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# REGUVEDA

YOUR MONTHLY REGULATORY UPDATE

We provide turnkey services spanning from product design and development, manufacturing unit design up to achieving the regulatory approvals of national as well as international level.

OPERON STRATEGIST
Transforming Thoughts In To Reality

## LATEST NEWS & UPDATES

### Centre to Reclassify Medical Devices to Streamline Regulation and Boost Sector Growth

NEW

**Upcoming Events this Month**

· Medicall Kolkata 2025

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OPERON STRATEGIST

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MEDICAL DEVICES REGULATORY UPDATES

# Medical Device News

## Centre to Reclassify Medical Devices to Streamline Regulation and Boost Sector Growth

The Indian government plans to reclassify 1,178 medical devices under the Medical Device Rules (MDR), 2017, categorizing them by risk profile into interventional radiology, radiotherapy, oncology, and Class A non-sterile/non-measuring devices. This move aims to streamline approvals, enhance regulatory clarity, and boost domestic production, reducing India's 86% dependence on imports.

With India's Medical Device sector projected to grow from $11B to $50B by 2030, Operon Strategist provides regulatory consulting, project management, and compliance support to help manufacturers navigate these changes and leverage government incentives.

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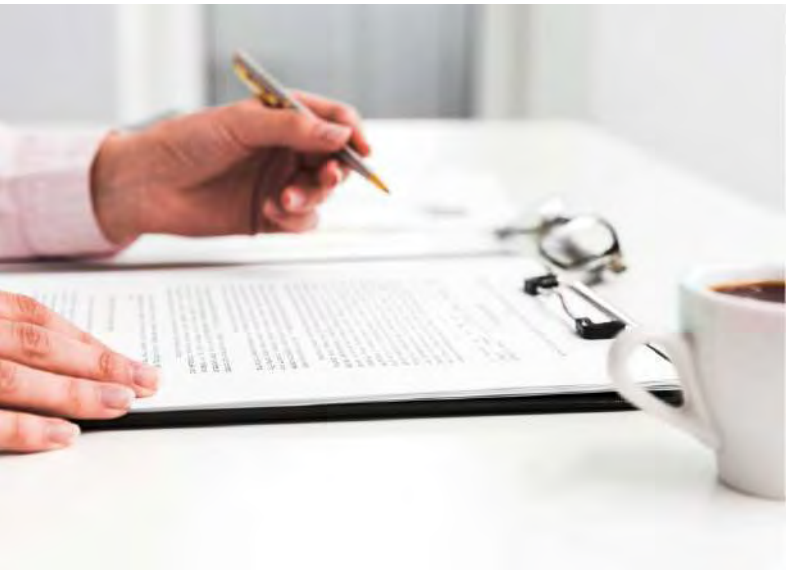

## USFDA Releases Draft Guidance for AI-Enabled Medical Devices

The U.S. Food and Drug Administration (FDA) has released draft guidance to support the development, regulation, and lifecycle management of AI-enabled medical devices. This marks the first comprehensive framework covering design, development, maintenance, and documentation to ensure device safety and effectiveness.

The guidance builds on the FDA's final policy on predetermined change control plans, helping manufacturers manage AI-driven updates post-market.

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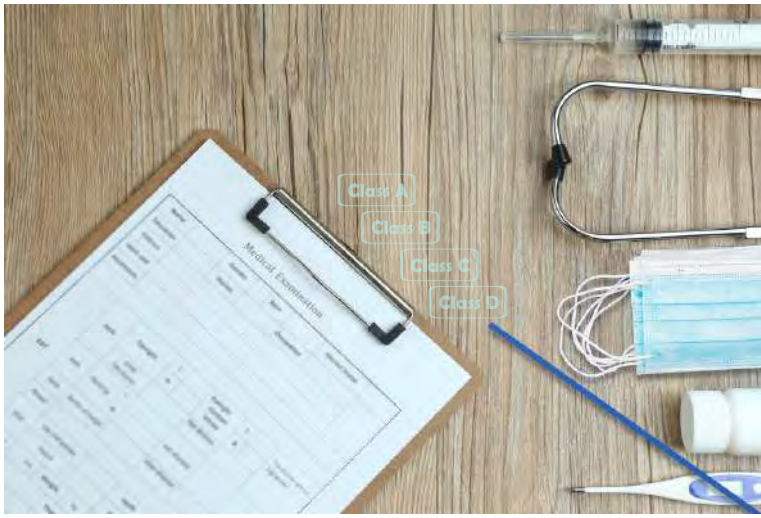
MEDICAL DEVICES REGULATORY UPDATES

# Medical Device News

## CDSCO Seeks Industry Feedback on Updated Medical Device Classification List




The Central Drugs Standard Control Organization (CDSCO) has released an updated medical device classification list, covering interventional radiology, radiotherapy, oncology, and Class A (non-sterile, non-measuring) devices. This revision aligns with MDR, 2017, and international standards, ensuring regulatory clarity.

