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MEDICAL PLASTICS DATA SERVICE

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

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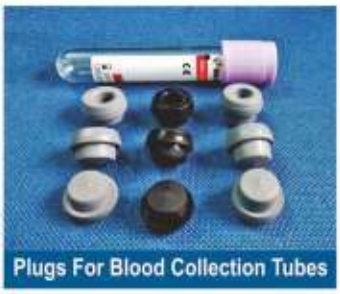
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"MEDICAL PLASTICS DATA SERVICE" participated
in the MEDICAL FAIR INDIA, (New Delhi, March 27 - 29, 2025)
and interacted with MedTech Industry Leaders & Professionals

HIGH LIGHTS

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Did You Know?

About innovation in Indian MedTech Startups

India's medical technology (MedTech) sector, currently valued at USD 12 billion in 2023, is on a trajectory to reach USD 50 billion by 2030, with a projected CAGR of ~20.1% from 2020 to 20303. This ambitious growth will be fuelled by several critical factors, including supportive government policies aimed at reducing import dependence and bolstering exports.

EY Parthenon's analysis of **100 MedTech start-ups** (50 Indian and 50 global) reveals:

- **Both global and Indian startups have common innovation themes** such as advancements in early disease detection, home-based care, advanced materials, minimally invasive techniques and integration of digital technologies
- Among Indian MedTech startups, **79%** of all innovations are driven by medical technology solutions [~63% of these (79%) solutions are digitally integrated]. Additionally, **21%** of all innovations are purely driven by digital solutions.
- **Indian startups are actively integrating digital solution** such as AI, IoT, and cloud computing to democratize healthcare with portable devices, remote monitoring and screening tools

As per, **Suresh Subramanian, National Lifesciences Leader, EY Parthenon India** "The growth of India's MedTech sector presents a unique opportunity to redefine healthcare on a global scale. The trends we're seeing today—ranging from the integration of digital health technologies to the rise of personalized care—are just the beginning. These innovations will be transformative, not only for healthcare providers but for the patients who will benefit from more accessible, efficient, and personalized care."

"With rising investments, strategic collaborations, and strong commitments from both global and Indian firms, India's MedTech industry is poised for sustained growth and success. The government's support in fostering innovation and scaling manufacturing will be key to unlocking this potential, positioning India not only as a leader in the domestic market but also as a global hub for MedTech innovation.", he added.

https://www.ey.com/en_in/newsroom/2024/11/over-70-percent-innovation-in-indian-medtech-startups-driven-by-digital-integration-several-factors-propel-industry-growth-ey-parthenon-report

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DATA SERVICE

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From the Editor's Desk

MedTech Ecosystem in India

The Indian Medical Device Industry is undergoing transformation from import reliance to global manufacturing hub. To achieve this goal, as per an Industry leader, "India must innovate across its product range, from high-volume, low-value items to advanced, high-value equipment. The path to future growth lies in adding value and enhancing competitiveness across the spectrum"

As highlighted in a very analytical article in this issue, Mr Jatin Mahajan, Managing Director, J.Mitra & Company has very rightly mentioned that "India is already considered the global hub for frugal MedTech innovation. India must focus on complementing Skill Development and Research & Development duo to drive growth and achieve self-reliance. Together, these two focus areas can create a fast-paced growth environment. The article makes various suggestions for Government to create a self-reliant and globally competitive Indian MedTech Sector.

As per a report by EY Parthenon, "With rising investments, strategic collaborations and strong commitments from global and Indian firms, India's MedTech industry is poised for sustained growth and success. Industry is advancing through three innovation models, incremental improvements, innovation and breakthroughs emphasizing on safety, accessibility, affordability and efficiency of devices"

MedTech Start-Ups

"Both global and Indian start-ups have common innovation themes such as advancements in early disease detection, home-based care, advanced materials, minimally invasive techniques and integration of digital technologies."

Innovations in Medical Plastics Disposables

Innovations in medical plastic disposables include antimicrobial plastics, smart disposables, biodegradable materials, and advanced manufacturing techniques like 3D printing and nanotechnology. However, there are challenges in adopting new technologies. For the benefit of our readers, this issue covers a recent study by a group of professionals to frame the challenges endured by Malaysian biomedical industries who use 3D printing technology for their manufacturing processes.

Importance of Risk Management for Plastic Materials & Components Suppliers

As explained in a very informative article by Mr Sanjay Shah of Unikal Consultants,"The relationship between materials and component suppliers and MedTech manufacturers is vital to ensuring compliance with ISO 14971. Suppliers are not merely providers of materials but also partners in the risk management process. By adhering to Regulatory standards, maintaining quality assurance, and fostering open communication, suppliers can significantly contribute to the successful implementation of risk management practices in the MedTech industry."

One more article by Mr Indrajit Ghosh, Global Chairman, MSME Chamber of Commerce and Industry, explains how the recycling of medical plastics remains a formidable challenge in India and worldwide. However, with advancements in technology, policy interventions, and multi-stakeholder collaboration, there is significant potential to turn this waste into a valuable resource..

Global Markets for Medical Disposables and Medical Devices

The Global Trends column highlights a very detailed report on "Europe Medical Disposable Product Market" along with Ecuador Medical Device Market. This issue also cover our regular features like Industry & Association News, Events etc.

D L Pandya

Innovations In Medical Plastic Disposables

Innovations in medical plastic disposables include antimicrobial plastics, smart disposables, biodegradable materials, and advanced manufacturing techniques like 3D printing and nanotechnology. These advancements aim to improve patient safety, streamline healthcare processes, and reduce the environmental impact of disposable medical supplies.
Here's a more detailed look at the key innovations:

1. Antimicrobial and Sterilizable Plastics:
   - **Antimicrobial Properties:** Medical-grade plastics with inherent antimicrobial properties are being developed to minimize contamination and infection transmission.
   - **Easy Sterilization:** These plastics are designed to be easily cleaned and sterilized, making them a preferred choice for medical equipment and disposable items.
2. Smart Disposables:
   - **Integration with Digital Health:** Disposables are being integrated with digital health solutions for better patient monitoring and real-time data analysis, ultimately contributing to improved patient outcomes.
   - **Nanotechnology:** Nanotechnology is being used to create advanced disposables with enhanced properties, such as faster wound healing or improved drug delivery.
3. Biodegradable and Biocompatible Materials:
   - **Environmentally Friendly:** Biodegradable plastics offer a more sustainable alternative to traditional plastics, reducing their environmental impact.
   - **Biocompatible Implants and Sutures:** Biocompatible plastics are being used in implants, sutures, and drug delivery devices that can dissolve in the body, eliminating the need for removal surgery.
4. Advanced Manufacturing Techniques:
   - **3D Printing:** 3D printing is enabling the creation of customized and personalized medical devices and implants.
   - **Nanofibers:** Advanced bandages made with nanofibers can accelerate wound healing and reduce infections.
   - **Automation and Supply Chain Management:** Advanced digital systems are optimizing logistics in hospitals and clinics, improving inventory control and minimizing waste.
5. Other Notable Innovations:
   - **Customization and Personalization:** Companies are using digital printing technology to personalize branding and designs, improving the user experience.
   - **Ergonomic and User-Friendly Designs:** Efforts are being made to improve the functionality of disposable products with simpler packing, spill-resistant containers, and better grip.
   - **Sustainable Solutions:** Focus is increasing on sustainable materials and practices, including biorecycling and the use of bioplastics.

Strengthening India's Medtech Ecosystem Through Skill Development and R&D

Jatin Mahajan
Managing Director, J Mitra & Company / Secretary,
Association of Diagnostics Manufacturers of India – ADMI

Indian MedTech, valued at approximately USD 11 billion in 2022 and with a projected CAGR of 12-14 percent, has been driving the growth of the Indian Healthcare industry. Indian MedTech will cross USD 50 billion by 2030 and become a significant global player. However, there is a significant import-export imbalance and a major trade deficit. While the imports in 2023-24 were roughly $8 bn, the exports stood at close to $4 bn. We are still importing nearly 70 percent of our medical equipment.

The Indian medical device imports majorly account for these five segments - electronic equipment (56% share), disposables and consumables (26.5%), in-vitro diagnostics (8.1%), implants (7.1%), and surgical instruments (2.3%). While we majorly lag in the electronic equipment segment, we have a long way to go in the other segments.

India is already considered the global hub for frugal MedTech innovation. India must focus on complementing Skill Development and Research & Development duo to drive growth and achieve self-reliance. Together, these two focus areas can create a fast-paced growth environment.

Global Best Practices

Countries like the US, Germany, and China have driven competitiveness through R&D and workforce development investments.

- heavy investments in R&D and government-backed skill enhancement programs drove China's rapid rise in the MedTech sector. Its made-in-China 2025 policy prioritizes medical devices and diagnostics, and this has resulted in the growth of its domestic MedTech industry, which exports to over 100 countries.
- Germany's research institutions like Fraunhofer-Gesellschaft created a MedTech ecosystem through collaborations with industry players to develop cutting-edge medical technologies
- The US has one of the most advanced MedTech industries globally. Supported by strong research institutions, government funding, and regulatory innovations. The NIH funds medical research, while the FDA handles fast-track approvals and standardizations.
- Japan's Agency for Medical Research and Development (AMRD) supports MedTech research through extensive funding, and the Ministry of Economy, Trade and Industry (METI) provides financing for AI-driven diagnostics and robotic-assisted surgery tools.
- The South Korean industry has benefitted greatly through the government's K-Bio and K-MedTech initiatives, positioning it as a leader. Osong Medical Innovation Foundation and the Daegu-Gyeong Buk Medical cluster have played a key role as specialized R&D hubs.

