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Knowledge Hub | Practitioner's Technical Guide

MEDICAL DEVICE PRODUCT DEVELOPMENT — A PRACTICAL PRIMER

From Concept to CDSCO Approval: A Guide for Indian Developers and Manufacturers

Covering MDR 2017 · CDSCO Classification · ISO 13485 · ISO 14971 · IEC 60601 · CE Marking · BIS

Introduction

Developing a medical device in India has never been more consequential — or more complex. India's medical device market is among the fastest-growing in Asia, and government policy under the Production Linked Incentive scheme and the Make in India initiative has created real commercial incentives for domestic development. At the same time, the regulatory environment has matured significantly: the Medical Device Rules 2017 and their subsequent amendments have created a structured, risk-based framework that demands genuine technical rigour from developers.

This guide is written for the team preparing to develop a medical device for the Indian market — whether you are a startup, an established manufacturer diversifying into healthcare, a hospital innovating a clinical solution, or a technology company applying digital capabilities to a regulated medical application. It covers the development process from concept to approval, the regulatory pathway under CDSCO, the international standards that govern medical device design and quality, and the specific considerations that the Indian context demands.

This guide is a primer, not a complete regulatory manual. Every device development programme has specific requirements that depend on the device's intended use, technology, risk class, and target markets. What this guide provides is the conceptual foundation and practical orientation that every development team needs before the detailed work begins.

SECTION 1 ■ WHAT IS A MEDICAL DEVICE UNDER INDIAN LAW

The definition that determines your regulatory obligations

The MDR 2017 Definition

Under the Medical Device Rules 2017, a ‘medical device’ means any instrument, apparatus, appliance, implant, material or other article — whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes — intended by the manufacturer to be used for human beings for one or more specific purposes. Those purposes include diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation or compensation for an injury or disability; investigation, replacement, modification or support of the anatomy or physiological process; supporting or sustaining life; and disinfection of medical devices.

The definition is broad, and the boundary between a medical device and a non-regulated product is not always immediately obvious. Software that analyses medical images is a medical device. Software that merely stores or transmits medical records may not be. A wearable that monitors heart rate for wellness purposes may not be a medical device; the same device marketed to detect atrial fibrillation almost certainly is. The intended use, as stated by the manufacturer, is determinative. Defining it carelessly is the most common early mistake in medical device development.

■ The Intended Use Trap

The single most consequential document in a medical device development programme is the Intended Use Statement. It determines your regulatory classification, your applicable standards, your clinical evidence requirements, and your labelling obligations. A vague or overly broad intended use statement does not reduce regulatory burden — it creates ambiguity that regulators will require you to resolve, typically at the worst possible moment in your programme.

Write the intended use statement with the precision of an engineer, the clarity of a clinician, and the awareness of a regulatory affairs professional. It is worth spending a full day on this document before anything else is designed.

What Is Notified Under MDR 2017

Not all products that meet the definition of a medical device are currently regulated under MDR 2017. The Rules apply to ‘notified’ devices — those listed in the schedules appended to the Rules. The list has expanded significantly since 2017 and continues to do so. As of 2025, CDSCO has introduced a new provision for manufacturers to apply for risk classification of devices not yet explicitly listed, providing a pathway for novel device categories. Developers of innovative devices should engage CDSCO early to confirm their regulatory status.

SECTION 2 ■ THE CDSCO CLASSIFICATION FRAMEWORK

How your device is classified — and what that classification demands

Risk-Based Classification: Classes A Through D

MDR 2017 classifies medical devices into four risk classes based on the degree of risk associated with the device's intended use, duration of contact with the patient, invasiveness, and dependence on a power source. Classification is determined by applying the classification rules set out in the First Schedule of the Rules. The class determines the regulatory pathway, the documentation requirements, the extent of clinical evidence required, and the applicable licence forms.