CDSCO invites industry feedback within 30 days of publication to refine the classifications. Stakeholders can review the list and submit comments via the CDSCO website.

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## PLI Scheme Medical Device Sales Boost to Rs 8,039.63 Crore in India

India's medical device sector has witnessed a significant boost, achieving sales of Rs 8,039.63 crore under the Production Linked Incentive (PLI) Scheme as of September 2024, with exports contributing Rs 3,844.01 crore. Launched in 2020, the scheme supports greenfield projects, offering 5% financial incentives on incremental sales for eligible manufacturers. It aims to enhance domestic production, address manufacturing challenges, and promote investment in key medical device categories, including radiology, implants, and cardio-respiratory devices.

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MEDICAL DEVICES REGULATORY UPDATES

# Medical Device News

## CDSCO & ICMR Release Draft Standard Evaluation Protocols for issuing license for IVDs


The Central Drugs Standard Control Organization (CDSCO) and Indian Council of Medical Research (ICMR) have released draft standard evaluation protocols for licensing in-vitro diagnostics (IVDs) under MDR 2017. Covering 14 tests, including Chikungunya, Dengue, and Zika virus diagnostics, these protocols aim to standardize performance evaluations and ensure quality compliance. Public feedback is open until February 15, 2025, after which the protocols will be finalized. Kits found Not of Standard Quality (NSQ) will not be eligible for re-testing without valid proof of changes.

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## North India's Largest Medical Device Park Near Noida Airport Set to be Established

Uttar Pradesh is set to establish North India's first dedicated Medical Device Park at Sector 28, YEIDA, near Noida International Airport. Spanning 350 acres, this initiative aims to enhance medical device manufacturing, reduce import dependency, and foster innovation. With ₹415 crore in investments and 59 companies already onboard, the park is expected to create 5,000 direct jobs. It will support various medical segments, including cancer care, imaging, cardiology, renal care, and implantable electronics. Operon Strategist is ready to assist manufacturers in achieving regulatory compliance and operational excellence in this transformative healthcare project.

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# TO KNOW MORE

## How End-to-End Solutions Simplify Regulatory Challenges in the MedTech Sector

Navigating the complex regulatory landscape of the MedTech industry is crucial for market access, patient safety, and product success. End-to-end regulatory solutions streamline compliance by covering every stage—from initial gap analysis and design validation to regulatory submissions and post-market surveillance. These solutions help manufacturers address evolving regulations, resource constraints, and global market variability. Partnering with an expert regulatory consultant like Operon Strategist ensures seamless compliance, risk management, and a competitive edge in international markets.


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## Beyond MDR and IVDR: 6 Critical Regulations Shaping Medical Device Compliance

Regulatory compliance extends far beyond MDR and IVDR. Medical device manufacturers must also navigate key regulations such as the EU AI Act for AI-driven devices, GDPR for data privacy, and RoHS/REACH for material safety. Additionally, the Radio Equipment Directive, Battery Regulation, and WEEE Directive play a crucial role in ensuring product safety, sustainability, and legal market entry.

Struggling with compliance? Operon Strategist provides expert guidance to simplify regulatory challenges and ensure seamless market access. Contact us today!

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## 10 Key Steps to Achieve EU AI Act Compliance for Medical Device

The EU AI Act introduces strict compliance requirements for AI-driven medical devices, particularly those classified as high-risk. Key steps include assessing AI systems, adapting QMS to AI-specific needs, ensuring robust risk management, strengthening data governance, and establishing human oversight mechanisms. Compliance also requires incident reporting, fundamental rights impact assessments, and appointing an EU Authorized Representative for non-EU businesses.

Need expert guidance? Operon Strategist helps manufacturers navigate AI compliance, ensuring seamless market entry. Contact us today!


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## 10 Essential Strategies for Effective Post-Market Surveillance under EU-MDR

Post-Market Surveillance (PMS) is a crucial part of EU-MDR compliance, ensuring the ongoing safety and performance of medical devices. This blog explores key regulatory requirements, proactive data collection methods, and 10 essential strategies for effective PMS, including leveraging modern tools, stakeholder collaboration, and regulatory updates. Discover practical solutions to overcome PMS challenges and ensure compliance with expert guidance from Operon Strategist.

