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REGULATORY APPROVAL OF IN VITRO DIAGNOSTIC MEDICAL DEVICES IN INDIA: CURRENT FRAMEWORK, REQUIREMENTS, CHALLENGES AND FUTURE PERSPECTIVES

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ABSTRACT

In vitro diagnostic (IVD) medical devices play a critical role in disease diagnosis, screening, prognosis, therapeutic monitoring, and public-health surveillance. In India, IVDs are regulated under the Drugs and Cosmetics Act, 1940 and the Medical Devices Rules (MDR), 2017, with regulatory oversight by the Central Drugs Standard Control Organisation (CDSCO). The MDR, 2017 established a risk-based regulatory framework in which IVDs are classified into Classes A, B, C, and D according to increasing individual and public-health risk. Regulatory requirements encompass device classification, manufacturing and import licensing, quality management systems, technical documentation, risk management, analytical and clinical performance evaluation, labelling, and post-market surveillance. Manufacturers are required to demonstrate compliance with applicable quality and performance requirements, while importers must additionally fulfil authorized representation and supporting documentation obligations. Post-market safety monitoring is supported through the Materiovigilance Programme of India. Although the Indian regulatory system has undergone substantial modernization, challenges persist in regulatory awareness, documentation quality, performance-evaluation infrastructure, approval timelines, adverse-event reporting, and regulation of emerging technologies. This review critically summarizes the regulatory

pathway for IVD medical devices in India and highlights future priorities including international harmonization, regulatory digitalization, stronger clinical evidence, enhanced materiovigilance, and preparedness for artificial intelligence, molecular diagnostics, and other next-generation diagnostic technologies.

KEYWORDS: In vitro diagnostic devices; CDSCO; Medical Devices Rules 2017; IVD regulation; clinical performance; quality management system; materiovigilance; India.

1. INTRODUCTION[1,2]

In vitro diagnostic medical devices have become indispensable components of healthcare systems. They are used to examine specimens derived from the human body, including blood, urine, tissues, saliva, and other biological materials, to provide information concerning physiological or pathological states, disease diagnosis, congenital abnormalities, compatibility, prognosis, and treatment monitoring. Unlike conventional medical devices that may interact directly with patients, IVDs generally perform their diagnostic function outside the human body.

The importance of IVDs has increased considerably with the growth of infectious-disease diagnostics, chronic-disease monitoring, molecular testing, immunoassays, genetic diagnostics, companion diagnostics, and point-of-care technologies. Diagnostic results frequently influence critical clinical decisions; consequently, inaccurate results may lead to inappropriate treatment, delayed diagnosis, unnecessary interventions, or significant public-health consequences.

Regulatory control is therefore essential to ensure that IVDs consistently meet predefined requirements for quality, safety, and performance. Regulatory authorities evaluate device design, intended use, manufacturing controls, analytical performance, clinical evidence, risk management, labelling, and post-market safety.

India has progressively moved from limited regulation of selected medical devices toward a comprehensive device-specific framework. The Medical Devices Rules (MDR), 2017, which came into effect on 1 January 2018, established a dedicated regulatory structure for medical devices and IVDs. The framework introduced risk-based classification, defined licensing responsibilities, Quality Management System (QMS) requirements, clinical performance provisions, import and manufacturing controls, and post-market surveillance.

The present review summarizes the principal components of this framework, with particular emphasis on risk classification, CDSCO approval, documentation, manufacturing and import licensing, performance evaluation, quality and risk management, post-market surveillance, challenges, and future regulatory directions.

2. Regulatory Framework for IVD Medical Devices in India[3,4]

The principal legal and regulatory foundation for IVD medical devices in India comprises the Drugs and Cosmetics Act, 1940, the Medical Devices Rules, 2017, subsequent amendments, notifications issued by the Ministry of Health and Family Welfare, and guidance documents and regulatory communications issued by CDSCO.

CDSCO functions as India's national regulatory authority for drugs and medical devices under the Directorate General of Health Services, Ministry of Health and Family Welfare. It is headed by the Drugs Controller General of India (DCGI).