Class	Risk Level	Examples	Key Requirement
A	**Low**	Tongue depressors, bandages, non-sterile gloves, examination lights	Manufacturing licence; Form MD-3/MD-5; self-certification against applicable standards
A (Sterile/ Measuring)	**Low– Moderate**	Sterile gauze, sterile catheters, calibrated measuring devices	CDSCO import/manufacturing licence; sterility validation; calibration records
B	**Moderate**	Hypodermic needles, suction equipment, non-active surgical instruments, ultrasound gel	CDSCO licence (MD-14/MD-15); technical documentation; performance testing
C	**Moderate– High**	Ventilators, infusion pumps, bone fixation systems, diagnostic imaging systems	Full CDSCO licence; clinical data; ISO 13485 QMS; IEC 60601 / relevant IEC/ISO standards
D	**High**	Cardiac pacemakers, implantable neurostimulators, HIV diagnostic kits, spinal implants	Strictest pathway; CDSCO approval with clinical investigation; SEC review possible; mandatory ISO 13485

The Importance of Getting Classification Right

Misclassification is one of the most expensive errors in a medical device regulatory programme. Underclassifying a device — placing a Class C device in Class B, for example — will result in rejection of the application or post-approval enforcement action. Overclassifying unnecessarily increases development cost and timeline without regulatory benefit. Where classification is genuinely ambiguous, CDSCO now accepts formal risk classification applications. Use this mechanism. The cost of a formal classification determination is trivial compared to the cost of a misdirected development programme.

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For devices with borderline classification — particularly combination products, software-based devices, and devices with both diagnostic and therapeutic functions — engage a regulatory affairs specialist before the development programme is scoped. The classification determines the entire resource requirement of the programme. A Class B programme and a Class D programme for similar technology can differ by a factor of five in time and cost.

SECTION 3 ■ THE DEVELOPMENT PROCESS — STAGE BY STAGE

The ten phases that take a device from concept to approved product

The Regulatory Logic of Medical Device Development

Medical device development is not a linear engineering exercise followed by a regulatory submission. Regulatory requirements are embedded throughout the development process, from the first articulation of the intended use through to post-market surveillance after approval. The developer who treats regulation as a final step — something to address once the device is designed and built — will encounter regulatory requirements that require redesign, retest, and additional clinical evidence that could have been anticipated and planned for from the outset.

The table below maps the ten phases of a medical device development programme to the key regulatory and standards touchpoints at each stage.

Phase	Key Activities	Regulatory / Standards Touchpoint
1. Concept & User Needs	Define intended use, user population, clinical need, competitive landscape	*Establish regulatory strategy; confirm device classification; identify applicable standards*
2. Regulatory Strategy	Select target markets (India, EU, US, others); map CDSCO pathway; identify standards matrix	*CDSCO classification determination; MDR 2017 pathway; ISO 13485 QMS setup begins*
3. Design Inputs	Convert user needs to verifiable design requirements; establish PRD	*Design controls per ISO 13485; ISO 14971 risk analysis begins; IEC 62304 (if software)*
4. Concept Development	Generate and evaluate design concepts; select preferred concept	*FMEA at system level; ISO 14971 risk file; IEC 60601 architectural considerations*
5. Detailed Design	Engineering drawings, BOM, software architecture, IFU draft	*Design review; ISO 10993 biocompatibility assessment plan; IEC 62366 usability plan*
6. Verification & Validation	Design verification against design inputs; design validation with users	*Test protocols per applicable IEC/ISO standards; biocompatibility testing; usability studies*

7. Regulatory Submission	Compile Technical File / DHF; CDSCO application via SUGAM portal	*CDSCO Form MD-14 (Class A/B) or MD-15 (C/D); Device Master File; Plant Master File*
8. Clinical Evidence	Clinical evaluation report or clinical investigation as required	*ISO 14155 for investigations; literature review for CER; in-country performance evaluation for IVDs*
9. Manufacturing & QMS	Production readiness; process validation; supplier qualification	*ISO 13485 manufacturing controls; process validation per applicable standards; GMP audit-ready*
10. Post-Market Surveillance	Complaint handling; vigilance reporting; periodic safety update	*MDR 2017 post-market obligations; CDSCO adverse event reporting; ISO 13485 PMS procedures*

Phase 1: Concept and User Needs

Every medical device development programme begins with the articulation of a clinical need. The most common failure at this stage is insufficient depth of understanding of the user, the use environment, and the clinical problem. Developers who have a strong clinical insight into the problem they are solving make better design decisions throughout the programme and generate more relevant clinical evidence. Those who proceed on assumption about clinical need typically encounter it as a gap during design validation or, more expensively, in post-market use.

