches

Grow your business confidently-choose

Compliance for Growth as your trusted compliance partner. Visit www.complianceforgrowth.com

LAUNCHING SOON....

Topic - Requirement Engineering

Title: Awareness session

Useful for: Medical device manufacturers, component manufacturers and service providers

COMING SOON...

MDQMS SOFTWARE

SaaS based Medical Devices Compliance Management system.

This will help you to manage

compliances for:-

ISO 13485 - ISO 14971

ISO 20416 - ISO 14644

ISO 15223

Open to Partnership Proposals

Contact: Bhupesh Sood (CEO)-9974803399



Medical Testing Parts May Get 100% Funding

New Delhi: The Centre is ready to provide 100% funding support for the acquisition of medical testing equipment, commerce and industry minister Piyush Goyal said Monday, and pitched for development of high-quality medical devices for global customers.

At two events of the healthcare and pharmaceutical industries, he said that domestic firms should bring technology partnerships, encourage joint ventures, and invite global innovators and large pharma companies to India.

"From BIS (Bureau of Indian Standards), we are willing to support 100% cost of the best testing equipment. The government of India will fund the acquisition of testing equipment... demand from us, there is no proposal from you. And we'll set up the most modern labs," Goyal said.

He also called for improving design, copyrights, patent laws, and the intellectual property right ecosystem so that internationally people come to India and enable it to harness its cost edge to emerge as a global hub of medical innovation.

"We must develop a critical component ecosystem by strengthening our domestic capabilities with high quality. We must create shared testing infra facilities where these equipment can be tested, benchmarked to the best in the world, certified and demonstrated to global customers," Goyal said, calling for bringing technology partnerships, joint ventures.

He called upon insurers and health-tech companies to build products and platforms that make the patient journey more

seamless, and ensure timely reimbursements.

He suggested industry co-design, co-develop licence wherever required and look for joint R&D centres with other countries, and train and certify caregivers and develop a skilled workforce capable of providing healthcare of international standards.

Encouraging more hospitals to publish honest and transparent treatment packages, Goyal said that hospitals must follow ethical practices and never attempt to cheat patients, as one wrong action can lead to loss of goodwill, business and credibility for India.

He suggested local hospitals establish tie-ups with hospitals globally, and ensure that only the National Accreditation Board for Hospitals & Healthcare Providers-enabled, verified and panelled hospitals are allowed to treat patients coming from abroad.

He insisted that quality healthcare cannot be different for Indians and foreigners.

To attract foreign patients, he suggested creating a pool of interpreters for patients arriving from different countries and speaking different languages, so that they have greater confidence and communication between patients and the medical system becomes easier.

"While 3.5 million patients have benefited from India's medical value tourism ecosystem in the last seven years, the country's target should be 10 million patients a year," he said.

(Economic Times, Sept. 08, 2026)

NITI Eyes Policy Support to Boost Medical, Dental Device Production

Public policy think tank NITI Aayog is exploring comprehensive policy interventions to boost domestic manufacturing of medical and dental devices in the country. With a focus on addressing regulatory hurdles, infrastructure gaps and cost disadvantages faced by Indian manufacturers, the policy body held a meeting on Wednesday with domestic devices and dental manufacturers, government officials from Department of Pharma (DoP), health, Indian Council of Medical Research (ICMR), experts from IIT Delhi and Mumbai, Department of science and technology in addition to

e-commerce platforms involved in trade of dental devices and technology in addition to Medical Devices Industry (AiMeD).

The meeting, chaired by NITI Aayog Vice Chairman Ashoke Lahiri on October 14, focused on identifying key challenges in domestic manufacturing and exploring regulatory, infrastructural and fiscal interventions needed to strengthen India's medical and dental device industry.

The consultation also aimed to identify opportunities for collaboration between the government and industry and formulate recommendations aligned with the country's healthcare priorities.

In a presentation submitted to NITI Aayog, the Association of Indian Medical Device Industry (AiMeD) called for a dedicated regulatory framework, simpler regulatory approvals and financial support to help domestic manufacturers compete with imported products.

The industry body said Indian manufacturers face a 10-15% cost disadvantage due to high capital and energy costs, logistics expenses, limited access to risk capital and inadequate testing and research infrastructure.

It also flagged the growing regulatory burden, saying setting up a manufacturing facility, which earlier took about 18 months, can now take nearly four years because of multiple approvals, overlapping authorities and changing requirements.

Dr Sunita Gupta, professor and head of department of Oral Medicine and Radiology at Maulana Azad Institute of Dental Sciences highlighted the issue regarding dental devices and sought solutions pertaining to make in India, people in the know told ET.

For the dental device sector, experts proposed developing a focused manufacturing plan based on product-wise import volumes and tender prices with further inputs from India's industry members.

India's medical device market is estimated at about \$11 billion and could exceed \$30 billion by 2030, according to AiMeD's presentation. However, the sector remains heavily dependent on imports particularly for high-end products, AiMeD said in its presentation to the policy think tank.

[https://economictimes.indiatimes.com/\(17 October 2026\)](https://economictimes.indiatimes.com/(17 October 2026))



Govt Eases Loan Licence Requirement For 'Outsourced' Sterilisation Of Medical Gear

New Delhi: Makers of medical devices will no longer require a separate loan licence for outsourced sterilisation as long as the sterilisation facility holds a valid licence under the Medical Devices Rules, 2017, according to a new government provision.

The new provision has, however, triggered a pushback from the industry, because it requires the licence number of the sterilisation facility to be printed on the label of the medical device. The Association of Indian Medical Device Industry (AiMed) warned that the requirement would hurt exports.

The medical device loan licence allows a company to use its own brand name on products manufactured by another licensed manufacturer. Under the new rules notified on August 20, such a company will not require this licence for the outsourced sterilisation process.

"This change is aimed at making compliance simpler, reducing unnecessary paperwork and supporting ease of doing business for medical device industry," health ministry said. AiMed said no other country required subcontractor details to be printed on pack and that doing so would hurt export flexibility and delay shipments.

"Manufacturers will be forced to wait for sterilisation by the specific subcontractor whose licence number is printed on the

packaging, removing the flexibility to choose the fastest available facility. This could delay shipments by two to three weeks instead of the current turnaround of under a week, a significant competitive disadvantage," said Rajiv Nath, forum co-ordinator, AiMed.

Nath has written to the health ministry seeking suspension and a review of the new rule. His letter requests the ministry to engage with industry stakeholders to explore alternatives that ensure patient safety without undermining competitiveness and exports. The government also amended Rule 63 of the Medical Devices Rules, 2017, to include the European Union among the recognised stringent regulatory jurisdictions for waiver of clinical investigation requirements.

With EU's inclusion, medical devices approved in Europe can benefit from waiver provisions in India, facilitating faster patient access to advanced medical tech without requiring a fresh round of clinical investigations, the ministry said.

Read more at:

https://economictimes.indiatimes.com/industry/healthcare/biotech/govt-eases-loan-licence-requirement-for-outsourced-sterilisation-of-medical-gear/articleshow/133476869.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst (Aug 25, 2026)

MANUFACTURER OF UNSTERILIZED Bulk Disposable Needles and Surgical Products



Available sizes for Needles 18G, 19G, 20G, 21G, 22G, 23G, 24G
with Imported Cannula & Components

GAUGE	COLOUR	DIAMETER
18G	PINK	1.20 MM
19G	CREAM	1.10 MM
20G	YELLOW	0.90 MM
21G	GREEN	0.80 MM
22G	BLACK	0.70 MM
23G	BLUE	0.60 MM
24G	PURPLE	0.55 MM

Production Facility

Automatic Needle Assembly Machine
With Testing Equipments like

- Penetration Force Measurement Test Unit
- Digital Bond Strength Test Unit

Beacon Plastics

9, Revabhai Estate Part-2, Opp. Shriji Hotel, C.T.M., Ahmedabad - 380 026.

Ph. : +91 9824041538 • E-Mail : beaconplastics@hotmail.com • www.beaconplastics.com

AN ISO 9001:2015 CERTIFIED COMPANY



eewaengineering

Since 1967

300+
Models

35000+
Customers

60+
Countries Export



PRECISION ENGINEERING - STRONGER SEALS SMARTER PRODUCTION

Your material is high-tech. Your dreams should be, too. EEWA's advanced sealing technology ensures 100% hermetic bonds on SMS and Polypropylene, meeting the rigorous demands of AAMI Level 3 and 4 protections. No needle holes. No leaks. Just pure barrier integrity.

Spunbond - Melt blown - Spunbond:

This is the industry standard. It's a trilaminate fabric.