The MDR, 2017 established a lifecycle-oriented framework covering the manufacture, import, sale, distribution, clinical performance evaluation, and post-market monitoring of IVD medical devices. Important features include risk-based classification, defined licensing authorities, electronic application processing through the SUGAM portal, QMS requirements, clinical performance evaluation, and post-market vigilance.

2.1 Distribution of Regulatory Responsibilities

Regulatory responsibility is divided principally between the Central Licensing Authority (CLA) and State Licensing Authorities (SLAs).

The CLA, functioning through CDSCO, is responsible for the import of all classes of IVDs, manufacture of Class C and Class D devices, approval of new IVD devices, permissions associated with clinical performance evaluation, and regulatory oversight of higher-risk devices.

The SLA primarily regulates manufacture of Class A and Class B IVD medical devices and monitors compliance of applicable manufacturing establishments within the respective state. This risk-based allocation allows greater regulatory scrutiny to be concentrated on devices presenting higher individual or public-health risks.

3. Risk-Based Classification of IVD Medical Devices[5,6]

Risk classification is the foundation of the Indian regulatory pathway. Under MDR, 2017, IVD medical devices are classified into four classes—A, B, C, and D—with regulatory control increasing progressively from Class A to Class D.

Classification considers the intended purpose, clinical significance of the information generated, impact of an incorrect result on patient management, individual patient risk, public-health implications, type of specimen, and consequences of false-positive or false-negative results.

Table 1: Risk-Based Classification of IVD Medical Devices in India.

Class	Risk Level	Typical Examples	Principal Manufacturing Authority
Class A	Low	Specimen containers, general laboratory reagents	State Licensing Authority
Class B	Low to moderate	Pregnancy test kits, urine test strips	State Licensing Authority
Class C	Moderate to high	Blood glucose systems, HbA1c kits, cardiac-marker assays	Central Licensing Authority/CDSCO
Class D	High	HIV kits, hepatitis B/C kits, blood-donor screening assays	Central Licensing Authority/CDSCO

The level of documentation and regulatory evidence increases with risk. Class A devices generally require comparatively basic technical documentation, whereas Classes C and D may require comprehensive technical dossiers, analytical and clinical performance data, detailed risk management, site inspection, and stronger post-market controls.

Correct classification is therefore a critical early regulatory decision because it determines the applicable licensing authority, documentation requirements, performance-evaluation expectations, and degree of regulatory review.

4. CDSCO Regulatory Approval Pathway[7,8]

The CDSCO regulatory process can be viewed as a sequence of interconnected activities extending from classification to post-market monitoring.

4.1 Device Classification

The manufacturer initially determines the applicable risk class based on intended use and associated individual and public-health risks.

4.2 Establishment of Quality Management System

Before regulatory approval, the manufacturer is expected to establish an appropriate QMS. The thesis identifies ISO 13485:2016 as the principal internationally recognized QMS standard for medical-device manufacturers.

The QMS encompasses design and development controls, supplier management, production controls, process validation, documentation, complaint handling, CAPA, internal audits, training, management review, and other lifecycle quality activities.

4.3 Technical Documentation

A technical dossier is prepared to establish the identity, intended purpose, quality, safety, and performance of the IVD. Important components include administrative information, device description, design information, manufacturing process, performance data, risk management, stability information, labelling, and Instructions for Use.

4.4 Electronic Application

Applications are submitted electronically through the CDSCO SUGAM portal with the applicable form, supporting documentation, quality certificates, performance reports, and prescribed government fee.

4.5 Regulatory Review

The regulatory review considers device classification, design, intended use, manufacturing information, QMS, analytical and clinical performance, risk management, labelling, and conformity with essential safety and performance principles.

Where deficiencies are identified, the applicant may be required to provide clarifications or additional supporting evidence.

4.6 Inspection

Depending upon device class and regulatory circumstances, manufacturing-site inspections or audits may be conducted. Inspections can evaluate infrastructure, equipment qualification, personnel competence, QMS implementation, validation, documentation, calibration, maintenance, and applicable contamination or sterility controls.