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# TO KNOW MORE

## Decoding IEC 62304 Software Safety Classification: What You Need to Know

Ensuring medical device software safety is crucial, and IEC 62304 provides the framework to achieve compliance. This standard categorizes software into Class A, B, or C based on potential harm, guiding risk management and development processes. Accurate classification, detailed risk assessments, and thorough documentation are essential for regulatory approval.

Need expert guidance? Operon Strategist helps medical device manufacturers navigate IEC 62304 compliance, from risk assessment to global regulatory approvals.

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## Malaysia Medical Device Registration

Entering the Malaysian medical device market requires registration with the Medical Device Authority (MDA) via the MeDC@St system. Devices are classified into four risk categories (A to D), with regulatory requirements varying accordingly. The process involves appointing a local Authorized Representative, preparing a technical file, ensuring GDPMD compliance, and undergoing MDA review.

Need expert guidance? Operon Strategist provides end-to-end support for seamless medical device registration in Malaysia.

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# TO KNOW MORE

## Medical Device Registration in Thailand: Regulatory Approval Process for Medical and IVD Devices


Entering the Thai medical device market requires compliance with the Thai FDA's regulations. Devices and IVDs are classified into four risk categories, each with specific documentation and approval requirements. The registration process includes appointing a local representative, verifying classification, preparing regulatory documents, and submitting applications to the Medical Device Control Division (MDCD).

Need expert guidance? Operon Strategist simplifies the approval process, ensuring compliance with Thai regulations.

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## Ensuring Safety and Quality: Global Regulations for Dental Cement Manufacturing

Dental cement manufacturing is a highly regulated process that demands adherence to international quality and safety standards. With growing advancements in dental materials, compliance with regulatory guidelines is essential for ensuring product reliability and market acceptance. Companies like Operon Strategist provide invaluable support to manufacturers in navigating the complex regulatory framework, ensuring smooth approval and market entry for dental cement products.

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# GLIMPSES OF THE ARAB HEALTH EXHIBITION

Operon Strategist had a productive visit to Arab Health 2025, engaging with industry professionals on medical device regulations, compliance, and market entry strategies. This event provided valuable insights into the evolving healthcare landscape, reinforcing our commitment to supporting manufacturers with expert regulatory solutions. For those we couldn't meet in person, our team remains available to discuss your regulatory needs.

Arab Health
By Informa Markets
2025

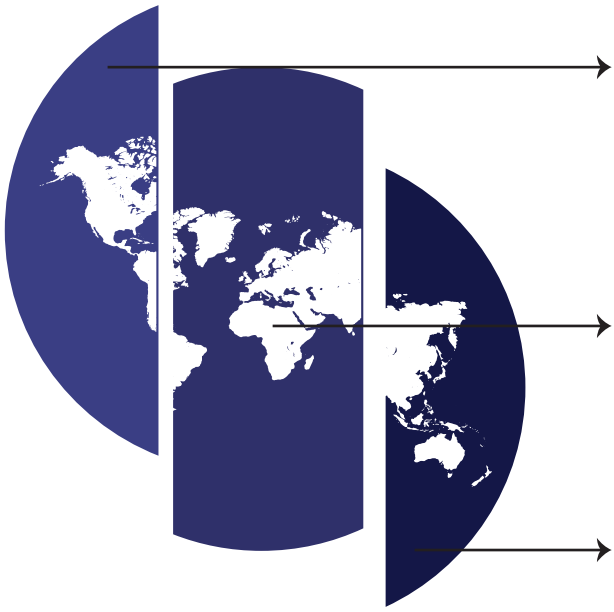
Dubai World Trade Center, Dubai.

# REGUVEDA

A GUIDE TO YOUR MONTHLY REGULATORY UPDATE

Operon Strategist, A Leading Medical Device Regulatory Consultant. Get Expert Assistance From Our Experienced Professionals And Transform Your Thoughts Into Reality.

## OUR SERVICES



- **Turnkey Project Consultant:**
- Product Feasibility And Detailed Project Report
- Manufacturing Facility Compliance
- Validation Documentation
- Clean Room Guidance
- Quality Management System (FDA 21 CFR 820, ISO13485, ISO 15378, MDSAP)

- **Regulatory Approvals:**
- FDA 510(K)
- CDSCO Registration
- CE Marking
- UKCA
- SFDA

- **Medical Device Design Development Documentation:**
- Drug Device Combination Product
- USFDA 21 CFR 820.30 Design Control Requirements

## CONTACT US

For more details regarding licence process and regulatory services .


enquiry@operonstrategist.com

+91-9370283428

Office No.14, 4th Floor, MSR capital, Morwadi, Pimpri, Pune 411 018