- Pneumatically controlled semi-automatic operation
- Seals polyethylene and other thermoplastic film / bag and any other thermoplastic film / bag quickly and efficiently.
- Seal Length available from 15" to 40" (depends upon model)
- Seal width 1 mm, 2 mm, 3 mm, 5 mm, 8 mm
- Equipped with Digital Timer
- Two parallel seals are available upon request
- Provision of Upper & Lower Jaw Heating Element

Compatible Materials:

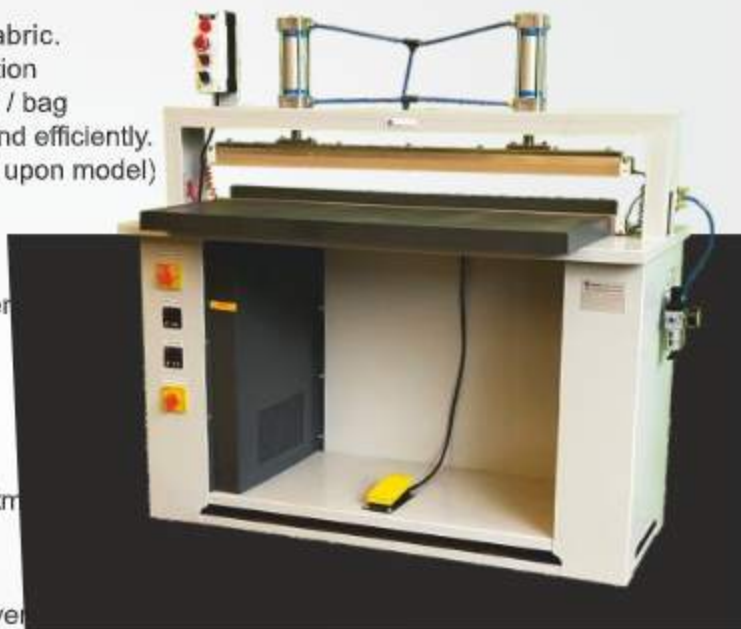
- SMS, SMMS, Spun bond PP, PE Laminated fabrics, Surgical Apparel.

Key Features:

- Digital PLC Control, Pneumatic Pressure adjustment, Custom Sealing Lengths.

Applications:

- Surgical Gowns, Drapes, Hoods, and Shoe Covers



Eewa Engineering Co. Pvt. Ltd.

Mobile : +91 98795 38559, 98250 38559

E-mail : contact@eewaengineering.com

Website : www.eewaengineering.com





ETO STERILIZER

ETHYLENE OXIDE GAS STERILIZER



Polymers Type



Medical Instruments



Long Lumens



Surgical Instruments



Medical Instruments



Implants Items



Fully Automatic Full Body Model



Fully Automatic Table Top Model



Sealing Machine



ETO Cartridge



All Type Indicators



Sterilization Roll

HPHV FULLY AUTOMATIC AUTOCLAVE STERILIZER.



Cylindrical on Stand

Gage
Compressed Air Not Required
HMI
Printer & Emergency Stop
Temperature &
Humidity Sensor
USB Port
SS 316L



Sliding Door Compact Model



Cylindrical Vertical Autoclave



A-103, 104, Swarnim Ind. Park, Ind Bakrol Dhamatvan Road, Bakrol Bujrang, Village : Bakrol, Ahmedabad.
Website : www.mapindus.com, Email : info@mapindus.com, mapindustries94@gmail.com
Abdul Hanif : M. 96873 41157, 9687771157

Healthium & Romsons Lead Race to Buy BL Lifesciences

Delhi-based medical devices co likely to be valued at about ₹2k cr, KPMG advising the promoters on stake sale.

Mumbai: KKR-owned Healthium Medtech and Temasek-backed Romsons Group are the major contenders to acquire an about 70-80% stake in Delhi-based medical devices manufacturer and distributor BL Lifesciences, said people aware of the development.

The company is likely to be valued ₹1,800-2,000 crore, the people said. KPMG is advising the promoters on the stake sale. BL Lifesciences, a fourth-generation family-owned business, primarily focuses on products for cardiac surgery, critical care, interventional cardiology, anaesthesia and surgical care.

Its portfolio spans perfusion systems such as heart-lung packs, oxygenators, cardioplegia sets; cath-lab kits, central venous catheters; invasive pressure-monitoring systems; and a broad range of surgical consumables including blood bags, instruments and wound-care products.

KKR and Temasek spokespersons declined to comment. An email sent to BL Lifesciences managing director Sunil Aggarwal did not elicit any responses till press time Monday.

KKR acquired Healthium (formerly Sutures India) in 2024 for about ₹7,000 crore, outbidding a consortium comprising Mankind Pharma, ChrysCapital and Novo Holdings, the controlling shareholder of Danish pharmaceutical giant Novo Nordisk.

Last month, Temasek acquired a minority stake in medical devices and hygiene products maker Romsons Group.

Temasek was also among the leading contenders to acquire Tynor Orthotics, an Indian manufacturer and brand of orthopaedic supports, mobility aids and rehabilitation products. However, homegrown private equity firm Kedaara Capital emerged as the winner, acquiring a 51% stake for about \$200 million (₹1,907 crore) in this August.

LARGE TRANSACTIONS

Private equity interest in India's medical devices sector has gained significant momentum, with several large deals recently

Private equity interest in India's medical devices sector has gained significant momentum, with several large transactions in recent years. US fund Warburg Pincus invested \$210 million in Meril Life Sciences in 2022 and later backed Chennai-based ophthalmic devices maker Appasamy Associates. Abu Dhabi Investment Authority invested \$200 million in Meril in 2025, valuing the company at around \$6.6 billion.

More recently, Motilal Oswal Alternates acquired a significant minority stake in Hyderabad-based Sensa Core Medical Instrumentation, a diagnostics and medical devices maker.

PEVC activity in medical devices represented 24% of overall pharmaceutical and healthcare investments since 2016 at \$2.4 billion across 54 deals.

<https://economictimes.indiatimes.com>

rapidfacto

Medical Device QMS Software

Always be ready for ISO & CDSCO Audits?

✓ INDIAN MDR ✓ ISO 13485 ✓ 21 CFR Part 11

8708856807

rapidfacto.com

GUJARAT'S MEDICAL DEVICE PARK

at Nagalpar, Rajkot

Opens for Industrial Plot Allotment

GIDC is Developing a Dedicated Park Spreading Across **336 Acres** for **Medical Devices Manufacturing**, with Common Infrastructure Facilities built around Medical Devices Manufacturing.

Online applications will be accepted from:

26th October 2026

For Manufacturers of Medical Devices, Equipment and Allied Components.

Important Points

- For application and other details, visit the link <https://egov.gidcgujarat.org/gidc/frmgeneralterms.aspx>
 - Contact details are available on <https://gidc.gujarat.gov.in/Pages/Contents/Contactus>
 - For portal-related queries, contact 9879110007, 9879110463, 9879110478 or 9879110482 during office working hours.
- GIDC Medical Device Park, Nagalpar, Rajkot, Gujarat



**ISO 9001:2015
Certified Company**

S. Nath & Co.

Excellence in Quality

Manufacturer & Exporter of
Surgical Disposable Products since 1980



- Infusion Set
- Blood Administration Set
- Urine Collection Bag
- Mucus Extractor
- Umbilical Cord Clamp
- Scalp Vein Set
- Measure Volume Set
- Microdrip Set
- Tubes & Catheters
- Specimen Containers

Address:

S.Nath & Co.

B.N. Estate, Near Uttam Dairy, Sukhramnagar,
Ahmedabad-380021, Gujarat, India.

Contact No: 9825360531

Website: www.snathco.com • E-mail: snathco@hotmail.com

Lubrizol And Polyhose Inaugurate Advanced Medical Tubing Facility In Chennai

New medical manufacturing site to produce precision extruded tubing for minimally invasive neurovascular and cardiovascular devices, supporting India's growing healthcare sector.

Lubrizol, a global specialty chemicals leader, and Polyhose, a leading manufacturer in fluid conveyance systems, today inaugurated a new medical manufacturing site in Chennai, Tamil Nadu. The facility will manufacture precision extruded medical tubing for minimally invasive devices, supporting India's rapidly growing medical technology and healthcare sectors.

John Valukas, President, Lubrizol Engineered Materials said, "Today's inauguration is an important milestone in Lubrizol's commitment to India and to supporting our customers in the global medical device industry. By combining Lubrizol's medical device expertise with the manufacturing strength of local partners in India, this facility will deliver advanced tubing solutions for life-saving neurovascular and cardiovascular applications. Our goal is to help our customers bring these critical technologies to patients faster, with reliable local supply and the highest quality standards."

Designed as a world-class operation, the ISO13485 facility provides customers with a reliable source of high-quality medical tubing, backed by dedicated quality control and the same rigorous standards applied across Lubrizol's global manufacturing network. This investment strengthens Lubrizol's ability to serve customers in India and across global markets.

Operations focus on delivering precision extruded tubing from a wide range of high-performance materials, including polyamides, nylon, Pebax, polypropylene, polyethylene, and Lubrizol's medical grade thermoplastic polyurethane (TPU).