User needs must be captured from actual users in actual clinical environments. Structured interviews with clinicians, nurses, patients, and caregivers, combined with direct observation of the clinical workflow the device will enter, provide the foundation for all subsequent design decisions. In India specifically, it is important to understand the healthcare environment where the device will be used — public hospital infrastructure, primary health centre settings, and private hospital environments impose very different requirements on device design, durability, power supply, and maintenance accessibility.

Phase 2: Regulatory Strategy

Regulatory strategy for a medical device is not a document produced at the end of development. It is a decision made at the beginning that shapes every subsequent development choice. The regulatory strategy defines: the target markets (India first, or India plus CE/US in parallel), the CDSCO classification and applicable pathway, the international standards matrix applicable to the device, the clinical evidence strategy, and the Quality Management System structure.

For Indian developers targeting both domestic and export markets, a dual-track strategy — developing to international standards (ISO 13485, ISO 14971, IEC 60601) from the outset, while managing the CDSCO pathway in parallel — is almost always more efficient than developing for CDSCO first and retrofitting international requirements later. International standard compliance provides significant leverage in CDSCO applications, because CDSCO recognises approval from reference markets (EU, US, Canada, Australia, Japan, UK) as a basis for expedited review.

Phases 3–5: Design Inputs, Concept, and Detailed Design

Design controls are the heart of the medical device development process under ISO 13485 and MDR 2017. They require that user needs are translated into documented design inputs, that the design is developed against those inputs, that design outputs are verified against design inputs, and that the final design is validated against user needs. This traceability — from user need to design input to design output to verification and validation — is the fundamental discipline of medical device design control and the primary evidence reviewed by CDSCO and other regulators.

Risk management under ISO 14971 must begin at concept stage and continue throughout the programme. The Risk Management File — a living document that captures hazard identification, risk estimation, risk evaluation, risk control, and residual risk assessment — is not a deliverable produced at the end of development. It is a process document that grows with the programme. CDSCO reviewers for Class C and D devices examine the Risk Management File in detail.

For devices with embedded or standalone software, IEC 62304 requires a software development lifecycle process that mirrors the hardware design control process: software requirements specification, architectural design, unit design and implementation, verification at each level, and system testing. The safety class of the software (A, B, or C under the current standard) determines the stringency of development and documentation requirements.

Phase 6: Verification and Validation

Design verification confirms that the design outputs meet the design inputs. It is conducted under controlled, laboratory conditions against defined acceptance criteria. Design validation confirms that the device meets the user needs and intended use under actual or simulated conditions of use, with actual or representative users. Both are required. A device that passes verification but fails validation has met its own specification but not its users' needs — which is the more consequential failure.

Biocompatibility testing per ISO 10993-1 is required for any device that contacts the patient, directly or indirectly. The biological evaluation begins with a risk-based assessment of contact type (surface contact, externally communicating, implanted), duration (limited, prolonged, permanent), and material characterisation. Testing requirements derive from this assessment. For Indian developers, biocompatibility testing can be conducted at NABL-accredited laboratories in India and is accepted by CDSCO.

Usability engineering per IEC 62366-1 requires both formative evaluation (iterative testing during development to identify and correct use-related risks) and summative evaluation (formal testing of the final design with representative users). Usability failures are the leading cause of adverse events in medical device use globally. Regulators are increasingly scrutinising usability engineering documentation, particularly for devices used by patients or caregivers outside clinical settings.