Skill Development

As per a KPMG report, India has a 40 percent deficit in skilled biomedical engineering, biotechnology, regulatory affairs, and manufacturing technologies professionals. And to address this challenge, India must implement a multi-pronged approach.

- Technology-driven renowned organizations like IIT, IISC, NIPER, and AIIMS should work hand-in-hand with MedTech companies to develop relevant courses.
- Skill centers dedicated to MedTech must be established to help bridge the gap between theoretical knowledge and practical expertise
- Stress on vocational training and upskilling through programs like the National Skill Development Corporation (NSDC) should be leveraged to train technicians and quality assurance professionals in MedTech manufacturing, calibration, regulatory compliances, etc.
- The Government should provide tax incentives for training and skill-development programs

Research & Development

In countries like the US and Germany, the allocation for R&D is 8 – 10 percent of the revenues. But in India, this figure stands at less than 1 percent. According to NITI Aayog, India's total healthcare R&D spending is less than 0.5% of GDP, significantly lower than developed nations. Raising this to at least 2% will be crucial. Without a robust R&D infrastructure and spending, innovation is not possible. To ensure cost efficiencies and global competitiveness, India must –

- Provide dedicated R&D grants for MedTech companies
- Public-private partnerships to establish MedTech innovation hubs with global research institutions like the German Fraunhofer Institutes and the US National Institutes of Health (NIH).
- India must establish a single-window clearance system for medical devices for faster approvals and ease of business.
- Universities and medical colleges must be encouraged to set up MedTech incubation Centers. BIRAC should provide the necessary funding and mentorship support

Way Forward

To create a self-reliant and globally competitive Indian MedTech

sector, the Government must –

1. Establish a dedicated MedTech R&D policy on funding, technology transfer, and academia-industry partnerships.
2. Creation of a MedTech-specific Skill Development mission, covering all aspects from device design to regulatory compliance.
3. Strengthening the existing EPC-MD to drive global market access
4. Enhance fiscal incentives by offering tax rebates and subsidies to companies investing in R&D and workforce training.
5. Standards harmonization with global standards like USFDA, EU MDR/IVDR, CE, and UKCA to drive smoother global market entry.

Focus and investment in skill development and R&D can transform the Indian MedTech landscape and bring it closer to its next phase of incremental growth.

FAST FACTS

EY Parthenon's analysis of new products and product extensions launched by leading global and Indian MedTech companies between **January 2023 and July 2024.** The research revealed that:

- **The industry is advancing through three innovation models,** incremental improvements, substantial innovation and breakthroughs emphasizing on safety, efficacy, accessibility/affordability, and efficiency of devices.
- **Digital technologies are at the core of innovation**

Challenges Of 3D Printing Technology For Manufacturing Biomedical Products: A Case Study Of Malaysian Manufacturing Firms

Additive manufacturing (3D Printing) has attracted increasing attention worldwide including in the healthcare & biomedical Industries. However, in Malaysia, insufficient acceptance of this technology by local industries has resulted in a call for government and local practitioners to promulgate the development of this technology for various industries, particularly for biomedical products.

A study was carried out by a group of professionals to frame the challenges endured by biomedical industries who use 3D printing technology for their manufacturing processes.

Following is the highlights of the study.

Introduction

Additive manufacturing (AM), also known as 3D printing involves use of digital CAD modelling to build 3D objects by joining materials layer-by-layer. The different methodologies used for additive manufacturing in the industry include fused deposition modelling (FDM), stereo lithography (SLA), selective laser sintering (SLS), and bio printing.

The vast majority of researchers have focused exclusively on engineering applications with focus on materials, processes, techniques, and machinery used in optimization.

Commonly, the 3D printing manufacturing process begins with a CAD drawing, followed by objects being sliced into layers, and, lastly, a layer-by-layer 3D build is printed. The 3D printing technology is equipped to fabricate functional parts with a wide range and combination of materials, including aluminium alloy [22], thermoplastic filaments, zirconia, carbon fibre-reinforced polymer composites , hydrogels, nanogels , and others. An ideal 3D printed biomaterial should morphologically mimic living tissue, be biocompatible, and be easily printable with tuneable degradation rates.

Advantages:

- Customise desired products in a short time;
- Create complex objects and shapes that otherwise might be impossible to create through any conventional method;
- Produce biocompatible products, such as organs or replacement tissues, in a short time compared to conventional methods;
- Cost-effective; and
- Non-requirement of storage of goods or materials.

Application of 3D printing for producing biomedical products

Recently, 3D printing technology has rapidly flourished in the industry for the purpose of designing, developing, and manufacturing new products.

There are numerous applications of 3D printing technology for producing biomedical products such as drugs, artificial skin, bone cartilage, tissue, and organs, and in cancer research and education.

Figure 1.

There are various examples of challenges that occur before, during, or after utilizing 3D printing technology for manufacturing biomedical products.

Research Methodology:

This study used a descriptive method to investigate the challenges of utilizing 3D printing on biomedical products in Malaysia, which involved interviews at Company X, Y, and Z. Three persons representing the top management of Companies X, Y, and Z were interviewed. They included an application engineer, a mechanical engineer, and a technical development manager. The qualitative case study method was chosen in this study, as it enables a strong description to address the research questions.

This study found several new elements in the challenge of utilizing 3D printing technology for manufacturing biomedical products. The figure provides an overview of the challenges faced when utilizing 3D printing technology for biomedical products.

The following Figure shows a summary of the challenges faced when utilizing 3D printing technology to manufacture biomedical products based on the literature.

Summary of the challenges of 3D printing technology for biomedical products.

In summary, the results show that in respect of processing and materials, there are eight challenges when utilizing 3D printing technology for manufacturing biomedical products, which are as follows:

- **Selection of a suitable binder:** various binders have varying effects on the product's biocompatibility, where the compatible one are the organic-based.
- **Poor mechanical properties:** the product should have adequate tensile and compress strength also flexible rigidity after printing process.
- **low dimensional accuracy:** product fitting requires a precise design, the challenge is to overcome the shrinkage of the product during the curing and cooling process

- **Powder agglomeration limitations:** the particulate powder must be distributed evenly before sintering to prevent agglomeration and low densification product.
- **nozzle size:** appropriate nozzle size will determine the printed structure and design accuracy.
- **distribution of size:** over or under-fit particles may cause defects on the finished products.
- **limited choice of materials:** sources of raw materials for the construction of a similar and suitable product to human organs and tissues are still limited; and,
- **texture and colour similarity/dissimilarity with organs:** customer demands are always beyond current capabilities, so they need to be aware of limitations.

These challenges were faced by the core players of the existing industry in 3D printing technology for biomedical products in Malaysia, which then arises another four significant processing and materials challenges as follows;

- **Low lifespan of the materials:** Inventory such as tracking records and storage of materials and product is crucial because most biomaterials have low lifespan, and expired compound reduces the quality of the product which makes the product brittle and causes cracking and discoloration
- **Customization of fit and design:** the concept of a product's recyclable design is difficult as the product is designed to the size and function of certain patients and cannot be used in other patients.
- **Layer height:** optimizing the best layer height is still dependent on multiple trials to check and find a solution that has been found as time consuming and costly.
- **Build failed:** loss of connectivity or buggy control performance on software-hardware to perform tasks, resulting in failure of network and access to the set framework.

Apart from this, in the management aspect, there are four challenges when utilizing 3D printing technology for manufacturing biomedical products, which are re-education of staff, high-priced products, and lack of guidelines, and cyber-security issues.

Nonetheless, marketing, patents, and copyright were found to be new challenges.

Overall, this study is important for the biomedical manufacturing sector as it offers information about the use of 3D printing technology for manufacturing biomedical products in developing countries such as Malaysia.

This study could be a guideline for new manufacturers, human resources and the management sector.

For new companies intending to adopt this technology, the qualitative sharing experience from this study will provide an early insight into what the company will encounter.

This paper highlighted the fact that, to manufacture medical product, 3D printing technology is safe and effective. Hence, this paper hopes that the challenges discussed will encourage and empower newbies, policy makers, and government sectors to carefully adopt this technology and respond to consumer trust and demand appropriately.

Medical Plastics and Their Recycling: Challenges and Opportunities in India and Globally

Indrajit Ghosh, Global Chairman
MSME Chamber of Commerce and Industry of India &
Chairman and Managing Director World GREXPO Foundation

The increasing reliance on plastics in healthcare has significantly enhanced medical outcomes by ensuring sterility, affordability, and efficiency. However, the flip side is the growing environmental burden caused by medical plastic waste. This challenge is particularly pronounced in a country like India, with its vast healthcare infrastructure and limited waste management capacity, and it resonates globally, where the demand for single-use plastics in healthcare continues to rise.

The Role of Medical Plastics in Healthcare

Medical plastics are essential for healthcare applications, offering benefits such as sterility, biocompatibility, and versatility. Common examples include syringes, IV bags, catheters, PPE, and medical packaging. Globally, the COVID-19 pandemic led to an explosion in the use of single-use plastics like gloves and masks, further highlighting their importance but also their environmental implications.

In India, the healthcare sector's rapid growth, coupled with increasing awareness of infection control, has led to an uptick in the use of medical plastics. However, much of this plastic waste is poorly managed, exacerbating pollution challenges.