Abhishek Shrivastava, Managing Director, Lubrizol IMEA said, "India is a strategic growth market for Lubrizol and a key hub for our investments in manufacturing, R&D and technical services. This medical manufacturing site in Chennai is another step in building a stronger local ecosystem for high-value, technology-driven products. By working closely with Polyhose and regional stakeholders, we aim to support innovation, create high-skilled jobs and enable India to become a more significant contributor to the global medical device supply chain."

Mittal Shah, Business Head, Medical Devices IMEA, Lubrizol said, "Minimally invasive procedures are transforming patient care, and high-precision tubing is at the heart of many of these devices. With this Chennai site, we are bringing world-class catheter tubing capabilities closer to our customers in India and across IMEA. This partnership with Polyhose will enable a broad range of devices utilizing high-performance materials, further strengthening our ability to partner with medical device OEMs in India across the full product development lifecycle."

Shabbir Yusuf Jamnagarwala, Founder & Managing Director, Polyhose said, "For more than three decades, Polyhose has partnered with global customers by delivering innovative extrusion and fluid conveyance solutions. Our collaboration with Lubrizol marks a new chapter in our journey, combining Polyhose's world-class manufacturing strengths with Lubrizol's deep materials science and medical device expertise to deliver advanced medical tubing solutions for the rapidly evolving healthcare industry. This investment reflects our commitment to innovation, creating skilled employment opportunities, and strengthening India's position as a trusted global hub for advanced medical device manufacturing."

The new site is set to expand India's capacity for precision extruded medical tubing, contributing to the country's focus on building domestic medical device manufacturing capabilities, reducing reliance on imports, and enhancing patient access to high-quality, safe product.

<https://www.expresshealthcare.in/news/lubrizol-and-polyhose-inaugurate-advanced-medical-tubing-facility-in-chennai/454049/> (22 June, 2026)

www.mediSourceasia.com
An Authentic Portal Site On Medical Technology
And Markets In Asia

Happy
Diwali
and a
Prosperous New Year



D L Pandya

MEDICAL PLASTICS
DATA SERVICE

www.medicalplasticsindia.com

www.imdiconferences.com

rapidfacto

Medical Device QMS Software

Always be ready for ISO & CDSCO Audits?

✓ INDIAN MDR ✓ ISO 13485 ✓ 21 CFR Part 11

8708856807

rapidfacto.com

COMPAMED 2026: Where Medical Innovation Begins

COMPAMED focuses on materials, components, technologies and services for the development and manufacture of medical devices. MEDICA showcases medical products, systems and solutions for use in hospitals and medical practices. Together, they cover the entire spectrum from technological development and manufacturing, through quality assurance, regulation and market access, to practical application in healthcare.

Medical innovation begins long before clinical application: with new materials, components and sensors; in electronics and microtechnology; or through innovative manufacturing processes. It is precisely this technological foundation of medical technology that COMPAMED 2026, taking place from 16 to 19 November in Düsseldorf, will be focusing on. More than 700 exhibiting companies will be presenting technologies, products and services for the development and manufacture of modern medical devices in Halls 8a and 8b.

As part of the strategic development of MEDICA and COMPAMED, the role of both events within the medtech value chain is being defined even more clearly. COMPAMED focuses on materials, components, technologies and services for the development and manufacture of medical devices. MEDICA showcases medical products, systems and solutions for use in hospitals and medical practices. Together, they cover the entire spectrum from technological development and manufacturing, through quality assurance, regulation and market access, to practical application in healthcare.

"COMPAMED brings together the companies that make medical innovation technically feasible and industrially viable. Here, medical device manufacturers can find specialist partners for materials, components, development and manufacturing. Together with MEDICA, this creates a link stretching from

technological development right through to use in hospitals and medical practices," explains Carmen Berger, Director of MEDICA & COMPAMED at Messe Düsseldorf.

Further information is available at: <https://www.compamed-trade-fair.com>.



Photo: COMPAMED in Düsseldorf – the world's leading international platform for the medical technology supply sector (© Constanze Tillmann/ Messe Düsseldorf).

08.10.2025 (Link for the Image: : https://www.compamed-trade-fair.com/compamedcache/pica/7/0/9/4/2/9/9871780328981/COMPAMED25_Entrance_Banner.jpg)

One Stop Solution for Medical Device & In Vitro Diagnostic Medical Device Regulatory Support



For Further Details

Contact : Ms. Viji S, Mobile : +91 9842533905, Email: vijiregulatory@gmail.com

Medical Fair India 2026 Concludes in Mumbai, Bringing Together 15,291 Healthcare Professionals from 15 Countries



32nd edition strengthens India's position as a growing hub for MedTech innovation, manufacturing, healthcare technology and global business collaboration

Mumbai, September 2026: The 32nd edition of **Medical Fair India**, India's No. 1 Trade Fair for Hospitals, Health Centres & Clinics, concluded successfully on 19 September 2026 at the Bombay Exhibition Center, Mumbai, bringing together **15,291 visitors from 15 Countries** and **500+ exhibiting brands from 11 countries represented by 306 companies** across three days of business networking, technology showcase and knowledge exchange.

Organized by **Messe Düsseldorf India**, the three-day exhibition provided a comprehensive platform for healthcare professionals, hospital procurement leaders, medical device manufacturers, technology providers, distributors, innovators and other stakeholders to discover new products and solutions across the healthcare and MedTech ecosystem.

The exhibition featured exhibitors from **Brazil, Germany, India, Italy, Japan, Republic of Korea, Malaysia, People's Republic of China, Singapore, Taiwan and the USA**, with country pavilions from China, Republic of Korea and Japan.

Mr. Ajay Kumar Gulati, General Manager, Messe Düsseldorf India, said "Medical Fair India 2026 has demonstrated the growing importance of collaboration across the healthcare and MedTech ecosystem. With 15,291 visitors from 15 countries and 500 exhibiting brands from 11 countries, the edition brought together a diverse community of healthcare professionals, manufacturers, technology providers and business decision-makers. The introduction of Medical Manufacturing India further strengthened the focus on India's evolving medical device manufacturing capabilities and supply chain. We are pleased to have provided a platform where the industry could exchange knowledge, explore new technologies and develop meaningful business connections. The strong participation and engagement throughout the three days reflect the continued relevance of Medical Fair India as a platform for the healthcare industry."

International Participation and Business Engagement

The 2026 edition witnessed strong international participation,

with visitors representing **25 countries**, alongside exhibitors from 11 countries. The exhibition also welcomed International Buyer Visitor Delegations nominated by organisations including **INCHAM – the Indian Chamber of Commerce in Peru, Mollymer Medical, Junkosha Inc., Seoul Business Agency (Republic of Korea) managed by Venture Blick, and the Israel Economic & Trade Mission in India.**

Four Conference Platforms Address Healthcare's Future

The exhibition was complemented by four conference platforms, with a total of 238 delegates and 103 speakers participating across the conference programmes including:

- 11th International Healthcare Conference,
- 2nd Healthcare Leadership & Nursing Excellence Summit
- 10th Future for Health (FTR4H) Conference
- Medical Manufacturing India Conference,

About the Organiser:

Messe Düsseldorf India Pvt. Ltd. is a wholly owned subsidiary of Messe Düsseldorf GmbH, one of the world's leading trade fair organizers. Messe Düsseldorf India organizes major exhibitions, including Medical Fair India, India Essen Welding & Cutting, wire India, Tube India, METEC India, FAMDENT Show & Awards, glasspex India, glasspro India, ProWine Mumbai, In-Store Asia, and Valve World Expo India. The company also serves as the exclusive representative of Messe Düsseldorf Group in India, assisting Indian firms in participating in Messe Düsseldorf exhibitions worldwide.

MEDICAL FAIR INDIA is an initiative of **MEDICARE ASIA**, the central business platform for the portfolio of Medical and Healthcare Exhibitions throughout Asia. MEDICARE ASIA seeks to foster strategic alliances, develop new offerings and create customer-centric strategies across the diverse Asian healthcare market, while building strong connections with Messe Düsseldorf's global healthcare trade fairs in Düsseldorf, including **MEDICA, COMPAMED and REHACARE.**

Media Contact:

Pinak Gupta

Director - Marketing Communications GuptaP@md-India.com



New Medical Manufacturing India Platform Strengthens MedTech Focus@ Medical Fair India 2026



One of the key highlights of Medical Fair India 2026 was the introduction of the **Medical Manufacturing India Pavilion & Conference**, a dedicated platform focused on raw materials, components, machinery, services and MedTech manufacturing solutions.

The new platform brought greater focus to India's medical device manufacturing ecosystem and supply chain, creating opportunities for manufacturers, technology providers and innovators to engage with the wider healthcare industry.

The newly introduced **Medical Manufacturing India Conference**, under the theme "From Design to Delivery: Strengthening India's Medical Device Manufacturing Ecosystem," addressed subjects including medical device components and manufacturing technologies, polymer-based medical devices, product innovation, start-ups and India's IVD supply chain.