4.7 Performance Evaluation

Higher-risk IVDs generally require stronger analytical and clinical performance evidence. For selected products, evaluation by CDSCO-designated laboratories may also be required.

4.8 Licensing and Post-Market Control

Following satisfactory review, the relevant manufacturing or import licence is granted. Regulatory obligations continue after commercialization through complaint handling, adverse-event reporting, CAPA, Field Safety Corrective Actions (FSCA), recalls, and periodic review of safety and performance.

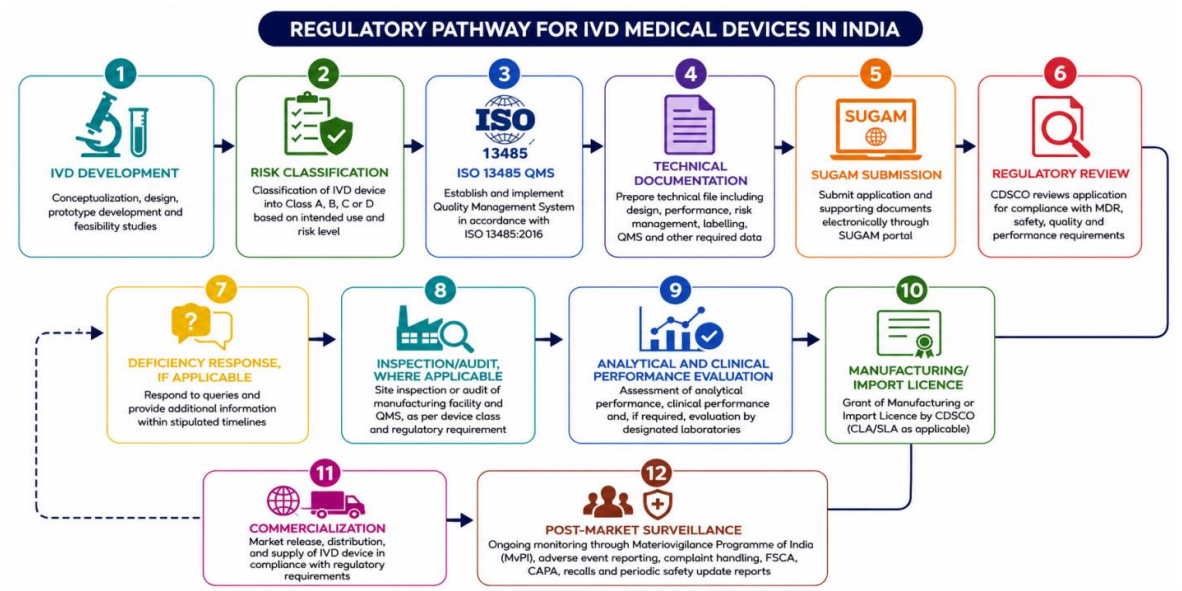

Figure 1. Simplified CDSCO Regulatory Pathway.

5. Manufacturing and Import Licensing[9,10]

Manufacturing and import activities require authorization under the Medical Devices Rules, 2017. The applicable pathway differs according to whether the device is manufactured domestically or imported.

Table 2: Major Licensing Forms Identified in the Indian IVD Pathway.

Regulatory Activity	Application Form	Licence/Permission
Manufacture – Class A & B	MD-3	MD-5
Manufacture – Class C & D	MD-7	MD-9
Import licence	MD-14	MD-15
Test licence	MD-12	MD-13

The thesis identifies the SLA as responsible for manufacturing licences for Classes A and B, whereas the CLA/CDSCO regulates manufacturing of Classes C and D. CDSCO regulates import of all classes.

For imported products, a foreign manufacturer is required to appoint an Authorized Indian Agent to undertake applicable regulatory responsibilities and communication with CDSCO. Supporting documentation can include the Device Master File, Plant Master File, ISO 13485 certification, Free Sale Certificate, Power of Attorney, performance evidence, risk-management documentation, labelling, and relevant regulatory approvals.