Challenges in Recycling Medical Plastics in India and Globally

The recycling of medical plastics is fraught with technical, regulatory, and logistical challenges that vary across regions.

1. Contamination Risks:

- **Global Context:** Medical plastics are often contaminated with biohazardous materials, posing health and safety risks. Globally, regulations prioritize infection control, often leading to incineration or landfill disposal.
- **India's Context:** With limited infrastructure for waste segregation, much of India's medical plastic waste ends up mixed with general waste, making recycling even more difficult.

2. Material Complexity:

Medical devices often combine various types of plastics or incorporate metals, making separation and recycling complex. This issue is universal, with many countries struggling to manage multi-material waste.

3. Lack of Infrastructure:

- **Globally:** While developed nations have some advanced recycling technologies, capacity remains limited for handling biohazardous plastics.
- **India:** Recycling infrastructure is underdeveloped, with a heavy reliance on informal waste pickers who lack the resources to process medical waste safely.

4. Regulatory Hurdles:

Strict regulations regarding the handling and disposal of medical waste discourage recycling efforts. Globally, compliance with these rules often limits innovative waste management solutions. In India, enforcement of biomedical waste management rules remains inconsistent.

Opportunities for Recycling Medical Plastics

1. Technological Innovations:

- **Chemical Recycling:** Globally, advanced chemical recycling technologies are emerging, capable of breaking down complex medical plastics into reusable raw materials. In India, investments in such technologies could help address the lack of scalable solutions.
- Mechanical Recycling: Pre-sorted non-contaminated plastics like medical packaging can be recycled through shredding and remolding.

2. Waste Segregation and Sterilization:

- **Global Best Practices:** Countries like Germany and Japan emphasize strict segregation of medical waste to facilitate recycling.

- **India's Efforts:** Hospitals in urban areas like Delhi and Bengaluru are piloting waste segregation and sterilization practices to recover recyclable plastics.

3. Bioplastics and Alternatives:

Biodegradable plastics are emerging as a sustainable alternative globally. India, with its emphasis on innovation and entrepreneurship, is seeing startups focus on bioplastics for medical applications.

4. Circular Economy Models:
Globally, initiatives to create a circular economy in healthcare plastics are gaining momentum, where used plastics are collected, sterilized, and recycled into new products. India could adopt similar models, particularly in urban healthcare systems.

Case Studies and Innovations

- **Global Case Study:**
  The **European Union** has launched initiatives like the "Health Plastics Recycling" program, promoting recycling in hospitals through advanced waste management systems.
- **India's Success Stories:**
  Organizations like **Aastha Surgical Waste Solutions** in Gujarat are working on innovative ways to segregate and sterilize medical waste for recycling. Public-private partnerships are beginning to address the challenge in metropolitan areas.

Strategies for Improvement In India:

1. **Policy Strengthening:** Enforce stricter implementation of biomedical waste management rules to ensure proper segregation and treatment of medical plastics.
2. **Infrastructure Development:** Invest in specialized recycling facilities for medical waste, especially in Tier 2 and Tier 3 cities.
3. **Public Awareness:** Educate healthcare workers and administrators about the importance of waste segregation and recycling.
4. **Support for Startups:** Encourage innovations in bioplastics and recycling technologies through subsidies and grants.

Globally:

1. **Cross-Border Collaboration:** Share technologies and best practices to improve medical plastic recycling.
2. **Research and Development:** Invest in scalable recycling technologies that can handle contaminated and composite plastics.
3. **Regulatory Reform:** Align policies to encourage recycling while maintaining safety standards.

Conclusion

The recycling of medical plastics remains a formidable challenge in India and worldwide. However, with advancements in technology, policy interventions, and multi-stakeholder collaboration, there is significant potential to turn this waste into a valuable resource. By integrating sustainable practices into healthcare systems, we can address the environmental impact of medical plastics while ensuring the continued delivery of quality healthcare.

Sustainability in healthcare is not just a goal—it is an urgent necessity for a healthier planet.

FAST FACTS

Recyclable medical device packaging

Becton, Dickinson and Company has developed a fully recyclable medical device package comprising two natural-fiber webs. This paper-based solution can be recycled in a single stream, reducing environmental impact while maintaining sterility through various sterilization methods including irradiation, gas, heat, and steam.

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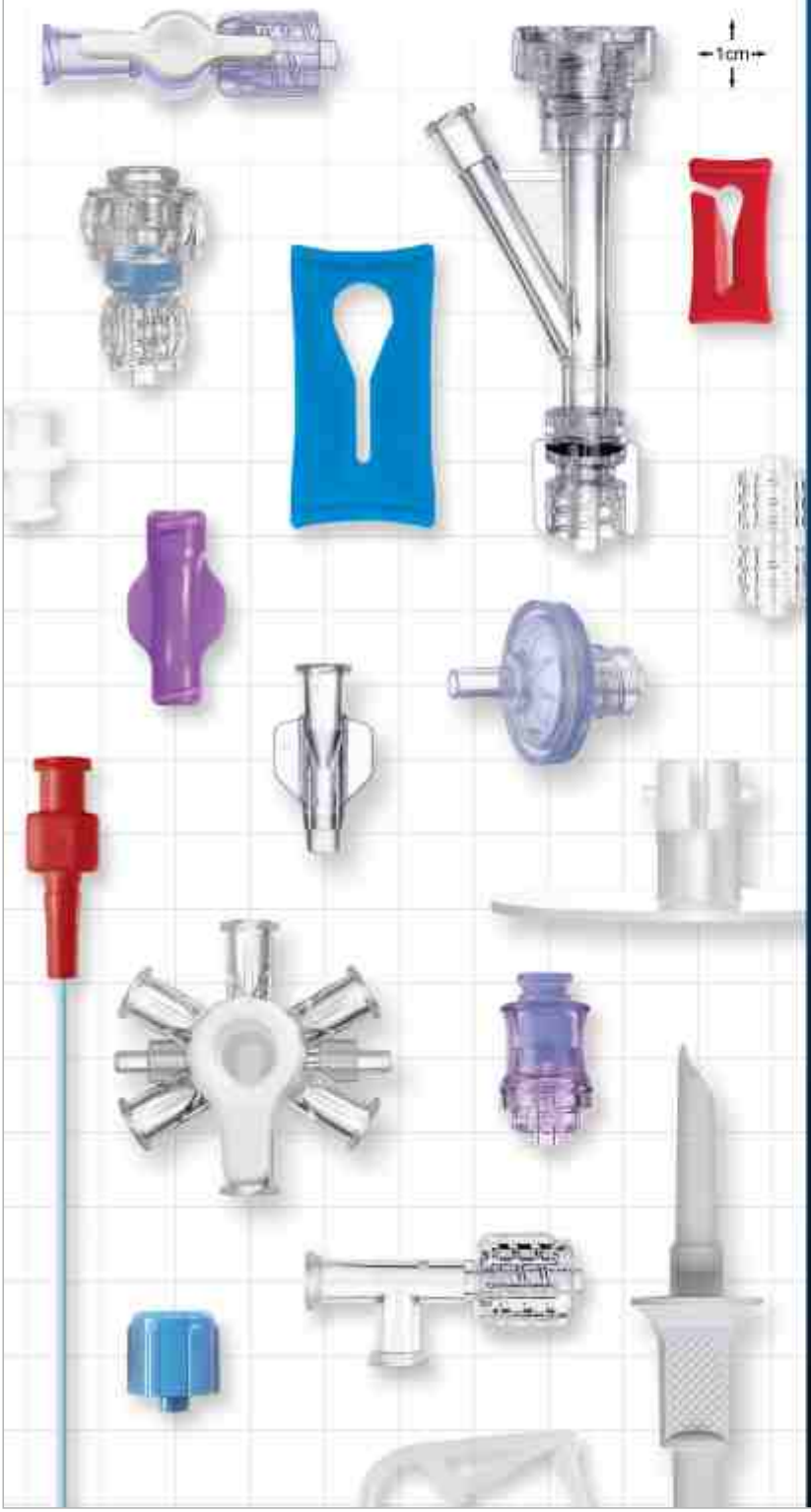

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INSPIRING PLASTICS PROFESSIONALS

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Module 4: Manufacturing Processes for Medical Plastics
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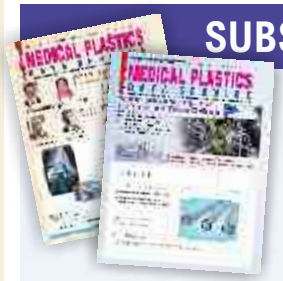