The successful introduction of Medical Manufacturing India,



alongside the continued development of digital health, diagnostics, healthcare infrastructure and MedTech-focused platforms, further expanded the scope of the event and created new opportunities for industry collaboration and business development.



From Design to Delivery : Strengthening India's Medical Device Manufacturing Ecosystem

17 - 18 September 2026

Session Partner

MEDICAL PLASTICS DATA SERVICE
A PREMIER COMPANY WITH SOLUTIONS FOR MEDICAL PLASTICS, MEDICAL DEVICES, LABORATORY AND PHARMA INDUSTRY

17th September 2026

Session Theme: Building Blocks of Medical Devices: Polymers, Components, Manufacturing Technologies and Sub-Assemblies
Moderators: Mr. D L Pandya, CEO, Medical Plastics Data Service & VP, SPE INDIA Medical Plastics Division

Participants:

- Freudenberg Medical – Mr. Falgun Jani, Business Head - India Region
- Evonik India Pvt. Ltd. - Mr. Anand Singh Rathore, Manager- Emerging Accounts & Growth Segments
- Ami Polymer PVT LTD– Dr. Priyabrata Pattnaik, Chief Executive Officer
- ET Elastomer Technik GmbH– Sudheesh Kanichattumadathil Sudhan, Quality Manager

18th September 2026

Session Theme: Manufacturing Polymer Based Medical Devices: New Technologies, Testing, Quality & Regulatory Challenge

Moderators : Mr. Falgun Jani, Business Head - India Region,

Freudenberg Medical Participants:

- MARCOPOL – Uday Rathi, Director – Business Development
- Carl Zeiss India (Bangalore) Pvt Ltd – Speaker details awaited
- Taymer International Inc - Gregory D'Souza, Designation: Sales - India

18th September 2026

Session Theme: New Product Innovations in Medical Devices and Opportunities for Start-up Companies

Moderators: Mr. Manoj Appukuttan, Formerly Vice President-Global Product Development and Engineering, Whole Time Director at Terumo Penpol Private Limited

Participants:

- Atal Innovation Centre, Bhabha Atomic Research Center (AIC BARC)
- ANUSHAKTI Foundation – Mr. Aadesh Suryarao, Chief Executive Officer
- Dr. Bipinchandra Sureshbhai Trada, Director – Toxicology Biocompatibility & Regulatory services, Medreg Biotox LLP
- Mr. Kunj Rajendrabhai Shah, Global Head, Sevitsil

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.

Annual Subscription (Incl. GST)

One Year		
	Dispatch through regular post	Dispatch through regular courier
1. Hard Copy	Rs. 590.00	Rs. 963.00
2. Only Soft Copy	Rs. 732.00	—
3. Hard Copy + Soft Copy	Rs. 826.00	Rs. 1251.00
Two Year		
1. Hard Copy	Rs. 1039.00	Rs. 1463.00
2. Only Soft Copy	Rs. 1251.00	—
3. Hard Copy + Soft Copy	Rs. 1451.00	Rs. 1876.00

Payment Options

- **Couriere Cheques / Demand Drafts** in favour of "Classic Computer Services".
- **Online payments (NEFT)**. Please send a confirmatory email for all NEFT transfers.
- Account Name : Classic Computer Services
- Bank : Punjab National Bank (C.G. Road Branch, Ahmedabad)
- Account Number : 10511010015730
- IFSC Code : PUNB0105110
- **For Online payment through :**



Pay at this Outlet using any UPI app



Helpdesk : 18001800/18002021

MERCHANT: CLASSIC COMPUTER SERVICES

SCAN & PAY



UPI ID: 9979093145m@pnb

SINCE 1994

MEDICAL PLASTICS DATA SERVICE

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

SUBSCRIPTION APPLICATION FORM

Subscription Period :

One Year

- ☐ Hard Copy
☐ Only Soft Copy
☐ Hard Copy + Soft Copy

Two Year

- ☐ Hard Copy
☐ Only Soft Copy
☐ Hard Copy + Soft Copy

Name : _____

Designation : _____

Company : _____

Products/Service Offered : _____

Address : _____

Postal Code : _____

Country : _____

Phone : _____

Fax : _____

E-mail : _____

URL : _____

Please attach business card if available

What is your Company's Primary Business :

Please Tick Wherever Applicable (✓)

- | | |
|---|--|
| ☐ Medical Device Manufacturer | ☐ Ancillary Services (Contract R&D, Design, Contract Mfg., Packaging, Testing, etc. Please Specify) |
| ☐ In Vitro Diagnostic Manufacturer | ☐ Manufacturing Consultancy |
| ☐ Medical Device or Diagnostic Distributor | ☐ Supplier to Medical Device Manufacturers |
| ☐ Pharmaceutical Manufacturer | ☐ Other Please Specify |
| ☐ Government | |
| ☐ University / College | |

Date : _____

Sign : _____

contact : **Classic Computer Services** B-4, Mandir Apartment, Opp. Jodhpur Char Rasta, BRTS Bus Stop, Satellite Road, Ahmedabad - 380 015. Gujarat, INDIA.
 Mobile : +91 98254 57563, E-mail : dlpandya@gmail.com • info@medicalplasticsindia.com
medicalplastics@gmail.com

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.

www.medicalplasticsindia.com

MEDICAL PLASTICS DATA SERVICE

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

NOW IN

34th
YEAR

Indian Medical Devices & Plastics
Disposables/Implants Industry

IMDI Conferences

Appreciation And Best Wishes From Industry Leaders & Readers



Shri Himanshu Baid

Managing Director, Poly Medisure Ltd., Faridabad

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



Dr. JK Sharma

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

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



Jitesh Shah

Director, Suru International Pvt. Ltd., Mumbai

Congratulation sir and I wish you many more successes !



Dr. S. S. Murugan

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

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



Anil Jauhari

(ex-CEO, NABCB), New Delhi

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



Rajnikant Shah

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

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



Kishore Khanna

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

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



Brian Reilly

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

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

Rajiv Nath

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



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



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

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

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

Dr. Sanjay Behari

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



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

Dr. Roy Joseph

Scientist G
Biomedical Technology Wing, (SCTIMST) Trivandrum



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

Dr. Renjith S

Scientist C
Biomedical Technology Wing, (SCTIMST) Thiruvananthapuram



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

Dr. Richa Dayaramani

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



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

Tim Galekop

TIGAMED, Global Consultancy Infection Prevention, Belgium



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

EtO Gas Scrubber With 99 % EtO Removal Efficiency With All Safety Measures.

EXCEL BALAJI STERILISATION CONCEPTS (EBSC) offers an efficient EtO Gas Scrubber with 99 % EtO removal efficiency with all safety measures.

TECHNOLOGY & PROCESS SYSTEM:

The counter current packed tower type scrubber makes our EtO scrubber most efficient for removal of EtO. The basic design of the scrubber, channels the gas flow upwards through a packed bed while the scrubbing liquid flows downward by gravity over the packing.

The internal components of the scrubbing system consist of a Packed Bed Tower (packing support plate, a packing bed, a liquid distributor, and a mist eliminator), Scrubbing Liquid Circulation Pump, Reactor Tank, and Control Panel.

The scrubbing solution consists of water and a small amount (usually < 5%) of sulphuric acid (H_2SO_4). The sulphuric acid catalyzes a hydrolysis reaction:



The principal product ($\text{C}_2\text{H}_6\text{O}_2$) is ethylene glycol, which is relatively inert and may be recycled for use as antifreeze.

Whole scrubbing systems is specially designed to ensure adequate dwell time to achieve reaction completion.

SPECIFICATIONS

- EtO Concentration : 1100 ppm (Typical),
- Removal Efficiency: Up to 99%

- Material of Construction: Polypropylene & MS Reinforcement
- Operating Weight: Approximate 1200 Kg
- EtO Removal Capacity per Unit per Cycle: 30 Kg of EtO @99% concentration.

FEATURES AND BENEFITS:

- No Hazardous By Products
- No High Temperature Duct
- Room Temperature Operation
- Minimum Energy Costs
- Low Maintenance and Monitoring.

APPLICATIONS:

- Chemical Reactors of EtO Manufacturing Plant
- Medical Disposable & Surgical Industry
- Contract Sterilization Facilities
- Spice & Food Processing
- Pharmaceutical Processes
- Storage Tank Venting
- EtO Bottling Plant

Purchase our EtO Gas Scrubber system and eliminate Ethylene Oxide emission from your facility.

Our design flexibility allows the use of preferred components and materials, ensuring that our system can be fully and safely integrated into your existing plant environment and methodologies.



EtO: HEALTH HAZARDS

A. Ethylene oxide can cause bodily harm if you inhale the vapor, if it comes into contact with your eyes or skin, or if you swallow it.