Phase 7: CDSCO Regulatory Submission

The CDSCO application is submitted through the SUGAM online portal. The application form (MD-14 for import licences for Class A and B; MD-15 for Class C and D) must be accompanied by the Device Master File (DMF), the Plant Master File (PMF) for the manufacturing site, clinical data, and QMS certification documentation.

For imported devices, an Indian Authorised Agent (IAA) is mandatory. The IAA must hold a valid wholesale or manufacturing licence in India and acts as the regulatory point of contact with CDSCO. For Indian manufacturers, an ISO 13485-certified QMS is required for the manufacturing licence. Every manufacturing site requires a separate licence application.

Typical approval timelines are 6 to 9 months for well-documented Class B devices, and 9 to 18 months or more for Class C and D devices, particularly if a Subject Expert Committee (SEC) review is triggered. Applications that are incomplete, inconsistent in their data references, or do not align the labelling and intended use statement with the technical file will attract Queries from CDSCO that extend timelines significantly. Preparation quality determines timeline.

Phase 8: Clinical Evidence

CDSCO requires clinical evidence demonstrating the safety and performance of the device for its intended use. For most Class B and some Class C devices, this can be satisfied through a Clinical Evaluation Report (CER): a systematic literature review of clinical data from equivalent or similar devices, combined with clinical data from the device under development if available.

For novel devices, higher-risk Class C devices, and all Class D devices, a formal clinical investigation (clinical trial) under ISO 14155 may be required. CDSCO has emphasised in-country performance evaluation for Class B to D IVDs (in-vitro diagnostics), regardless of prior international approval. Indian developers should factor clinical investigation timelines into their programme planning: a properly conducted clinical investigation under ISO 14155 and Good Clinical Practice requirements typically takes 12 to 24 months from protocol approval to report completion.

■ The Clinical Evidence Gap

The most common cause of prolonged CDSCO review for Class C and D devices is inadequate or poorly structured clinical evidence. A literature review that merely summarises papers without critically appraising their relevance to the specific device, or a clinical investigation report that does not follow ISO 14155 structure, will generate extensive CDSCO queries.

The Clinical Evaluation Report is a regulatory document, not a scientific summary. It must demonstrate, with documented methodology, that the available clinical evidence — from literature, from equivalent devices, and from the device itself — is sufficient to support the claimed safety and performance profile. Engaging a qualified clinical affairs specialist for this document is not optional for Class C and D devices.

Phases 9–10: Manufacturing and Post-Market Surveillance

The Quality Management System established under ISO 13485 must be operational before a manufacturing licence is issued and must be maintained throughout the product's market life. It covers design and development controls, supplier qualification, incoming inspection, manufacturing process controls, final product release, distribution controls, complaint handling, and corrective and preventive action.

Post-market surveillance is not optional under MDR 2017. CDSCO requires adverse event reporting, periodic safety update reports for higher-risk devices, and complaint handling systems. Post-market

surveillance data feeds back into the Risk Management File and may require design changes, label updates, field safety corrective actions, or, in serious cases, recall. Building a functioning post-market surveillance system before first market release is a legal obligation and a patient safety imperative.

SECTION 4 ■ THE STANDARDS FRAMEWORK — A COMPREHENSIVE REFERENCE

The IEC, ISO, and BIS standards that govern medical device development

How Standards Work in Medical Device Regulation

International standards do not grant regulatory approval. They are the 'how' behind the regulatory 'what': they define the technical methods, the documentation disciplines, and the evidence structures that demonstrate a device is safe and performs as intended. Regulators — CDSCO, the FDA, and the European Notified Bodies — use compliance with recognised standards as the primary mechanism for assessing technical submissions.

Standards are categorised into three types. Horizontal standards apply broadly to most medical devices: ISO 13485, ISO 14971, IEC 62366-1, and ISO 15223-1 fall into this category. Semi-horizontal standards apply to devices sharing a particular technology or characteristic: IEC 60601-1 for all medical electrical equipment, IEC 62304 for all devices with software, ISO 10993 for all devices with patient contact. Vertical or particular standards apply to specific device types: IEC 60601-2-27 for cardiac monitoring equipment, IEC 60601-2-36 for intravascular ultrasound, and so on. A comprehensive standards matrix maps all three layers to every device.