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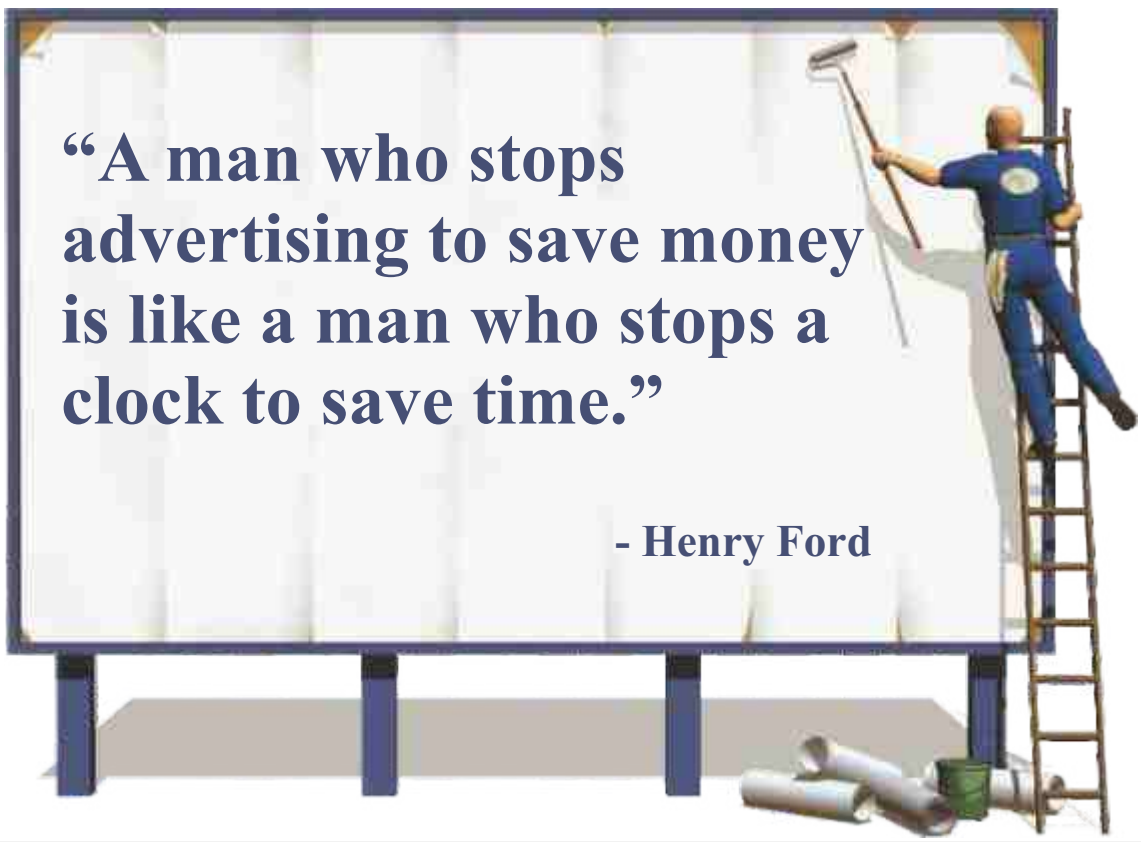

Importance of Risk Assessment as per ISO 14971 and the Role of Materials & Component Suppliers in the Medtech Industry

Sanjay Shah
Unikal Consultant

Regulatory Compliance plays major role:

In the medical technology (MedTech) industry, compliance with regulatory standards is critical for ensuring the safety and effectiveness of medical devices. One of the key standards governing the risk management process is ISO 14971, which provides a framework for manufacturers to identify, evaluate, and mitigate risks associated with medical devices. While manufacturers play a leading role in this process, materials and component suppliers are equally influential in ensuring compliance with ISO 14971.

This article explores the various ways in which suppliers contribute to the overall risk management strategy within the MedTech sector.

The MedTech industry uses a wide array of components and materials, including metals like stainless steel, titanium, polymers like silicon and polyethylene, and composites, depending on the specific application. The material selection needs to be based on its biocompatibility, strength, durability and resistance (does not change their properties) to various sterilization processes.

Why there are component manufacturers and suppliers, instead of complete in-house facilities for manufacturing Medical Devices?

The manufacturing of medical devices requires dozens or hundreds of parts to be manufactured in concert and delivered to the final assembly line. To obtain the necessary components, they usually must settle for what the small local shops have the capabilities to manufacture but when it comes time for production, they often use different sources.

Whether it's medical imaging systems, dialysis machines, blood analyzers, cell counters, or other types of equipment, we tend to see some commonality when it comes to the manufacturing processes used to make medical devices in high volumes.

What are the critical requirements for components suppliers:

Component suppliers are not the part of the Medical Device manufacturing unit but they supply component from which, after due assembling & manufacturing process, medical device is manufactured.

At the same time, they are critical part of the manufacturing process. Hence, they need to comply with certain regulatory process like Quality Management System and record keeping as per ISO 13485, selecting the right raw materials and their storage, handling, traceability and dispatch.

During the selection of raw materials, their required specifications and following due process so as not to modify their basic properties is critical.

Why this is critical?

Medical devices have risk factor involved. It also includes components used in the final device.

The component manufacturers have to follow guidelines in raw material selection, manufacturing processes and their control and handling the same including packaging for supply to ultimate Medical Device manufacturers.

What is Risk factor and how it is assessed and ultimately applicable to the final device?

Introduction to Risk Management

Risk Assessment for Materials and components and their suppliers

In the Medtech industry, the safety and efficacy of medical devices are paramount. To ensure compliance with international safety standards, ISO 14971 plays a critical role in guiding manufacturers through the process of risk management. This article highlights the importance of risk assessment under ISO 14971 and discusses the essential contributions of materials and component suppliers.

Understanding ISO 14971

ISO 14971 is the international standard for risk management in the medical device sector. It provides a framework for manufacturers to identify, evaluate, and control risks associated with medical devices throughout their lifecycle. The standard emphasizes a systematic approach to risk management, which is essential for ensuring patient safety and regulatory compliance.

ISO 14971 outlines the systematic approach to risk management throughout the lifecycle of a medical device. It encompasses the following key phases:

- **Risk Analysis:** Identifying potential hazards associated with the device.

- **Risk Evaluation:** Assessing the acceptability of the identified risks.
- **Risk Control:** Implementing measures to reduce risks to an acceptable level.
- **Post-Market Surveillance :** Monitoring the device's performance and risks after it has been marketed.

Importance of Risk Assessment

1. **Patient Safety:** The primary goal of risk management as per ISO 14971 is to mitigate risks that could potentially harm patients. By identifying hazards and assessing risks, manufacturers can implement controls to enhance user safety.
2. **Regulatory Compliance:** Compliance with ISO 14971 is often a requirement for market approval in many jurisdictions. A thorough risk assessment demonstrates that a manufacturer has taken necessary steps to ensure the safety and effectiveness of their devices.
3. **Product Development:** Incorporating risk assessments early in the design and development phases allows manufacturers to make informed decisions, avoid costly design changes, and reduce time to market.
4. **Market Access:** A well-documented risk management process can facilitate smoother interactions with regulatory bodies, potentially leading to quicker approvals and market access.
5. **Continuous Improvement:** Risk assessment is an ongoing process. It promotes a culture of safety and quality, encouraging continuous monitoring and improvement throughout the device's lifecycle.

Role of Materials & Component Suppliers

1. **Quality Assurance:** Suppliers play a vital role in providing high-quality materials and components that meet safety standards. Their adherence to ISO 14971 enhances the overall risk mitigation strategy of medical device manufacturers. Suppliers provide critical raw materials that directly affect the safety and performance of medical devices. Compliance with ISO 14971 begins at the material level, where suppliers must ensure that their materials meet specific quality standards and regulatory requirements. This includes providing certificates of analysis and compliance with relevant legal and regulatory regulations.
2. **Collaboration in Risk Management:** Suppliers are integral in identifying potential risks related to materials and components. Their expertise can help manufacturers assess risks associated with raw materials, biocompatibility, and durability, thus contributing to a more comprehensive risk assessment.
3. **Regulatory Knowledge:** Suppliers who are knowledgeable about regulatory requirements can provide manufacturers with insights into compliance-related issues associated with materials and components. This collaboration helps in streamlining the risk assessment process.
4. **Innovation and Development:** As the demand for advanced medical technologies grows, suppliers can contribute to innovation. By developing new materials or components that reduce risk (such as biocompatible materials), suppliers enhance the safety profile of medical devices.
5. **Documentation and Traceability:** ISO 14971 emphasizes the importance of documentation throughout the risk management process. Suppliers are responsible for maintaining comprehensive documentation, including specifications, testing results, and traceability records. This information helps device manufacturers in evaluating risks associated with specific materials and components.
4. **Compliance with International Standards:** Suppliers should align their processes with international standards relevant to the materials and components they provide. This includes compliance with ISO 13485 (Quality Management Systems for Medical Devices) and other applicable industry standards. Adhering to these standards ensures that suppliers contribute to the overall risk management framework effectively.
5. **Training and Support:** Effective communication and training from suppliers can enable device manufacturers to understand the risks associated with different materials and components better. Suppliers can offer training sessions on handling materials safely and the implications of using specific components in medical devices.
6. **Product Lifecycle Management:** Risk management continues throughout the product lifecycle, and suppliers play a crucial role in post-market surveillance. By providing data on product performance, addressing issues promptly, and being responsive to feedback, suppliers support continual risk assessment and management efforts of the manufacturers.

Conclusion

The relationship between materials and component suppliers and MedTech manufacturers is vital to ensuring compliance with ISO 14971. Suppliers are not merely providers of materials but also partners in the risk management process. By adhering to regulatory standards, maintaining quality assurance, and fostering open communication, suppliers can significantly contribute to the successful implementation of risk management practices in the MedTech industry. As the industry evolves, fostering strong partnerships and aligning efforts among all stakeholders will be essential for enhancing device safety and compliance.

Europe Medical Disposable Products Market Outlook, 2028

The Europe Medical Disposable market to add USD 45 Billion from 2023 to 2028 driven by factors such as well-established healthcare systems.

Europe is a hub for medical device innovation. Advancements in technology have led to the development of sophisticated and specialized disposable medical products that improve patient care, enhance diagnostic capabilities, and make medical procedures more efficient.

Many European countries have robust healthcare systems with high levels of government expenditure. As the population ages and healthcare needs increase, there is a continuous growth in healthcare spending, which includes investments in medical disposables.