B. Effects of overexposure:

1. Ethylene oxide in liquid form can cause eye irritation and injury to the cornea, frostbite, and severe irritation and blistering of the skin upon prolonged or confined contact. Ingestion of EtO can cause gastric irritation and liver injury. Acute effects from inhalation of EtO vapors include respiratory irritation and lung injury, headache, nausea, vomiting, diarrhea, shortness of breath, and cyanosis (blue or purple coloring of skin). Exposure has also been associated with the occurrence of cancer, reproductive effects, mutagenic changes, neurotoxicity, and sensitization.

1. EtO has been shown to cause cancer in laboratory animals and has been associated with higher incidences of cancer in humans. Adverse reproductive effects and chromosome damage may also occur from EtO exposure.

a. Reporting signs and symptoms: You should inform your employer if you develop any signs or symptoms and suspect that they are caused by exposure to EtO.

EMERGENCY FIRST AID PROCEDURES:

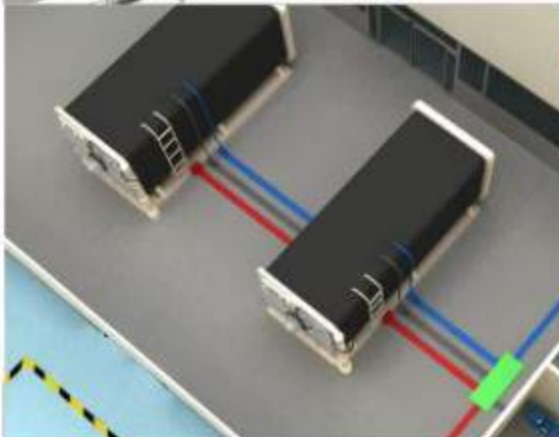
A. Eye exposure: If EtO gets into your eyes, wash your eyes immediately with large amounts of water, lifting the lower and upper eyelids. Get medical attention immediately. Contact lenses should not be worn when working with this chemical.

B. Skin exposure: If EtO gets on your skin, immediately wash the contaminated skin with water. If EtO soaks through your clothing, especially your shoes, remove the clothing immediately and wash the skin with water using an emergency deluge shower. Get medical attention immediately. Thoroughly wash contaminated clothing before reusing. Contaminated leather shoes or other leather articles should not be reused and should be discarded.

C. Inhalation: If large amounts of EtO are inhaled, the exposed person must be moved to fresh air at once. If breathing has stopped, perform cardiopulmonary resuscitation. Keep the affected person warm and at rest. Get medical attention immediately.

D. Swallowing: When EtO has been swallowed, give the person large quantities of water immediately. After the water has been swallowed, try to get the person to vomit by having him or her touch the back of the throat with his or her finger. Do not make an unconscious person vomit. Get medical attention immediately.

E. Rescue: Move the affected person from the hazardous exposure. If the exposed person has been overcome, attempt rescue only after notifying at least one other person of the emergency and putting into effect established emergency procedures. Do not become a casualty yourself. Understand your emergency rescue procedures and know the location of the emergency equipment before the need arises.



EtO Gas Mixtures & Disposable Cartridges
Automatic, Semi Automatic & Manual EtO Sterilizers
EtO Scrubbers (Air Pollution Control Solutions)



Corporate Office : 401, Sanidhya- A,
Prahlanagar Road,
Satellite, Ahmedabad-380015, Gujarat, India
Ph: +91-79-40067245, 09228008275,
Email: info@etosterilization.in
Website: www.etosterilization.in

Plant : 513, Bahutha, Savli Road,
Vadodara - 391755 Gujarat, India

FOLLOW US



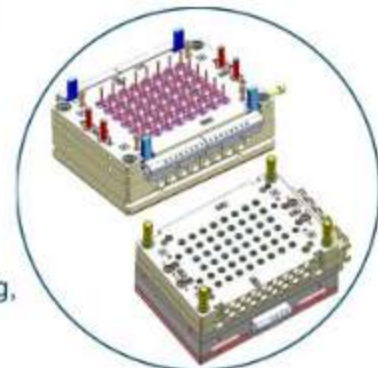
Addition to Engineering - New Production
Facility for Medical Device Manufacturing

**Clean Room with
ISO 13485**

MEDICAL PLASTIC COMPONENTS



Molding in Clean Room



Commercial Tool Room

Our Capabilities

- Our services include reverse engineering, design, 3D printing, proto development, mass production.
- Assemblies & Contract Manufacturing.
- Medical plastics for diagnostic equipment, surgical instruments, ortho products, endoscopy devices, medical tubes, PRP devices, etc.,
- Raw material handling PP, PET, ABS, PC, PLA, PEEK, PS, Pebax ect.,



73058-14196



+91 422 6616500



www.lecsindia.com



contact@lecsindia.com , info@lecsindia.com



Contract Manufacturing

LAKSHMI ELECTRICAL CONTROL SYSTEMS LIMITED

ARASUR COIMBATORE, TAMIL NADU, INDIA-641407

Sayujya 2025

सायुज्य 2025

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

Globally Ranked Top 10 Lab for Medical Device Testing*

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

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



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



2. Chemical Characterization (Extractable & Leachable Testing) (ISO 10993-18 & ISO 10993-17)



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



4. Microbiological Testing Services



5. Packaging Integrity Testing



6. Stability Testing Services & Transport Simulation Testing



7. Mask, PPE, Gloves & Textile Performance Testing



8. Performance Testing of Medical Devices



9. Performance Testing of Rapid In Vitro Diagnostic Kits



10. Research & Development Services For Devices



11. Clinical Study (CER)



12. Regulatory Dossier Preparation



13. IPR Management Services

With Best Compliments From

Shri.Mulubhai Kandoriya
(Managing Director)

Dr.Rina Gokani
(Director & CSO)
+91 90996 16769

Dr.Manish Rachchh
(Director & CEO)
+91 90999 81023

Mr.Mayur Kandoriya
(Director & CMO)
+91 99099 19545

Email Your Inquiry On : info@accuprec.com



NORTH AMERICA OFFICE:
Accuprec Research Labs Inc.
Delaware, USA

CANADA OFFICE:
Accuprec Research Labs Inc.
Hamilton, ON, Canada

REGISTERED OFFICE:

Opp. Zydus Pharmez, Changodar-Bavla Highway,
Near Matoda Patiya, Po. : Matoda, Ahmedabad
382 213, Gujarat, INDIA.



SCAN QR CODE
FOR MORE DETAILS

*As per two Independent Reports Published by:

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

<https://t.ly/60dfo>
<https://t.ly/c4-g2>

Visit us on www.accuprec.com | Stay connected with us on

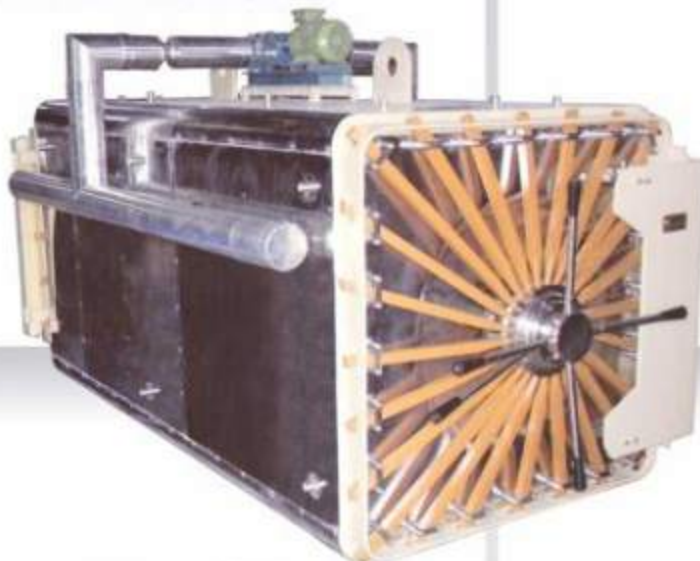


AMBICA MEDICARE ENGINEERING

An ISO 9001-2008 Certified Company



- ♦ Fully Automation-PC Base/PLC Base-Touch Screen
- ♦ Semi Automation
- ♦ Manual Type



Auto - Sliding Door
Auto - Center Door
Manual Type Door



- ETO Sterilizer Plant
- 100 % ETO Sterilizer – Table Model
- Steam Sterilizer Plant - Auto Clave
- Dry Heat Sterilizer
- Multicolumn Distillations Plant
- Pharmaceutical Sterilizer Tunnel
- Pure Steam Generator
- CIP System
- SIP System
- Pressure Vessel
- WFI Vessel
- Chilling Tank
- Rubber Stopper washer Sterilizer – Bunk Processor

Ambica Engg & Fabricators Ambica Medicare Engineering

Plot No. 362, B/s Om Shant School, Near Sakriba Party Plot, Amraiwadi Road, National Highway, Ahmedabad-380 026.
Phone : 079-25856820 Fax : 079-25856820/25395927 M : 09426009872 / 09998716586
E-mail : ambicamedicare@yahoo.co.in Website : www.ambicamedicareengg.com
Contact - Mr. J. R. Panchal, Mr. Amit J. Panchal

Promoted by



Supported by



ELECTRON BEAM FACILITY FOR STERILIZATION OF MEDICAL DEVICES

SAFE • RELIABLE • PRECISE

INDIGENOUS TECHNOLOGY. GLOBAL STANDARDS. TRUSTED BY INDUSTRY.