Standard	Category	What It Requires of the Developer
ISO 13485:2016	**QMS**	Quality Management System for design, development, production, installation, and servicing of medical devices. Mandatory for CDSCO manufacturing licence. Covers document control, design control, corrective action, and post-market surveillance.
ISO 14971:2019	**Risk Management**	Systematic process for identifying hazards, estimating and evaluating risks, controlling risks, and monitoring effectiveness of controls across the entire product lifecycle. Foundational to all regulatory submissions worldwide.
IEC 60601-1:2005+AMD2:2020	**Electrical Safety**	General requirements for basic safety and essential performance of medical electrical equipment. Mandatory for all powered medical devices. Supplemented by collateral standards (60601-1-2 for EMC, 60601-1-6 for usability, 60601-1-11 for home care) and particular standards for specific device types.

IEC 62304:2006+AMD1:2015	**Software Lifecycle**	Software lifecycle processes for medical device software and software components. Defines safety classes A, B, C. Required for any device with embedded or standalone software. Update to 2nd Edition expected 2026.
ISO 10993 Series	**Biocompatibility**	Biological evaluation of medical devices. ISO 10993-1 guides the risk-based biocompatibility assessment framework. Relevant parts address cytotoxicity, sensitisation, genotoxicity, implantation, haemocompatibility, and chemical characterisation. Required for any device with patient contact.
IEC 62366-1:2015+AMD1:2020	**Usability Engineering**	Application of usability engineering to medical devices. Requires formative and summative usability evaluation. Addresses use-related risks and is increasingly scrutinised by regulators globally.
ISO 14155:2020	**Clinical Investigations**	Design, conduct, recording, and reporting of clinical investigations of medical devices in human subjects. Required when clinical data must be generated rather than sourced from literature or equivalent device data.
IEC 82304-1:2016	**Software as Medical Device**	Health software product safety and security. Applies to standalone software intended for use as a medical device (SaMD). Distinct from IEC 62304 which covers software embedded in hardware devices.
ISO 15223-1:2021	**Symbols & Labelling**	Symbols to be used with information to be supplied by the manufacturer. Defines the graphical symbols acceptable for use on labels, packaging, and in Instructions for Use.
CE Marking (EU MDR 2017/745)	**European Market**	Required for placing devices on the EU market. Classified under four risk classes (I, IIa, IIb, III). Technical Documentation, QMS, and for higher classes, involvement of a Notified Body. Provides significant regulatory leverage in CDSCO applications as a recognised reference market.
BIS (IS Standards)	**India — BIS**	Bureau of Indian Standards has IS standards for specific medical device categories. BIS certification (ISI mark) may be required for certain devices under Quality Control Orders. Check the latest BIS notifications for your device category.

The CE Mark and Its Value in India

CE marking under the EU Medical Device Regulation 2017/745 (EU MDR) is the most rigorous pre-market regulatory assessment available for medical devices, and it is recognised by CDSCO as reference market approval that can significantly reduce documentation requirements and expedite Indian regulatory review. For Indian developers with export ambitions, developing to CE Mark standard from the outset is almost always the correct strategy.

CE marking requires a Technical Documentation file structured around general safety and performance requirements, a complete QMS under ISO 13485, a rigorous clinical evaluation, and for Class IIa and above,

assessment by a European Notified Body. The investment is substantial. The commercial and regulatory return — access to the EU market and accelerated CDSCO approval — typically justifies it for any device with genuine export potential.

SECTION 5 ■ COMMON DEVELOPMENT PITFALLS — AND HOW TO AVOID THEM

The mistakes that cost Indian medical device developers most

Pitfall 1: Starting Design Before Regulatory Strategy Is Settled

The most expensive regulatory mistake is designing a device and then discovering that the design, as built, does not satisfy the regulatory pathway you need. Regulatory strategy must precede design work. The applicable standards, the classification, the clinical evidence requirements, and the target markets must all be known before the first engineering drawing is made.