Disposable medical products are crucial in preventing HAIs, which can lead to longer hospital stays, increased healthcare costs, and, in severe cases, patient mortality.

The use of disposable items like gloves, masks, and sterile equipment reduces the risk of infection transmission. Europe has a high standard of healthcare, and patients expect the best possible care.

This demand for quality healthcare services leads to the increased adoption of disposable medical products that adhere to strict standards of hygiene and safety.

Europe has stringent regulations governing the quality and safety of medical devices, including disposables. These regulations, such as the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR), instill confidence in the quality and reliability of disposable medical products, driving demand. Disposable medical products offer healthcare providers convenience and efficiency. They eliminate the need for cleaning and sterilization, reducing turnaround times between patient procedures and improving overall healthcare service delivery.

Europe has an aging population, which often requires more frequent and specialized healthcare services. This demographic trend increases the overall demand for disposable medical products used in diagnostics, treatment, and long-term care. The number of surgical procedures, including minimally invasive surgeries, is on the rise in Europe.

Disposable surgical instruments, drapes, and sterile kits are essential for maintaining high levels of hygiene and preventing post-surgical complications. The emphasis on early disease detection and prevention has led to increased demand for disposable diagnostic tools and screening kits. These products play a critical role in public health programs and regular check-ups.

According to the research report "Europe Medical Disposable Market Outlook, 2028," published by Bonafide Research, the Europe Medical Disposable market is anticipated to add USD 45 Billion from 2023 to 2028. The adoption of telemedicine and home healthcare services has been on the rise in Europe. This has led to increased demand for disposable medical products used in remote patient monitoring, diagnostics, and self-administered treatments. Sustainability concerns have prompted a shift toward environmentally friendly disposable medical products.

Manufacturers are exploring biodegradable materials and recycling programs to reduce the environmental footprint of medical disposables. The trend toward providing more healthcare services in outpatient settings and day surgery centers has increased the demand for disposable medical products used in these environments. Data collection and analytics in healthcare are becoming more prevalent.

Disposable medical products with built-in sensors and data collection capabilities are being developed to support data-driven healthcare decisions. Economic factors, including healthcare budget constraints and cost containment efforts, continue to influence the adoption of disposable medical products as they can offer cost-effective solutions compared to reusable alternatives.

There is a growing emphasis on preventive healthcare measures, leading to increased demand for disposable products used in vaccination, health screenings, and preventive diagnostic tests. Disposable kits for home healthcare management, such as diabetes care kits, wound care kits, and medication administration kits, are gaining popularity, enabling patients to manage their conditions more effectively.

Some healthcare facilities are adopting hybrid models that combine disposable and reusable medical products to balance cost-efficiency and sustainability. The integration of disposable sensors and wearable devices is enabling healthcare providers to remotely monitor patients' vital signs and health parameters, allowing for early intervention and reducing the need for in-person visits. Disposable testing kits and monitoring devices for various conditions, such as diabetes, hypertension, and pregnancy, are becoming more prevalent, enabling patients to take control of their health from the comfort of their homes.

Europe Medical Disposable Market based on country : the market is divided into Germany, United Kingdom, France, Italy, Spain and Russia. Germany boasts a well-established and highly

regarded healthcare system. The country's robust healthcare infrastructure includes a vast network of hospitals, clinics, and healthcare providers. This extensive healthcare ecosystem creates a substantial demand for medical disposables. Germany is known for its advanced medical device manufacturing capabilities. The country is home to numerous companies specializing in the development and production of high-quality medical disposables. These companies leverage cutting- edge technologies and materials to create innovative products.

Germany consistently ranks among the top European countries in terms of healthcare expenditure. A significant portion of this expenditure is allocated to medical devices, including disposable medical products. This consistent investment fuels market growth. Germany has a strong regulatory framework for medical devices, ensuring that products meet high-quality and safety standards. The emphasis on adherence to quality regulations enhances consumer trust in medical disposables manufactured in the country.

Germany hosts some of the largest and most influential medical device trade fairs and exhibitions in Europe, such as MEDICA. These events serve as platforms for networking, showcasing new products, and fostering international collaborations, driving market growth. The German government, as well as private investors, continually invest in healthcare and medical technology. This financial support bolsters research, development, and manufacturing in the medical disposable sector. Germany is a preferred location for clinical research and trials, attracting pharmaceutical and medical device companies. This environment fosters the development and testing of new medical disposable products.

In terms of product type the market is divided into Sterilization Supplies, Drug Delivery Products, Diagnostics and Laboratory Disposables, Disposable Masks, Non-woven Disposables, Disposable Gloves, Dialysis Disposables, Wound Management Products, Incontinence Products, Respiratory Supplies, Disposable Eye Gear, Hand Sanitizers and Others (Disposable Protective Clothing, Bedpans, Urine bags and sharps Containers).

In Europe, as in other regions, infection control is a top priority in healthcare. Sterilization supplies are essential for maintaining the sterility of medical instruments and equipment, reducing the risk of healthcare-associated infections (HAIs), and enhancing patient safety. Sterilization supplies encompass a broad range of products, including sterilization wraps, pouches, indicators, and packaging materials. These supplies are used for the sterilization of various medical devices, from surgical instruments to endoscopes. The European region is a hub for medical device manufacturing. Manufacturers require sterilization supplies to package and sterilize their products before they reach healthcare facilities. This contributes to the consistent demand for these supplies. Hospitals and healthcare facilities across Europe rely heavily on sterilization supplies for their daily operations. Surgical instruments, diagnostic tools, and implantable devices must undergo rigorous sterilization processes before use. Sterilization supplies are crucial for surgical procedures, where maintaining sterility is paramount. Surgical drapes, gowns, and sterile wraps are used to create sterile fields in operating rooms. Endoscopy is a common diagnostic and surgical procedure. Endoscopes must be thoroughly cleaned and sterilized before each use, driving the demand for sterilization supplies. Veterinary clinics and hospitals use sterilization supplies to ensure the safety of surgical instruments and equipment used in animal healthcare. Advances in sterilization methods, such as low-temperature sterilization techniques like hydrogen peroxide vapour and ethylene oxide gas, require compatible sterilization supplies for safe and effective sterilization processes. The trend toward pre-packaged sterile medical devices, which are ready for use upon opening, drives the demand for sterilization supplies used in the packaging and sealing of these devices.

According to the report based on Raw Material the market is divided into Plastic Resin, Nonwoven Material, Rubber, Paper and Paperboard, Metals, Glass and Others. Nonwoven materials excel in providing an effective barrier against microorganisms and fluids, making them ideal for medical disposables where infection control and containment of bodily fluids are critical. This includes products like surgical gowns, drapes, and face masks. Nonwoven materials can be manufactured to meet stringent sterility requirements, which is essential for medical disposables that come into contact with patients' skin or body cavities. Nonwoven materials are known for their soft and fabric- like texture. This quality is crucial for disposable products that need to be comfortable for patients, such as wound dressings, bed linens, and baby diapers. Nonwoven materials can be engineered to be breathable, allowing air and moisture vapor to pass through while still maintaining a barrier against liquids and microorganisms. This is important for products like surgical drapes and gowns to keep healthcare professionals comfortable during procedures. Many nonwoven materials are hypoallergenic and non-irritating to the skin, making them suitable for medical disposables used on individuals with sensitive skin or allergies. Nonwoven materials are relatively easy to process using techniques such as meltblowing, spunbonding, and needle punching. This ease of manufacturing facilitates the efficient production of medical disposables to meet market demand. Nonwoven disposables are designed for single-use applications, reducing the risk of cross-contamination in healthcare settings. This disposability aligns with the principles of hygiene and infection control.

Based on end user the market is divided into hospitals, Outpatient/Primary Care facilities, Home Healthcare and other. Europe has a rapidly aging population, leading to an increased prevalence of chronic conditions and a greater need for home healthcare services. As individuals age, they often prefer to receive care in the comfort of their homes. There is a growing emphasis on patient-centred care, which includes delivering healthcare services tailored to individual needs and preferences. Home healthcare allows for personalized care plans, and disposable medical products play a crucial role in this setting. Home healthcare is often more cost-effective than inpatient care. Patients can reduce expenses related to hospital stays and travel, making it an attractive option for both patients and healthcare systems. Patients with chronic diseases like diabetes, hypertension, and respiratory conditions often require continuous monitoring and care. Home healthcare allows for the management of chronic conditions through the use of medical disposables such as glucometers, blood pressure cuffs, and respiratory devices. Patients who have undergone surgery or medical procedures can continue their recovery at home. Medical disposables like wound dressings, catheters, and drainage bags are essential for post-surgery care. Infusion therapy, including the administration of medications and fluids, can be done at home with the use of disposable infusion sets, IV catheters, and related medical supplies. Advances in technology have led to the development of portable diagnostic and monitoring devices that patients can use at home. These devices often require disposable components for testing and hygiene.

https://www.bonafideresearch.com/product/230979893/europe-medical-disposable-products-market

Ecuador Medical Devices Market

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Country Profile

The name of this country comes from the simple fact that it is situated on the Equator (denoting the word Ecuador in Spanish). Ecuador has Colombia in the north, Peru in the east & south and the Pacific Ocean in the west. Ecuador has 10% of the planet's plant species, 8% of its animal species, and 18% of its bird species, and is one of the largest producers of corn, cacao, rose, banana and orchids in the world. Ecuador, in 2008, became the first country to grant constitutional rights to nature to "exist, persist, maintain and regenerate its vital cycles, structure, functions and processes in evolution", like the rights of a human being. One more interesting point is the world-famous Panama hats are produced in Ecuador but since Panama Canal workers wore them, the name Panama hats became popular. The country's Capital, Quito, is the highest official capital city in the world. The official language is Spanish.