A state of the art e-beam facility dedicated to safe, effective and sustainable sterilization of medical devices.



e-beam, sterilized
products exported to
35+
COUNTRIES

40+
Industry Users

2.5 Cr+
medical devices sterilized



FACILITY FEATURES

- ✓ Indigenous electron linear accelerator (Linac) technology
- ✓ Barcode based product tracking
- ✓ Electronic process integrity monitoring
- ✓ Traceable dosimetry



LICENSES & QMS ACCREDITATIONS



AERB license for plant operation



FDA license for sterilization of Risk Class A & B medical devices



CDSCO license for sterilization of Risk Class C & D medical devices



ISO 9001 : 2015
ISO 13485 : 2016



SERVICES OFFERED

- ✓ Sterilization service for all risk class of medical devices
- ✓ Precise and controlled dose delivery
- ✓ Guidance on dose establishment
- ✓ Dose audit
- ✓ Sterilization process development and validation
- ✓ Product irradiation certificate

WIDE RANGE OF MEDICAL DEVICES PROCESSED WITH e-BEAM



ADVANTAGES OF e-BEAM



Terminal
sterilization



No residue left



No chemical/
isotope used



Fast turnaround
time



Less material
degradation and
color changes



Radiation can be
switched ON/OFF



Customization of
irradiation batch size

PRECISE DOSE. PROVEN SAFETY. POWERING HEALTHCARE EXCELLENCE.

ARPF

<https://www.rrcat.gov.in/technology/accel/mal/ebprf.html>



0731-248 7480



info@aicipihub.in



Turning ideas into solutions with speed & confidence.



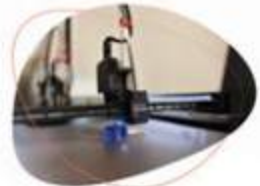
Validated faster



Global regulatory
confidence



From concept to
production tooling



Lower cost change



Connected device
integration



Sustainable by design



Single source,
global delivery



De-risked investment

Connect with Us!

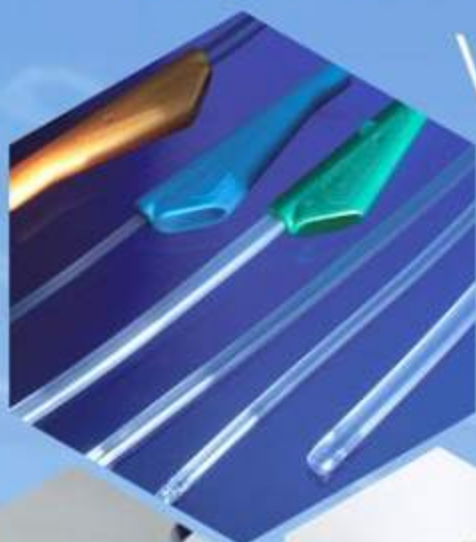
Website



LinkedIn



Invisible Contribution.. Visible Success!



Food Grade Compound : PVC Compound for Bottle & Jars, Drinking & Water Purifier Tubing.

Medical Grade Tubing & Compound for :
Transfusion : IV infusion set, Measure volume set, Scalp vein set, Blood administration set, Peritoneal dialysis transfusion set.

Surgery : Chest drainage catheter, Yankaur suction set, Thoracic trocar catheter, Intra costal drainage bag, Drainage system.

Urology : Urine bag, Urethral catheter, Foley ballon catheter, Nelaton catheter, Peadiatric urine collection bag.

Gastroenterology : Ryle's tube, Feeding tube.

Anaesthesia : Suction catheter, Oxygen mask, Nasal Oxygen catheter.

Miscellaneous : Infant mucus extractor.

Rigid-Extra Soft moulding Compound to meet the standard as per USP, IP & ISO.

Master Batches : Food Grade & General Purpose.



PVC COLOURING COMPOUNDING & PROCESSING

64, GIDC, Phase-I, Opp. Citizen Industries, Naroda,
Ahmedabad-382 330. Phone : 079-2281 2004,
Telefax : +91 79 2282 2006. E-mail : info@pvcplastics.com
Website : www.pvcplastics.com

WHY **FANUC** ROBOSHOT

IS A PREFERRED CHOICE OF MEDICAL DEVICE
MANUFACTURERS WORLDWIDE?

Versatile All Electric Injection Moulding Machine



Power Up with Advanced Features Like:



Space-Efficient Design:
Optimised for clean room moulding with a minimised floor space footprint.



World-Class CNC Control:
Features the industry's most reliable, operator-friendly platform providing multiple solutions through a single interface.



AI-Driven Quality:
Advanced processing with embedded AI for rigorous quality control and full production traceability.



Smart Factory Ready:
IoT-enabled for centralized management, easy automation integration, and seamless factory connectivity.



Sustainable Performance:
Maximizes energy efficiency through intelligent servo technology and smart power-saving features.

Get to know www.fanucindia.com Contact US roboshotsales@fanucindia.com

88,500 ROBOSHOT Sold World Wide | 42+ Years of Experience

Precision Inverter Chillers

for Medical Component Moulding

Manufactured in India using Japanese Technology

Chiller Features



Larger Operating Range
(from 10 to 30°C).



Precise Temperature Control
as low as $\pm 0.1^\circ\text{C}$ from set point.



Wider Ambient Temperature
(from 10 to 50°C).



Environmental Friendly - R410A
energy efficient refrigerant.



Large customer base in India

Ideal for moulding high-quality medical components



Blood Sample
Collection Tube / Vial



Surgical Instruments



Syringe Components



Implantable Parts

Sales & Service network available throughout the country

📍 Manufacturing plant and Head Office at - S.F.No : 100/2A, Avinashi Road,
Arasur, Coimbatore - 641 407, Tamilnadu, India.

R R PATEL

Since 1988

We are dealing in Ethylene Oxide Mixture Gas for sterilization and all type industrial gas like Carbon Dioxide Gas, Helium, Zero Air, Nitrogen, Oxygen Argon and Dry Ice since 1988



Ethylene Oxide Mixture Gas For Sterilization

**Plant 1****Plant 2**

Company Highlights

- Established in 1988 in Ahmedabad, We manufacture and supply Industrial Gases - Pure - 100 grade gases & all type of Gas Mixtures.
- Leading organization engaged in **Delivering Consistent Quality** liquid and gas cylinders, high quality graded gases & their mixtures to broad spectrum of industries.
- **Two Filling Stations** with total filling capacity of 20 MT per day.
- Plants equipped with **Sophisticated Analytical Instruments** to measure oxygen, Moisture, CO2 in PPM & percentage level.
- Have adopted **Advance Cylinder Re-Conditioning System** to achieve the optimum product quality by reducing the moisture content from cylinders.
- **Robust In-House Logistic Infrastructure** for **Un-Interrupted / Timely Delivery** of gas cylinder for un-interrupted needs of end users.
- Can Provide **Duracell & Porta-Cryo** to the customers requiring bulk quantity of liquid materials.

Ethylene Oxide	Diluent Gas	Flammability
10%	90% Carbon Dioxide	Non-Flammable
20%	80% Carbon Dioxide	Non-Flammable
30%	70% Carbon Dioxide	Non-Flammable
90%	10% Carbon Dioxide	Flammable

R R PATEL
Since 1988

R. R. Patel Industrial Gases (P) Ltd.

Survey No. : 407, B/H Waterman Industries, Sarkhej - Bavla Highway, Village : Moraiya, Sanand, Ahmedabad - 382 213.
Mobile : 97277 22437 • GST No. : 24AAACK8917F1ZM • CIN No. : U99999GJ1990PTCO13969 • E mail : rrpateindustries@gmail.com

Plot No. 1501, Nr. Tikampura Patiya, Vatva G.I.D.C. Phase - III, Ahmedabad - 382 445.0
Mobile : 97277 22435.

JAIN RUBBERS

Manufacturers of Rubber Products for Medical Disposables & Rubber Stoppers for Pharmaceutical Packaging.



Plugs For Blood Collection Tubes



Float Valves / 'Y' Conn. Discs



Injection Sites / Latex Bulbs



Syringe Gaskets



Stoppers / Needle Covers

Manufacturing and Exporting Medical Rubber Products since, 1992.
ISO - 9001:2015 certified.

Medical Rubber Products compliant to Global Standards. Available in various polymers Natural Rubber, Polyisoprene (Latex-free), Butyl, Bromobutyl, Silicone etc., meeting IS/ISO/IP standards. Wide Range of Products. Single source for all your medical rubber requirements.