This distinction between domestic manufacture and import is important because imported products require additional evidence concerning the foreign manufacturing establishment and authorized representation in India.

6. Regulatory Documentation Requirements[11,12]

Documentation is one of the most important determinants of successful regulatory review. The level of evidence is proportional to device risk.

Major categories include administrative documents, device description, technical documentation, QMS documentation, performance-evaluation evidence, risk-management documentation, manufacturing records, labelling, regulatory certificates, and post-market surveillance documentation.

Table 3: Principal Documentation Categories for IVD Approval.

Category	Representative Information
Administrative	Application form, manufacturer details, authorized agent, fee information
Device description	Device name, intended use, principle, methodology, specimen, configuration
Design/technical	Design verification and validation, manufacturing process, specifications
QMS	Quality manual, SOPs, CAPA, audits, training, supplier controls
Analytical performance	Accuracy, precision, sensitivity, specificity, LOD, LOQ, linearity
Clinical performance	Diagnostic sensitivity/specificity, PPV, NPV, clinical accuracy
Risk management	Hazard analysis, risk evaluation, controls, residual risk, benefit-risk
Manufacturing	Process flow, validation, equipment qualification, production controls
Labelling	Product label, IFU, storage, shelf life, warnings and precautions
Post-market	Complaints, adverse events, FSCA, recalls, CAPA, vigilance reports

Higher-risk Class C and D products require more comprehensive documentation than lower-risk products. Incomplete performance evidence, inadequate risk-management information, inconsistent labelling, missing validation records, and poorly organized dossiers can result in regulatory deficiencies and delays.

7. Quality Management and Risk Management[13,14]

Quality management is central to ensuring consistent performance of IVD medical devices. ISO 13485:2016 provides a structured QMS framework covering product realization and manufacturing activities. Important elements include design controls, document and record control, supplier qualification, process validation, training, equipment maintenance and calibration, complaint handling, CAPA, internal audits, and management review.

Risk management complements the QMS by systematically identifying hazards, estimating and evaluating associated risks, implementing risk-control measures, assessing residual risk, and reviewing the overall benefit-risk relationship.

The thesis identifies ISO 14971 as the principal reference for medical-device risk management. Typical documentation includes a risk-management plan, hazard identification, risk analysis, risk evaluation, control measures, residual-risk assessment, benefit-risk analysis, and a final risk-management report.

Integration of quality and risk management is particularly important for high-risk IVDs because diagnostic errors can affect not only individual patients but, in the case of transmissible diseases and blood screening, broader public health.

8. Analytical and Clinical Performance Evaluation[15,16]

Performance evaluation provides the scientific evidence necessary to establish that an IVD performs according to its intended purpose.

8.1 Analytical Performance

Analytical performance establishes the technical capability of the device to detect or measure the target analyte accurately and consistently.

Important parameters include.

- Accuracy
- Precision

- Repeatability
- Reproducibility
- Analytical sensitivity
- Analytical specificity
- Limit of detection
- Limit of quantification
- Linearity and measuring range
- Interference
- Stability

8.2 Clinical Performance

Clinical performance demonstrates the ability of the device to generate clinically meaningful results in the intended population and use environment.

Important parameters may include diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, clinical accuracy, reproducibility, agreement with reference methods, and other measures appropriate to the diagnostic claim.

Analytical performance therefore establishes whether the device can reliably measure the analyte, while clinical performance determines whether the resulting information accurately reflects the relevant clinical condition.

For higher-risk devices, particularly Classes C and D, more extensive performance evidence may be necessary. Depending on the device, CDSCO may also require evaluation through designated laboratories. Clinical performance evidence is consequently one of the most important scientific components supporting regulatory approval.

9. Post-Market Surveillance and Materiovigilance[17,18]

Regulatory responsibility continues throughout the commercial lifecycle of an IVD medical device. Post-market surveillance is necessary because certain problems may become apparent only after a product has been used extensively under routine clinical conditions.

Important post-market activities include adverse-event reporting, complaint investigation, trend analysis, CAPA, FSCA, product recalls, periodic safety evaluation, and maintenance of appropriate distribution and traceability records.