The population size is 1.8 cr. Mestizo (people of mixed Indigenous and White origin) make up more than 75% of the population. Like a typical LATAM country, urbanization is predominant and the urban population is 63%. As per a recent estimate, the median age of the population is 28 years. Traditionally this was a farming country but recently there was the discovery of oil. Ecuador is a member of the Organization of the Petroleum Exporting Countries (OPEC). The focus is now on agribusiness, marine industry, mineral resources, and also industry. This followed fast growth and progress in healthcare expenditure, education and housing boosts.

Ecuador has become a hub for drug gangs due to its location between Colombia and Peru, the top two producers of cocaine in the world. There has been a significant increase in violent crime in recent times. In 2024, the newly elected President Noboa declared a temporary state of emergency in the country because of this problem, and the help of the army was sought in this regard!

Regulatory Framework and Product Classification

In Ecuador, Agencia Nacional de Regulación, Control y Vigilancia Sanitaria (ARCSA) is responsible for medical devices and so, the registration for medical devices is regulated by this agency. Like many LATAM and European countries, the classification for registration has four classes. The expression of each class has changed (below) but the broad classification structure is the same.

Class I: Low-risk devices
Class II: Moderate-risk devices
Class III: High-risk devices
Class IV: Critical Risk devices

An authorised agent is required here also, for the outside manufacturers. The documentation requirements are in three parts-

Authorized representative's documents
The letter of appointment of the authorized representative, Authorization granted by the owner (duly legalized), Representative's permit for operation, List of medical devices applied for, and payment receipt

Manufacturer's documents
Certificate of Free Sales, Certificate of Foreign Government, Export Certificate, GMP Certificate granted by the country of origin or the ISO Certificate (all documents copies notarized).

Technical documentation
Quality reports, Sterility reports issued by the manufacturer, Finished product specs, Product description (Including lists, diagrams, and images..), Stability reports signed by the responsible person, Explanation of the batch code, Labels and instructions for use (in Spanish), Technical specifications of the primary and secondary packaging, an outline of the manufacturing process (the flow chart), Bio-functionality / Biocompatibility reports if applicable

Ecuador Highlights

- A possible incremental market, with LATAM documents available
- A future opportunity (Current - a typical LATAM feature)

Medical Devices Market

Economic growth in the country has not been very strong but this has not affected the growth and demand of its medical device and equipment market as per the imports data. In the healthcare technology markets, the segment of Medical Devices is the largest, with a market volume of US$0.84bn (larger in comparison to per capita numbers of India). The estimated growth rate is 5.5% p.a., almost in line with the global growth rate.

The trend of LATAM in favour of telemedicine solutions, and innovative, technologically advanced products is observed here also, governed by better healthcare outcomes expectations. Market for the portable and wearable medical devices to monitor health conditions in real time is also growing.

Life expectancy is 74 years (77 years for women and 71 years for men). The heavy prevalence of tobacco use (10.6%), the prevalence of overweight and obesity (66.8%) and insufficient physical activity were also reported. Obesity numbers have increased by close to 20% in ten years.

A favourable import climate but corruption in the system are important features.

Opportunities and Challenges

Practically very low local manufacturing, longer life expectancy and heavy import dependence along with documentation almost similar to the LATAM countries make a case for this market as a possible incremental opportunity, rather than a focus market, like Chile or Brazil.

AIMED
Association of Indian Medical Device Industry

AiMeD & Regulatory Updates

Medical Devices Makers Demand 7.5% Safeguard Duty On Imports

"Excess capacity in China is also hurting international prices of medical devices, especially in regions like Africa and Middle East."

Rising "indirect imports" from China coupled with falling exports have prompted domestic medical device manufacturers to seek intervention from the commerce minister Piyush Goyal. In a letter to Goyal, the association of Indian medical device industry (AiMeD) has said that the imports of medical devices from countries like Hong Kong (28%), Malaysia (24%) and Singapore (13%) have shot up in the period from April 2024 to January 2025 due to the likely diversion of Chinese-origin goods transiting through these countries to India.

"The imports from these countries have surged in order to circumvent regulatory restrictions from Central Drugs Standard Control Organisation (CDSCO) on Chinese goods as well as to circumvent trade restrictions imposed by Department for Promotion of Industry and Internal Trade (DPIIT) on neighbouring countries," said Rajiv Nath, forum coordinator at AiMeD.

The letter said that the excess capacity in China is also hurting international prices of medical devices, especially in regions like Africa and Middle East. "Globally, the prices are under a lot of pressure as Chinese products are being dumped due to excess capacity. This is due to the restrictions being imposed by USFDA and other tariff barriers being put in place by the US government on Chinese devices," Nath said.

The association has urged the minister to safeguard the sector by removing zero and 5% "concessional duty" on medical devices, and has also asked for a minimum 7.5% on all medical devices. "If imports keep rising at the current pace, it will become unviable to Make in India.

The sector is facing a double whammy of rising imports and declining exports. For instance, the exports growth in the April 2024 and January 2025 averaged 6%, which was significantly lower than 12% growth in FY24.

Even though the growth in overall imports of medical devices between April 2024 and January 2025 (8.86%) is almost at the same levels as in FY24 (9%), data shows that 11 product categories have witnessed 15% surge in imports in the April 2024 and January 2025 period. This include endoscope, syringes and needles, linear ultra sound scanners, oxygen therapy apparatus, orthopedic apparatus, dental cement, etc.

https://www.financialexpress.com/business/industry/medical-devices-makers-demand-7-5-safeguard-duty-onnbsp-imports/3811827/ - April 16, 2025

AiMeD Applaud's Gujarat Government Decision for Revocation of Dual Pricing Order on Stents

" We are very thankful to Govt of Gujarat and Health Minister Shri Rushikesh Ganeshbhai Patel ji for promptly acting on our request to him and Shri Mansukhbhai Mandaviya ji and assuring us that they are repealing the discriminatory differential pricing order of Cardiac Stents by Department of Health and Family Welfare, Government of Gujarat. This is a major step towards supporting Make In India efforts and instilling confidence in domestic industry that commands over 70% of Indian Stent market and more so for the many Gujarat based Manufacturers like Meril , SMT , AMS , SLTL etc. that has not only championed an Atma Nirbhar Bharat vision of the Honourable Prime Minister but proudly exported Brand India to over 100 Countries and employ thousands of Indians" stated an elated Rajiv Nath, Forum Coordinator, AiMeD.

"A Differential Pricing Policy between the USFDA and Indian Drug Regulators CDSCO India was going to set a bad precedent not only detrimental to strategically importing domestic manufacturing interests but possibly dangerous for Patient Safety. Indian Stents are clinically validated and used in 100+ Countries including those with stringent regulations. Products no longer sold in the USA and other developed countries, were allowed to be implanted in Indian patients under the guise of premium imports and a false narrative on the quality and doubts on efficacy of Indian Stents without backing of Clinical Studies by some Doctors lobbying on behalf of these US MNCs via a lucrative kickback incentive system that needs to be investigated. This assurance given to us for revocation is a welcome relief"Said Mr Gaurav Aggarwal , Jt. Coordinator, AiMeD & Mg Director, INvolution .

The issue was related to a Notification by Gujarat Government that had recently introduced different prices for Stents to be used to treat patients under the flagship Ayushman Bharat Health insurance Scheme. According to a report by Indian Express, an order has revealed that Stents approved by the United States Food and Drug Administration (will be priced Rs 25,000 per Stent, and those cleared by the Indian Drug Regulator costing less than half or Rs 12,000 per Stent.

Currently, all Drug-Eluting Stents (DES), used to treat blocked heart arteries, are priced at Rs 35,000. The Indian Express report had revealed that Indian Medical Manufacturers had raised concerns over the new pricing policy, calling it "discriminatory" and urging the Government to "ensure fair competition" in the market.Stent implants under the Ayushman Bharat Scheme in Gujarat accounted for an expenditure of Rs 429 crore since the scheme's rollout in 2018, Indian Express reported.

Export Promotion Council for Medical Devices (EPCMD) Launched

The Export Promotion Council for Medical Devices (EPCMD), established under the aegis of Department of Pharmaceuticals with the support of Department of Commerce (Government of India) and YEIDA (Government of Uttar Pradesh) in the year 2023, is a Launchpad for taking India-manufactured medical devices globally. EPCMD is India's dedicated agency for propelling the nation's medical device industry onto the global stage.

As a strategic bridge between manufacturers, policymakers, and international markets, EPCMD is committed to unlocking export

potential, driving innovation, and ensuring India's medical technology stands at the forefront of global healthcare.

With a sharp focus on regulatory harmonization, trade facilitation, and market intelligence, EPCMD empowers Indian medical device manufacturers—both emerging and established—to navigate international trade complexities and expand their footprint. From cutting-edge diagnostics to life-saving implants, we champion "Made in India, for the World" with a vision of making India a global hub for high-quality, affordable medical devices.