JAIN RUBBERS PVT. LTD.

Admn. Office : F-75, Sipcot Industrial Complex
Gummidipoondi - 601201, Tamilnadu, India.
Te.: 9444275273 / 9840443762.
Email: jainrubbers@yahoo.com
Website : www.jainrubbers.com



**Life-O-Line
TECHNOLOGIST**

FOR COMFORT IN BREATHING
(AN ISO, CE, WHO & GMP CERTIFIED COMPANY)

Life O Line Technologist

Plot No.: 864/1, Near Indian Petrol Pump, Hirapur Cross Road, Mahemdabad Road, Ahmedabad -382435. Gujarat, India.
Mob.: +91 9898162576 • Web.: www.lifeonline.com • Email.: lifeonline2011@yahoo.com

Manufacturers & Exporters of Disposable Medical Devices

ANESTHESIA & RESPIRATORY CARE

- Nasal Cannula - Adult / Paed / Neo
- Oxygen Mask - Adult / Paed
- High Concentration Mask
- Nebulizer Mask - Adult / Paed
- Nebulizer Kit With Mask & T Pcs.
- Multiflow Ventury Mask - Adult / Paed
- Swivel Mount - Std & Exp.
- T Oxygenator With Tubing
- Breathing Filter - All Type
- 3 Ball Spirometer
- Ambu Bag - Adult / Paed / Neo
- Ventilator Circuit - All Type
- Bain Circuit - Adult / Paed
- Endotracheal Tube Plain & Cuf fe
- Aircursion / Anesthesia Mask
- B-pap Mask & C-pap Mask All Type

INFUSION THERAPY

- Central Venous Catheter
- Pressure Monitoring Line
- 3-Way Extension Line
- Measure Volume Set
- Dial Flow Regulator
- I. V. Set With Flow Regulator
- Codan Set

MISCELLANEOUS

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

UROLOGY & NEPHROLOGY

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

GASTROENTEROLOGY

- Mucus Extractor
- Infant Feeding Tube
- Ryles Tube
- Stomach Tube
- Kher T Tube
- Levins Tube
- Selum Sump Tube

SURGERY & DRAINAGE

- Suction Catheter
- Thoracic Drainage Catheter
- Abdominal Drainage Kit
- Close Wound Suction Set
- Yankaur Suction Set
- Umbilical Cord Clamp



AN ISO 9001:2015
AN ISO 13485:2016
WHO & GMP
CERTIFIED COMPANY





Medical Device Solutions:

Your Medical Device End-To-End Provider

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

SMC[®] Ltd.

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



www.medicalfair-india.com

India's No.1 Trade Fair For Hospitals, Health Centres and Clinics

**Connect, Witness &
Lead the Future of
Healthcare**

13-15 March 2027

Hall 4 & 5, Bharat Mandapam
(Pragati Maidan) New Delhi

20-22 August 2027

Hall 2 & 3, Bombay Exhibition Center
Goregaon (E), Mumbai



Special Features



AiMeD - Make In India Pavilion



Clin Lab / IVD Pavilion & Conference



Future for Health Digital Health Start-up
Pavilion & Conference



Dedicated Platforms for
Raw Materials, Components, Machinery, Services
& MedTech Manufacturing Solutions

MMI Pavilion & Conference



International Conferences



MT India Healthcare Awards

Show Highlights 2027



15,500 m²
Exhibit Area



500+
Exhibiting Brands
from 14+ Countries



18,000+
Visitors from
30+ Countries



450+
Delegates



4
International
Conferences

For more information, please contact: Adarsh Verma, Director - Projects | VermaA@md-india.com | 91-124-4544 507

An initiative by



Supported by



Media Partner





Your Trusted OEM Partner for Specialized Components and Devices in Medical, Defence & Avionics.

Precision Engineering Company Specializing in Wire/Tube Forming, Grinding, PTFE Tube Extrusion & Heat Shrink Tubing, and a Wide Array of High-Precision Cutting-Edge Innovations.

TRUSTED BY

SmithNephew



MicroVentron
TERUMO

Heraeus

Boston
Scientific

Theragenics

COOK
MEDICAL



www.glowtronics.com



marketing@glowtronics.com

MADE IN INDIA, FOR THE WORLD



Purifying Lives...



Manufacturing of Sterilization range of products including Autoclavable Polymer Sterilization trays and Anodised Aluminium Sterilization trays. Serving the medical fraternity for more than 2 decades.



BIOPOLYMER



+91 93845 60061



mail@endosys.org



www.endosys.org



Sterilization Solutions as per the International Standards ISO 9001:2015, ISO 13485:2016, CE, US FDA

SHRIRAM TEKNOR LTD.

Global Expertise. Stronger Commitment.
Engineered for Excellence.

ENGINEERED POLYMER SOLUTIONS



MEDICAL
COMPOUNDS



KINK
RESISTANT
COMPOUNDS



SPECIALITY
COMPOUNDS

Engineered for Healthcare, Industrial
& Critical Applications



HIGH GLOSS
HIGH TRANSPARENCY
MATT FINISH



EXTRUSION
INJECTION MOULDING
BLOW MOULDING



CONSISTENT QUALITY
RELIABLE PERFORMANCE
TRUSTED SOLUTIONS



QUALITY YOU CAN TRUST
ISO 9001 & ISO 13485
CERTIFIED PLANT



COMPLIES WITH
ISO 3826 | ISO 10993 | USP CLASS VI



STERILIZATION
ETO | STEAM
GAMMA | E-BEAM



Marketing Office
Plot No. 82, Sector 32 Inst. Area
12003, Haryana, India
Ph. +124-4513700



Works
Shriram Nagar, Kota - 324004
Rajasthan, India
Ph. +91-744-2480011



polytek.co.in



info@polytek.co.in



Medicall
hospital needs expo

Medicall Comes To Mumbai



49th Edition | DEC 2026



MUMBAI NESCO

400+

Exhibitors

10,000+

Hospital Products

15,000 +

Visitors

49th
Edition

Mumbai | 8 - 10 Dec 26
Nesco

50th
Edition

Kolkata | 19 - 21 Feb 27
Biswa Bangla Mela Prangan

51st
Edition

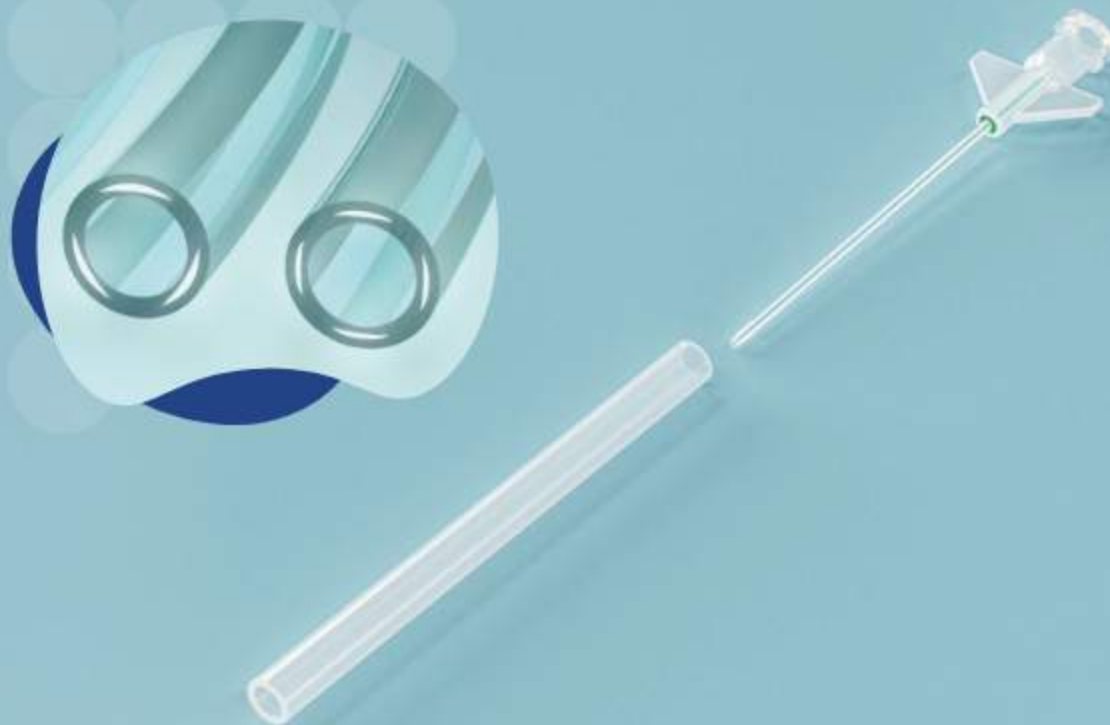
Hyderabad | 2 - 4 Apr 27
Hitex Exhibition Center

52nd
Edition

Chennai | 30 Jul - 1 Aug 27
Chennai Trade center



For enquiries: +91 7305 789 789 | www.medicall.in | info@medicall.in



Indwelling Venous Catheters

Peripheral indwelling venous cannulas for parenteral infusion

What you can expect:

- Manufacturing in all customer specific dimensions
- Good processability when forming the tip and expanding the cannula end
- 3 or 4 x-ray contrast stripes (BaSO₄)
- Gauge sizes G14-G26
- Very good blood and bio compatibility

Further possible components:

- Needle protection by tube or molded part
- Butterfly
- Silicone valve sealing tube

Contact us!