India's Materiovigilance Programme of India (MvPI) supports collection and evaluation of medical-device adverse events and contributes to regulatory decision-making.

Effective materiovigilance requires participation from manufacturers, importers, healthcare professionals, hospitals, patients, laboratories, and regulatory authorities. Under-reporting of adverse events and limited awareness of vigilance obligations remain significant areas requiring improvement.

Post-market information should also feed back into risk-management and quality systems. Emerging safety signals may therefore trigger investigation, CAPA, labelling changes, FSCA, or product recall.

10. International Harmonization[19,20]

The Indian regulatory system increasingly reflects internationally recognized medical-device principles. Important reference frameworks identified in the thesis include IMDRF principles, ISO 13485, ISO 14971, WHO guidance, and other internationally recognized approaches.

Nevertheless, differences remain between Indian requirements and regulatory systems such as the United States FDA framework and the European Union In Vitro Diagnostic Regulation. Consequently, manufacturers targeting multiple jurisdictions may need region-specific regulatory strategies and documentation.

Table 4: Broad Comparison of IVD Regulatory Approaches.

Parameter	India	United States	European Union
Principal regulator/system	CDSCO/CLA/SLA	US FDA	EU IVDR framework
Fundamental approach	Risk based	Risk based	Risk based
Indian classes	A–D	Different US device classification/pathways	A–D under IVDR
Quality system	Medical-device QMS requirements	FDA quality-system requirements	IVDR/QMS requirements
Performance evidence	Analytical and clinical performance	Performance evidence based on pathway/device	Scientific validity, analytical and clinical performance
Post-market monitoring	PMS/MvPI	FDA post-market controls	PMS/vigilance under IVDR
Major Indian electronic platform	SUGAM	FDA electronic systems	EU electronic regulatory systems

International harmonization can reduce duplication, facilitate global market access, encourage international trade, and improve confidence in Indian-manufactured diagnostic

devices. However, harmonization should preserve the ability of national authorities to respond to local public-health needs.

11. Current Regulatory Challenges[21,22]

Despite major progress following implementation of MDR, 2017, several practical challenges remain.

11.1 Regulatory Awareness

Start-ups, SMEs, and some domestic manufacturers may have limited familiarity with device classification, documentation, risk management, clinical performance, and post-market obligations. Regulatory misunderstandings can lead to incorrect classifications and deficient submissions.

11.2 Documentation Quality

Incomplete or inconsistent technical documentation remains a major source of regulatory queries. Particular difficulties can involve risk-management files, analytical or clinical performance evidence, stability data, labelling, and validation reports.

11.3 Clinical Performance Infrastructure

Generation of robust clinical evidence can be difficult because of limited access to appropriate samples, representative patient populations, accredited laboratories, multicentre infrastructure, and specialized expertise.

11.4 Approval Delays

Incomplete applications, incorrect classification, delayed responses to deficiency letters, insufficient evidence, and inspection scheduling can increase approval timelines.

11.5 Post-Market Surveillance

Under-reporting of adverse events, incomplete complaint investigations, inconsistent reporting practices, and delayed corrective actions can reduce the effectiveness of post-market surveillance.

11.6 Emerging Technologies

Artificial intelligence, machine learning, digital pathology, genomic diagnostics, next-generation sequencing, companion diagnostics, point-of-care molecular technologies, and

cloud-connected diagnostic platforms create new regulatory questions relating to software validation, cybersecurity, data integrity, algorithm transparency, and lifecycle management.

11.7 Skilled Workforce and Infrastructure

Continued growth of the IVD industry requires trained regulatory professionals, biomedical engineers, quality specialists, clinical researchers, and accredited testing facilities. Limited availability of specialized expertise can affect both industry compliance and regulatory efficiency.

12. Future Perspectives[23,24]

India's IVD regulatory framework is expected to continue evolving as diagnostic technology becomes increasingly digital, personalized, decentralized, and data driven.

