



INDIA MEDICAL DEVICE REGULATORY MAP

A practical orientation for global RA teams entering the Indian market.



START HERE: WHAT IS THE PRODUCT IN INDIA? ▶

1 Confirm the Indian regulatory identity

Confirm the intended purpose, technology, and claims. Determine whether the device is invasive, active, software, implantable, sterile, or subject to special standards. Classify under the Medical Device Rules, 2017 and applicable standards notified.



Purpose & claims



Technology & type



Risk attributes



Standards & applicability

2 Choose the regulatory route

CLASS A



Low risk

Low individual and public health risk. Subject to basic controls.

CLASS B



Low–moderate risk

Low to moderate individual and public health risk. Requires additional controls over Class A.

CLASS C



Moderate–high risk

Moderate to high individual and public health risk. Requires greater scrutiny, performance data, and quality controls.

CLASS D



High risk

High individual and public health risk. Highest scrutiny with stringent quality, performance, and post-market controls.

Classification is based on the Fourth Schedule of the Medical Device Rules, 2017. Scrutiny, documentation, and review depth rise substantially from Class A/B to Class C/D.

3 Build the Indian market-access infrastructure



CDSCO / Medical Device Rules

Understand the Medical Device Rules, 2017, notified amendments, and circulars.



Indian Authorized Agent

Appoint an Indian Authorized Agent (mandatory) to act as liaison with CDSCO and be responsible for compliance and communications.



Import or Manufacturing Licence Setup

Obtain import licence (Form MD-15) for imported devices or manufacturing licence (Form MD-9) for Indian manufacturers as applicable.



Online Submission / Documentation Controls

Prepare e-submissions via the SUGAM portal. Establish document controls, versioning, and traceability.

4 Build the evidence stack



Administrative
Device description, intended use, class, standards, previous approvals, and regulatory history.



Quality / QMS
QMS aligned with ISO 13485 and applicable Indian requirements. Robust CAPA and supplier controls.



Safety & performance
Risk management, verification & validation, bench testing, and performance data.



Clinical evidence / usability
Clinical evaluation as applicable. Usability engineering and human factors evidence.



Labeling / claims
English labeling as per Rules. Claims aligned with evidence and permitted scope.



RA TRAP TO AVOID

Do not underestimate how classification, local agent setup, licence pathway (import vs. manufacture), and state vs. central expectations can affect timing and execution.



STRATEGIC INSIGHT

Early classification, strong Authorized Agent alignment, and a clean, standards-aligned technical file prevent avoidable queries and review cycles.



INDIA MEDICAL DEVICE: HOW THE WORK ACTUALLY FLOWS

From classification to commercialization — with the decision points a newer RA professional should watch.

A Program flow

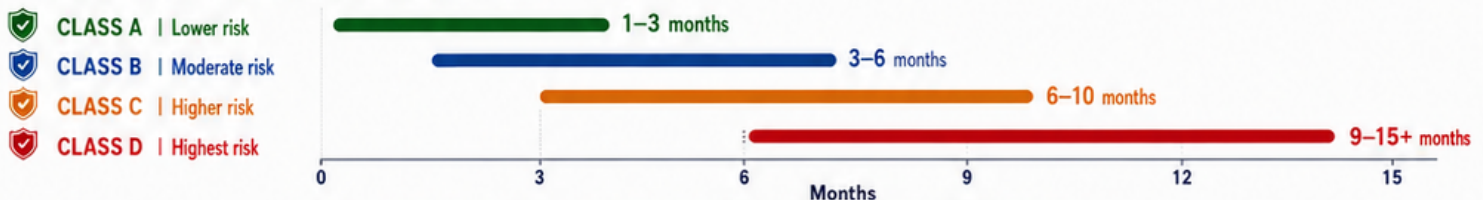


B What gets heavier as the class rises?

Signal	CLASS A	CLASS B	CLASS C	CLASS D
Pathway intensity	Low ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Evidence intensity	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Clinical support	Not usually required ● ● ● ● ●	Limited ● ● ● ● ●	Moderate ● ● ● ● ●	Extensive ● ● ● ● ●
QMS readiness	Basic ● ● ● ● ●	Moderate ● ● ● ● ●	High ● ● ● ● ●	Very high ● ● ● ● ●
Post-market control	Lower ● ● ● ● ●	Moderate ● ● ● ● ●	Higher ● ● ● ● ●	Highest ● ● ● ● ●

C Indicative route-based planning ranges

Planning ranges are Hopstone estimates based on typical experience and may vary by device complexity, evidence quality, completeness, workload, and CDSCO timelines.



These ranges are Hopstone planning estimates, not CDSCO promises. Actual times vary.

D Labeling & language essentials

EN English labeling / IFU All labeling and IFU must be in English. Use clear, accurate, and validated translations if used.	Authorized agent & import details Include name and address of Authorized Agent in India and importer details.	Claims control Claims must be supported by evidence and consistent with intended use.	Instructions / user information Provide complete instructions for safe use, indications and limitations.	Vigilance / PMS Include PMS plan, adverse event reporting, and customer complaint information.
---	---	---	--	--

E High-impact Indian decision points

Imported vs locally manufactured pathway setup Ensure correct pathway, documents, and labeling requirements from day one.	Software / connected devices Class and evidence change with intended use and data impact. Document rationale.	Sterile or implantable implications Expect additional sterility, biocompatibility, and performance evidence needs.	Stronger scrutiny for Class C / D Expect deeper review of clinical evidence, risk management, and QMS effectiveness.
---	---	--	--

F PRIMARY RESOURCES USED FOR THIS TRAINING AID

- CDSCO – Central Drugs Standard Control Organization
<https://cdsco.gov.in/medical-devices>
- Medical Devices Rules, 2017 (as amended)
<https://cdsco.gov.in/medical-device-rules-2017>
- SUGAM – CDSCO Online Portal
<https://sugam.cdsco.gov.in/>
- Hopstone Capital & Consulting – hopestonecapital.com



IMPORTANT

Current product-specific requirements and CDSCO guidance govern. Confirm classification, evidence, labeling, and submission obligations before execution.