RAUMEDIC Pte. Ltd. – asia@raumedic.com – Mobile: +919740899661

TEKNIPLEX
Healthcare

The Compound **Behind the Device**

TekniPlex Healthcare formulates the medical-grade PVC compounds that become tubing, devices, and delivery systems. The Flexchem®, Elastichem®, and rigids families give device makers a tested starting point, with flexibility, clarity, and rigidity tuned to the application. Compounding, extrusion, and finished components stay under one roof, so the material is right before the first part is ever made.

Medical Device
Pharma
Diagnostics

Dinesh Rai, Director of Sales , Healthcare India and SE Asia
TekniPlex, #78, 79 Ecotech-1 Extn, Gautam Buddha Nagar, Greater Noida,
Uttar Pradesh-201310, India | Mobile: +91-7428919120 +91-9999258151
E: dinesh.rai@tekni-plex.com

TEKNIPLEX
Materials Science Solutions



500+
CUSTOMERS

100+
PRODUCTS



Cleaning & Disinfection
Validation



Steam Sterilization
Validation for Reusable
Medical Devices



Method
Suitability &
Validation



Physical
Properties - Tensile
& Tear Strength



Accelerated
Ageing/ Stability
Studies



Sterile Barrier
System - Package
Seal Integrity



Antibacterial &
Anti Fungal activity



Transport &
Packaging Validation



Clean Room
Validation - Air
Sampling, Swab &
Settle Plate



A COMPREHENSIVE TESTING LAB FOR MEDICAL DEVICES & SURGICAL PRODUCTS

TRUSTIN, an esteemed testing laboratory within the Medical Device industry, is honoured to possess accreditations from both NABL and CDSCO. With a focus on Testing & Validation services, TRUSTIN caters to a wide spectrum of Medical Device classifications, from Class A to Class D. Their remarkable expertise is evident in providing unparalleled services for regulatory submissions and ensuring unwavering product quality assurance.

TRUSTIN maintain a strong quality management system to ensure the accuracy, reliability, and traceability of our results.

With our extensive array of testing services, cutting-edge facilities, and experienced team of professionals, TRUSTIN is dedicated to aiding in the advancement and assessment of safe and efficient medical devices. We aim to be a reliable partner for all our customer, providing reliable data and valuable insights to facilitate regulatory approvals and enhance patient safety.



WhatsApp



Email



Website

UNIT I
RK Complex, First Floor, Plot No.303/B,
B-Block, Thiruneermalai Road,
Parvathypuram, Chrompet,
Chennai, Tamil Nadu 600044

UNIT II
Plot No C 24/1, SIPCOT
Medical Devices Park,
Oragadam Phase II, Eraiyur Village,
Kancheepuram, Tamil Nadu 602 118

Mumbai Office
Commodity Exchange Building,
Office No: 125, 1st floor,
Plot No: 2, 3 & 4, Sector 19,
Vashi, Navi Mumbai - 400705.

+91 7092923302

vinusha@trustingroup.in

+91 7092923302

customercare@trustingroup.in

www.trustingroup.in



Organized By



HOSPICA™

THE GUJARAT HOSPITAL & HEALTHCARE EXPO



Supported By

EXHIBITOR INVITATION

BE A PART OF GUJARAT'S PREMIER HEALTHCARE PLATFORM

We cordially invite you to participate as an Exhibitor at **HOSPICA™ 2026** – The Gujarat Hospital & Healthcare Expo, a focused, business-driven exhibition connecting the entire healthcare ecosystem under one roof.



EXPECTED FOOTFALL VISITORS

4,000–5,000+

Healthcare Professionals

From Gujarat & Rajasthan

WHY EXHIBIT AT HOSPICA™ 2026?



MEET & CONNECT

with Key Decision Makers from Hospitals, Nursing Homes, Clinics & Healthcare Institutions



SHOWCASE

your innovative Products, Solutions & Technologies to a Targeted Audience



GENERATE

High-Quality Leads and Expand your Business Network



BUILD

Brand Visibility and Strengthen your Position in the Growing Healthcare Market



EXPLORE

New Opportunities in Gujarat & Across India

GUJARAT'S
MOST AWAITED
HEALTHCARE
EXHIBITION



28 & 29 NOVEMBER 2026



Vigyan Bhawan, Science City

Ahmedabad – 380 060, Gujarat, India



PREMIUM OCTONORM STALLS



3m x 6m Stall



3m x 3m Stall



2m x 2m Stall



Bare space
6000 per sq. meter.

WHO YOU WILL MEET

- ✓ Hospital Owners & Administrators
- ✓ Nursing Home Owners
- ✓ Doctors & Medical Practitioners
- ✓ Procurement & Purchase Managers
- ✓ Biomedical Engineers
- ✓ Distributors & Dealers
- ✓ Government Health Officials
- ✓ Healthcare Consultants & Investors

FOCUS SECTORS

- Medical Equipment & Devices
- Hospital Infrastructure & Furnishing
- Diagnostics & Imaging
- Pharma & Pharmaceuticals
- IT Solutions & Digital Health
- Laboratory & Pathology
- Consumables & Disposables
- Rehabilitation & Physiotherapy
- Emergency & Critical Care
- And Many More...

SPONSORSHIP & STALL RATES ★★☆☆

PARTNERSHIP / STALL	AMOUNT (₹)	STALL SIZE	AMOUNT (₹)
Exclusive Platinum Partner Sponsorship	25,00,000	Stall 3m x 3m	1,00,000
Gold Sponsorship	15,00,000	Stall 2m x 2m	50,000
Silver Sponsorship	10,00,000	Bare space	6,000 per sq. meter.
Lecture Seminar Sponsorship	2,00,000	–	–
Product Video Sponsorship	1,00,000	–	–

18% GST APPLICABLE ON THIS AMOUNT



EXHIBITORS STALL BOOKING
ARE NOW OPEN.

BOOK YOUR STALL TODAY.



FOR EXHIBITOR BOOKING &
SPONSORSHIP ENQUIRIES

Ashish Zinzuwadia

+91 75677 30999

info@ahna.org.in



SAVE
THE DATE



SHOWCASE
YOUR INNOVATION



CONNECT
WITH EXPERTS



GROW
YOUR BUSINESS

HOSPICA™ 2026
Where Healthcare Meets Business

LEADERS IN BIOCOMPATIBILITY TESTING, CHEMICAL CHARACTERIZATION AND BIOLOGICAL SAFETY ASSESSMENT OF MEDICAL DEVICES.

- Strong Scientific Reputation and Regulatory Experience.
- Cost Effective and High-Quality Testing.
- Currently work with companies in 50+ countries.
- Reports are readily accepted by FDA, Notified Bodies and other Global Regulators.
- Committed to scientific and service excellence.



Dr. T S Kumaravel MD, PhD, DABT, FRCPath
Chairman



Dr. S S Murugan PhD
Managing Director

800+
Client

50+
Countries

1200+
Devices
Tested

7000+
Biocompatibility
Tests

75+
Chemical
Characterization

220+
Years of Combined
Experience

OUR SERVICES

- Biological Evaluation Plan (BEP)
- Chemical Characterization with Risk Assessments
- Full Range of Biocompatibility Testing
- Toxicological Risk Assessment (TRA/BER/BSA)
- Biological Evaluation Report (BER/BSA)
- Consultations on Biocompatibility Strategy
- Specialised services for ISO 10993 and ISO 18562

TESTING DOMAINS

- Cardiovascular
- Orthopaedic
- Neurological
- Ocular
- Urological
- Surgical
- Respiratory
- Gastro-intestinal
- Haematological
- Dental
- Personal Care
- Raw materials

ACCREDITATIONS

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



Test Facility
444 Gokulam Street,
Mathur, Chennai
600068
INDIA

UK
4 Exchange, Colworth
Science Park,
Sharnbrook,
MK44 1LZ

IRELAND
Lee View House,
South Terrace
Cork

USA
Suite 100N #1005,
4701 Sangamore Road,
Bethesda,
MD 20816

QOSINA

Small Parts.

Big Possibilities.

*Your design starts with a component.
Qosina doesn't stop there.*

7,000+ single-use parts, backed by
engineering and sourcing support
from concept to launch.



Go beyond components at qosina.com

**Before You
Spec It ▼**



Talk To
an **Engineer**



Download
The Drawings



Order a
Free Sample