Whether it's advocating policy reforms, enabling B2B partnerships, or ensuring compliance with global standards, **EPCMD is committed to work closely with the Indian medical device stakeholders.**

The Chairman Mr R S Kanar in his message on the EPCMD website has extended "gratitude to the Government of India for establishing the Export Promotion Council for Medical Devices (EPCMD), a testament to the growing recognition of the medical device sector as a sunrise industry. This initiative marks a pivotal step in making India a global hub for MedTech innovation and manufacturing." He furher mentioned that "India's MedTech industry is ready to go global. With the right strategy, collaboration, and innovation, we can not just compete but lead. I invite all industry players to partner with EPCMD and be part of this journey."

India's medical device exports reached USD 3.22 billion in January 2025, growing at a CAGR of 13.35% over the past four years. However, imports still stand at USD 7.3 billion, signalling both challenges and immense opportunities. EPCMD is committed to bridging this gap by enhancing global market access, regulatory compliance, and strategic partnerships for Indian manufacturers.

EPCMD empowers India's medical device industry by providing regulatory and policy support to navigate global compliance, offering market intelligence to identify emerging opportunities, and facilitating global networking to connect with key players and expand reach.

(https://epcmd.in/chairmans-message)

CDSCO establishes "Coordination Division" to Stramline Operations

The Central Drug Standard Control Organization (CDSCO) has established a "Coordination Division" to better manage its numerous tasks and streamline operations. This new division, effective immediately, aims to free up key personnel to focus on priority areas, such as approving drugs, regulating clinical trials, and coordinating activities with state drug control organizations.

Key Points:

- **New Division:** A "Coordination Division" has been created within CDSCO headquarters.
- **Purpose:** To streamline operations and allow key personnel to focus on core responsibilities.
- **Rationale:** CDSCO faces a growing workload with limited resources.
- **Impact:** This move is expected to improve efficiency and effectiveness in the regulatory process, potentially reducing delays in processing applications and streamlining inspections and audits.
- **Functions:** The Coordination Division is tasked with preparing monthly reports for the Cabinet, managing special assignments from senior leadership, and other coordination-related tasks.

CDSCO Introduces Automated Process For Compliance Certificate Applications For Medical Device Manufacturers

The existing method has been upgraded to a new functional online system, prompting manufacturers to re-submit fresh MSC and NCC applications.

The Central Drug Standard Control Organisation upgraded the provision for auto-generated Market Standing Certificate for export purposes under Medical Devices Rules, 2017-reg.
The notice shared on April 9, 2025, stated, "The current online application workflow for the grant of Market Standing Certificate (MSC) and Non-Conviction Certificate (NCC) for medical devices licensed by Central Licensing Authority is upgraded in the Online System for Medical devices with a new workflow for auto-generated MSC and NCC certificate."

Therefore, the CDSCO requests all concerned stakeholders to re-submit fresh MSC and NCC applications from the date of issuance of this notice. Additionally, the regulatory body also notifies that all current MSC and NCC applications received by CDSCO in the old workflow will be automatically rejected by the system.

Another notification from the CDSCO published on April 9, 2025, indicates that the provision for the system auto-generated Neutral Code under the Medical Devices Rules, 2017, has also been upgraded. The provision will be available through the existing online system of the Medical Devices portal. Consequently, the existing provision for issuance of Neutral Code by the Central Licensing Authority will be non-functional from the date of implementation of the new procedure.

The notification signed by Dr Rajeev Raghuvanshi also mentions that under the new provision, the manufacturers having valid manufacturing licenses can obtain the Neutral code through the option available in the approved manufacturing license from their dashboard for downloading the Neutral Code.

The CDSCO requests that all the concerned stakeholders must obtain system auto-generate Neutral code under Medical Devices Rules, 2017 through the new provision for export purpose.

According to the CDSCO, these upgrades were made to promote ease of business and to simplify the regulatory procedure.

https://www.expresshealthcare.in/news/cdsco-introduces-automated-process-for-compliance-certificate-applications-for-med-device-manufacturers/448652/

AMTZ Joins Hands With FORGE To Build India's Strongest MedTech Innovation Ecosystem

In a landmark move to accelerate India's medtech innovation ecosystem, the Andhra Pradesh MedTech Zone (AMTZ) has partnered with FORGE Innovation & Ventures to launch a state-of-the-art Forge Factory, Academy, and Accelerator within the Medivalley Research Square at MedTech Zone. This strategic collaboration aims to build the country's strongest innovation ecosystem for medical technology—one that nurtures emerging entrepreneurs, accelerates product development, and strengthens India's self-reliance in affordable healthcare solutions.

In partnership with Medtech Zone, FORGE Innovation & Ventures will establish three core components—each designed to strengthen a distinct stage of the startup journey. The Forge Factory will offer physical infrastructure, including labs and prototyping facilities, where startups can build, test, and validate their medtech devices in real-world conditions. The Forge Academy will serve as a talent and capability development platform, offering training, mentoring, and upskilling programs for entrepreneurs, engineers, and researchers—focusing especially on industrial medtech, product design, regulatory pathways, and emerging technologies. Meanwhile, the Forge Accelerator will support early-stage startups through curated acceleration programmes that provide access to seed capital, business model development, and go-to-market strategies, with a focus on both domestic and global markets.

Dr. Jitendar Sharma, MD & founder CEO of AMTZ, described the partnership as a significant leap toward nurturing medtech entrepreneurs in India. "This collaboration with FORGE aligns seamlessly with our vision to make India a self-reliant hub for affordable healthcare technologies. Together, we will build an enabling ecosystem for startups where innovators can fearlessly test, refine, and launch transformative solutions,"

Echoing this sentiment, Vish Sahasranamam, co-founder & CEO of FORGE Innovation & Ventures, said, "We are thrilled to join hands with AMTZ, India's premier medtech zone whose infrastructure is unparalleled in the country. Through this partnership, we aim to build a thriving open innovation network that not only supports startups but also contributes meaningfully to India's public health systems."

The Medivalley Research Square at AMTZ already houses a dynamic ecosystem of medical device manufacturers, research labs, and healthcare innovators. With the addition of Forge's integrated support system, the zone is expected to become a Launchpad for disruptive medtech innovations that address both local healthcare challenges and global market needs.

https://www.pharmabiz.com/NewsDetails.aspx?aid=177334&sid=2

Setting The Record Straight: USTR Claims Vs India's Medical Device Policy

The United States Trade Representative (USTR) has highlighted issues in its 2025 National Trade Estimate (NTE) report about barriers to exporting medical devices to India. These concerns include high tariffs, price controls, and unclear guidelines for importing refurbished medical devices. The USTR earlier expressed concerns about the lack of adjustments in price caps for essential medical devices such as coronary stents and knee implants. In this context, it is important to understand the issues involved and address the claims made by US multinational corporations (MNCs) via the USTR.

India's Medical Devices Policy 2023 is an initiative aimed at reducing the country's 70 per cent dependence on imports, primarily from the US, which has a significant presence in the market. The reliance on imports has affected accessibility, availability, and affordability, leading the government to introduce production-linked incentive (PLI) schemes, medical device parks, and regulatory changes under the Central Drugs Standard Control Organisation (CDSCO), Bureau of Indian Standards (BIS), and the Legal Metrology Regulations. The policy promotes domestic manufacturing through medical device parks, schemes for research and development, and fair competition, especially for micro, small and medium enterprises (MSMEs) addressing India's various medical and healthcare needs.

Multinational corporations, especially US-based firms, continue to engage in anti-competitive practices such as acquiring local companies to create monopolies and limiting the sale of essential components like X-ray tubes to domestic manufacturers. The Covid-19 pandemic highlighted India's susceptibility to supply-chain disruptions and monopolistic pricing by global entities. Nonetheless, the USTR inaccurately characterises India's policy as protectionist, ignoring the country's legitimate requirements for healthcare security and self-reliance.

India has banned imports of refurbished, repaired, and second-hand medical devices to boost domestic manufacturing and ensure patient safety. High-end new machines remain available for those who can afford them, providing choices without harming local industry. While this policy promotes a competitive market, India must still tackle challenges related to availability, accessibility, and affordability due to its large population and low income. This move counters US MNCs' narrative and positions India as an emerging global medical device hub rather than a protectionist market.

The USTR incorrectly portrays India's medical devices sector. It criticises India's tariffs, which are nominal at 7.5 per cent, and the Indian industry seeks a reasonable increase to 10–15 per cent to support domestic manufacturing. The USTR also opposes price controls by India's National Pharmaceutical Pricing Authority (NPPA) on coronary stents and knee implants, alleging restricted market access for US firms. Despite this, reimbursement rates for US-made stents in some Indian states are nearly double those for Indian manufacturers due to unethical marketing practices, overlooking India's affordability concerns and purchasing capacity.

The USTR raises several concerns: regulatory challenges, despite reforms by CDSCO and BIS; customs clearance delays, though Indian Customs has reduced import times; and intellectual property issues, such as patentability criteria and compulsory licensing, which protect public health.

The USTR also objects to local content requirements, deeming them discriminatory, despite their importance in promoting domestic manufacturing under the 'Make-in-India' initiative. The US Buy American policy similarly restricts Indian manufacturers from bidding for US government contracts. Additionally, the USTR objects to data privacy regulations, even though India

aligns its policies with global norms to protect sensitive healthcare data. It also challenges India's standards and certifications, overlooking their significance in ensuring quality and safety, like the emphasis on accreditation, certification, and standards in the US. Lastly, it protests market withdrawal restrictions, which are implemented to prevent sudden supply disruptions and safeguard patient interests.