Pitfall 2: Treating ISO 13485 as a Paperwork Exercise

ISO 13485 certification is required for a CDSCO manufacturing licence. Many Indian manufacturers obtain it through an intensive documentation exercise that creates a certified QMS on paper without embedding it in actual development practice. A QMS that exists in documents but not in behaviour will fail during a CDSCO facility inspection and will generate non-conformances during Notified Body audits for CE marking. More importantly, a QMS that is not genuinely followed does not protect patients.

Pitfall 3: Inadequate Risk Management from the Start

Risk management under ISO 14971 is a lifecycle activity. It begins at concept stage and continues through post-market surveillance. Developers who treat it as a deliverable to be completed before submission will produce a Risk Management File that does not accurately reflect the development history of the device, that has gaps in hazard coverage, and that does not demonstrate the risk-benefit analysis that regulators require. CDSCO reviewers for Class C and D devices are experienced in identifying these gaps.

Pitfall 4: Underestimating Clinical Evidence Requirements

Clinical evidence requirements for medical devices in India have increased materially since 2017 and continue to increase. Developers who budget only for a literature review, or who assume that Class B devices require no clinical data, frequently encounter CDSCO queries requesting additional clinical evidence that extends their timeline by six months or more. Build clinical evidence planning into the programme from the beginning.

Pitfall 5: Ignoring the Indian Use Environment

Devices designed for the controlled environment of a European hospital, then submitted for CDSCO approval without validation in Indian clinical settings, carry real risk of clinical failure after approval. India’s healthcare settings — variable power supply, high ambient temperatures and humidity, variable technical literacy of operators, and diverse patient populations — impose specific requirements that a device

developed and validated only in temperate, stable-power environments may not meet. This is not merely a regulatory concern. It is a patient safety concern.

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The five pitfalls above are avoidable. Every one of them is the consequence of starting the programme without adequate regulatory and quality systems expertise in the core team. Medical device development is not a domain where regulatory knowledge can be acquired as needed during the programme. It must be present at the programme's inception. The cost of regulatory expertise at the start of a programme is a fraction of the cost of a regulatory failure halfway through it.

Building a medical device for the Indian market?

This guide has given you the conceptual foundation. What it has not provided — by design — is the depth of implementation: the device-specific standards matrix for your technology, the precise CDSCO documentation requirements for your device class, the clinical evidence strategy appropriate to your device and market, and the QMS architecture that will satisfy both CDSCO and international regulators simultaneously.

INFINITY supports medical device developers through the complete development journey — from regulatory strategy and classification determination through design controls, risk management, standards compliance, clinical evidence planning, CDSCO submission, and manufacturing readiness. We combine deep regulatory knowledge with engineering and clinical expertise to help Indian developers build devices that are safe, approvable, and commercially viable.

Contact us at infinitynixai.com — let us help you build it right from the start.

Quick Reference: Key CDSCO Forms and Timelines

Form / Requirement	Applies To	Typical Timeline
MD-3	Manufacturing licence for Class A (non-sterile, non-measuring)	*State licensing authority; 30–90 days*
MD-5	Manufacturing licence for Class B devices	*CDSCO; 3–6 months*
MD-6 / MD-7	Manufacturing licence for Class C / Class D devices	*CDSCO; 6–18 months; SEC review may apply*
MD-14	Import licence for Class A (Sterile/Measuring) and Class B devices	*CDSCO; 6–9 months for complete applications*

MD-15	Import licence for Class C and D devices	*CDSCO; 9–18+ months; clinical review; SEC possible*
ISO 13485	QMS certification required for all manufacturing licences	*Certification audit: 3–6 months from QMS implementation*
SUGAM Portal	All CDSCO applications submitted online via sugammdonline.cdscoonline.gov.in	*Digital submission; online fee payment; document upload*

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CDSCO Regulatory Strategy · ISO 13485 QMS · Risk Management (ISO 14971) · Clinical Evaluation · CE Marking · IEC 60601 Compliance

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