12.1 Greater International Harmonization

Further alignment with IMDRF principles, ISO standards, WHO guidance, and internationally accepted regulatory practices could reduce duplication and facilitate international acceptance of Indian-manufactured products.

12.2 Regulatory Digitalization

The SUGAM portal has established an important foundation for electronic regulatory submissions. Further digitalization could support paperless dossiers, real-time application tracking, integrated regulatory databases, and more efficient regulatory review.

12.3 Strengthening Clinical Evidence

Greater emphasis on multicentre studies, diverse patient populations, real-world evidence, improved statistical methodology, and continuous performance monitoring could strengthen confidence in innovative diagnostic products.

12.4 Enhanced Materiovigilance

Electronic adverse-event reporting, active surveillance, data analytics for signal detection, integration with hospital systems, and improved communication between healthcare institutions and regulators could strengthen post-market monitoring.

12.5 Indigenous Manufacturing

Government initiatives including Make in India and Atmanirbhar Bharat provide opportunities to expand domestic IVD manufacturing. Regulatory capacity building should

develop in parallel so that increased domestic production is accompanied by robust quality, safety, and performance controls.

12.6 Artificial Intelligence and Digital Diagnostics

Future regulatory systems will increasingly need to address Software as a Medical Device, AI-based diagnostic algorithms, machine-learning validation, cybersecurity, data integrity, software updates, and lifecycle management.

Regulatory approaches should enable innovation while ensuring transparency, reproducibility, clinical validity, cybersecurity, and patient safety.

13. Recommendations[25,26]

Based on the regulatory issues identified in the source thesis, several measures could strengthen India's IVD regulatory ecosystem.

1. Periodically update regulatory guidance to address rapidly evolving diagnostic technologies.
2. Increase regulatory training and awareness among manufacturers, start-ups, healthcare professionals, and regulatory personnel.
3. Expand accredited laboratories and clinical performance evaluation centres.
4. Strengthen MvPI and encourage timely reporting of device-related adverse events.
5. Improve harmonization with internationally accepted regulatory principles and standards.
6. Continue digitalization of submissions and regulatory review processes.
7. Improve clarity and organization of technical-documentation expectations.
8. Strengthen training in ISO 13485 QMS and ISO 14971 risk management.
9. Develop specific regulatory approaches for AI, SaMD, genomic diagnostics, cybersecurity, and next-generation diagnostic technologies.
10. Encourage domestic innovation and manufacturing while maintaining rigorous evidence requirements for safety and performance.

14. CONCLUSION

In vitro diagnostic medical devices have become essential to disease detection, screening, monitoring, prognosis, and public-health decision-making. Their increasing technological complexity requires a regulatory system capable of balancing innovation, market access, and patient protection.

India has established a comprehensive risk-oriented framework through the Medical Devices Rules, 2017 and regulatory oversight by CDSCO. Classification into Classes A, B, C, and D allows regulatory controls to be proportionate to device risk. The approval pathway integrates risk classification, QMS implementation, technical documentation, analytical and clinical performance evaluation, risk management, electronic submission, regulatory review, licensing, and post-market monitoring.

ISO 13485-based quality systems and ISO 14971-based risk management provide important foundations for lifecycle control. Similarly, analytical and clinical performance evaluation provides the scientific evidence required to demonstrate reliable diagnostic performance. After commercialization, MvPI, adverse-event reporting, complaint handling, CAPA, FSCA, and recalls contribute to continued monitoring of device safety and performance.

Important challenges nevertheless remain, including documentation deficiencies, limited regulatory awareness, performance-evaluation constraints, approval delays, under-reporting of adverse events, infrastructure limitations, and rapidly evolving digital technologies. Continued harmonization, digitalization, stronger clinical evidence, improved materiovigilance, expanded regulatory capacity, and appropriate oversight of artificial intelligence and software-based diagnostics will be essential.

Overall, the Indian IVD regulatory framework provides a strong foundation for protecting public health while supporting innovation and domestic manufacturing. Continued modernization and convergence with internationally accepted principles can further improve regulatory efficiency, global competitiveness, and access to safe, reliable, and clinically effective diagnostic technologies.

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