The Indian medical device industry faces challenges from international trade dynamics, regulatory barriers, and domestic policy inconsistencies. There are external challenges — for instance, in the West Asia and North Africa (WANA) region, Chinese product dumping depresses prices as the US Food and Drug Administration (USFDA) has cracked down on Chinese imports. Similarly, in the European Union, the delays and high costs for Conformity Euro penne (CE) certification and renewals affect Indian exporters' market access. Likewise, in Japan, the weaker yen and Indonesia's preference for local manufacturing reduce India's competitiveness. Further, CDSCO delays in issuing licences and Free Sale Certificates are also hindering Class C and D indigenous manufacturers from accessing global markets.

Low tariffs (0–7.5 per cent) discourage local manufacturing, coupled with Harmonised System (HS) misclassification by importers to reduce duties. Additionally, private hospitals prefer high-margin imported brands and even inflated maximum retail price (MRP) tags. Consequently, the benefits of low duty do not result in lowered MRPs.

Policy updates are necessary, including revising the Global Tender Exemption (GTE) list to remove 119 medical devices manufactured in India. Multinational companies lobby for mandatory USFDA/CE requirements to limit Indian competition in government tenders. Current Government e-Marketplace (GeM) procurement norms allow relabelled imports with less than 20 per cent domestic content without verification. Given this context, enforcing local value addition criteria is important to support Indian medical device manufacturers.

While exposing such misguided narratives of the USTR for MNCs, India's policymakers should focus on supporting domestic medical device manufacturers in any trade negotiations to ensure the availability, accessibility, and affordability of medical devices for India's large and low-income population. Reliance on imports has resulted in high costs and supply vulnerabilities, while practices by multinational corporations may impact self-reliance. An effective Make-in-India strategy can enhance healthcare infrastructure, reduce costs, and provide quality medical devices to all, promoting equitable healthcare for millions.

Rajiv Nath is Forum Coordinator, AiMeD and Ram Singh, Professor & Head, IIFT New Delhi.

https://www.business-standard.com/economy/analysis/setting-the-record-straight-ustr-claims-vs-india-s-medical-device-policy-125040700952_1.html?1744031160

Qosina Expands Tubing Portfolio Through New Collaboration with AdvantaPure™

Qosina, a global leader in the distribution of medical biopharmaceutical components, is pleased to announce an exciting new collaboration with AdvantaPure™, the high-purity products division of NewAge™ Industries designed to anticipate and satisfy the evolving needs of the pharmaceutical and biopharmaceutical manufacturing industries.

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"Our collaboration with AdvantaPure marks an important step forward for Qosina as we continue to expand our offerings and provide greater value to our customers," said Lee Pochter, CEO of Qosina. "This partnership underscores Qosina's commitment to meeting the critical needs of the life sciences industry. With the addition of AdvantaPure's trusted tubing solutions, Qosina is strengthening its ability to offer off-the-shelf convenience and flexibility to customers worldwide."

As part of this collaboration, Qosina will showcase this partnership and the AdvantaPure tubing offering at its booth (3317) during the Interphex trade show in New York, NY, April 1-3, 2025. Attendees will have the opportunity to explore the breadth of AdvantaPure tubing available through Qosina.

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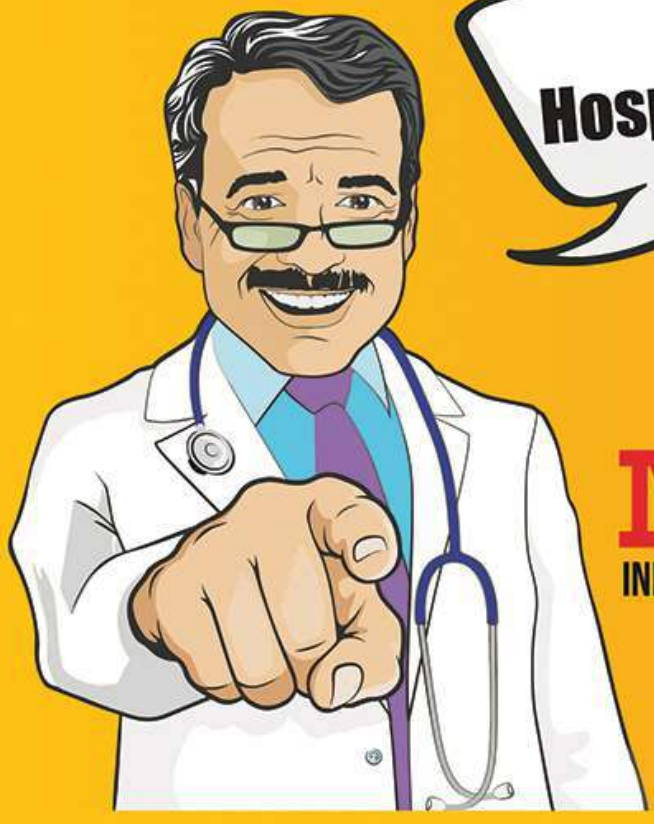

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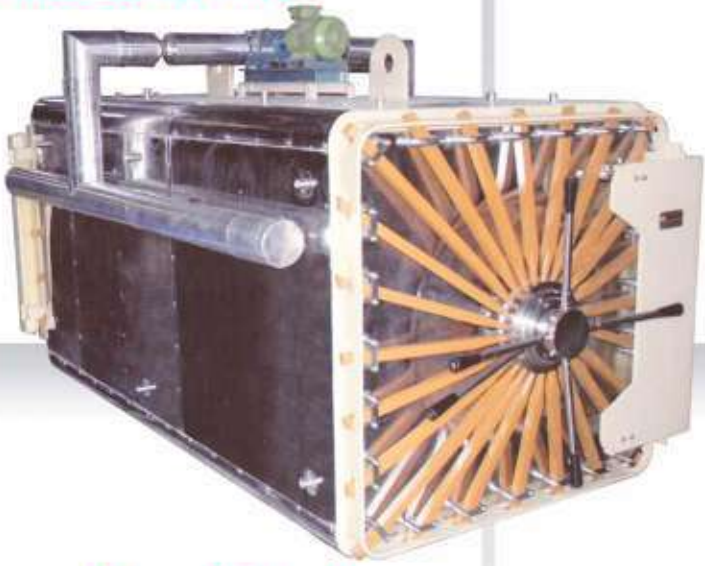

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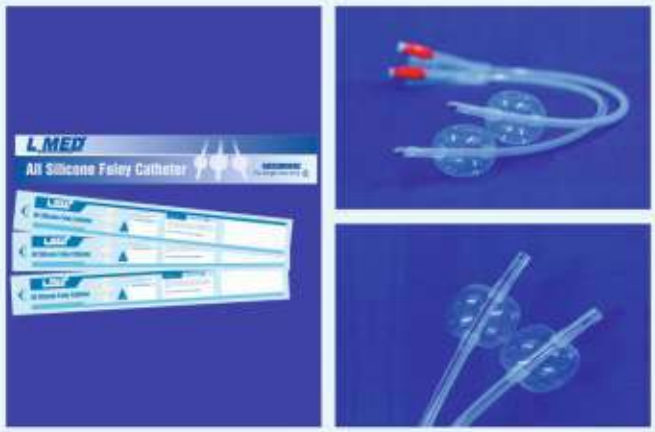

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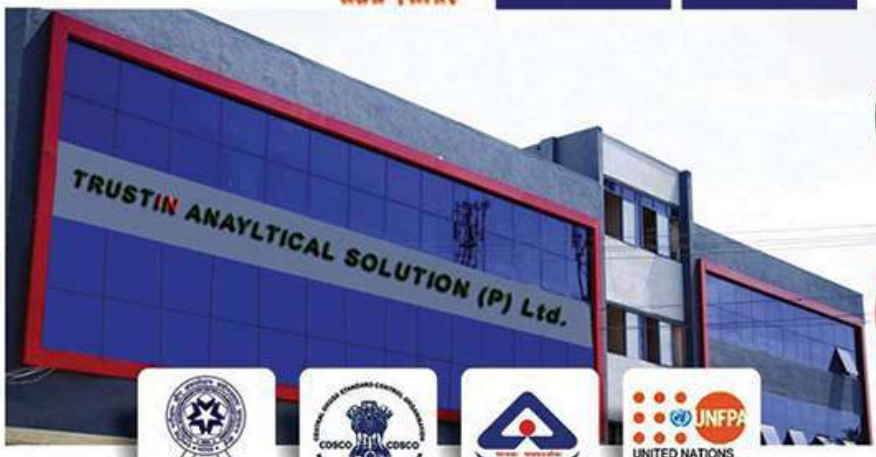

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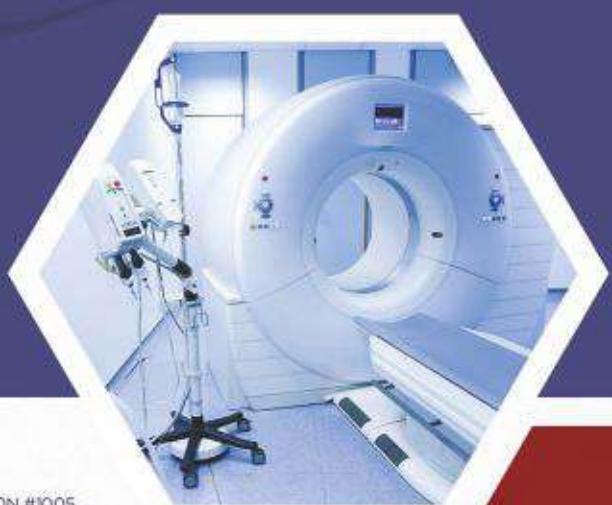

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