MIIMD RESOURCE #001

India Medical Device Classification Navigator

Understand • Verify • Navigate • Explore

A practical, source-linked guide for navigating India's medical-device risk-classification information under the Medical Devices Rules, 2017.

MIIMD SOURCE CHECK

Last verified: 20 September 2026 | **Primary authority:** CDSCO | **Core framework:** Medical Devices Rules, 2017
Review cycle: Quarterly | **Next review:** December 2026

What this resource helps you do

• Understand the A–D risk-classification framework.

• Define the device and its intended use before searching classification information.

• Go directly from the CDSCO Medical Device & Diagnostics page to the risk-classification lookup.

• Use CDSCO's dated category-wise classification publications when the online lookup is not enough.

• Distinguish a final classification publication from a draft/open-comment item.

• Follow the official CDSCO route when a device is not found in published classification information.

• Verify the current position before using classification information for regulatory or licensing action.

IMPORTANT

MIIMD is not a regulator, certification body, legal adviser or regulatory adviser. MIIMD does not assign a risk class to a specific device and does not confirm regulatory compliance. This guide is a navigation aid; the current position must be verified directly with CDSCO.

Official starting points

→ CDSCO Medical Device & Diagnostics

→ Medical Devices Rules, 2017

→ CDSCO Risk Classification Approved Device Details

1. Before you start: define the product correctly

Classification depends on the device's intended use and the applicable classification parameters. Do not begin by guessing a class from the product name alone.

Record these details first

• **Product/device name:** the actual device or product name, not only the brand name.

• **Intended purpose:** what the manufacturer says the product is intended to do.

• **Medical purpose:** for example diagnosis, prevention, monitoring, treatment, alleviation, support of anatomy/physiology, or another purpose covered by the medical-device definition.

• **Device characteristics:** software, accessory, implant, invasive/non-invasive, sterile/non-sterile, measuring/non-measuring, single-use/reusable, powered/non-powered — record only what is actually applicable.

• **Manufacturer information:** use the manufacturer's own labelling, IFU/eIFU and relevant promotional material as applicable.

WHY THIS MATTERS

CDSCO's FAQ states that the Central Licensing Authority classifies medical devices based on intended use and the parameters in the First Schedule. CDSCO also states that its risk-classification list is dynamic.

→ Medical Devices Rules, 2017 — official CDSCO page

→ CDSCO Medical Device & Diagnostics

→ CDSCO Medical Device FAQ — classification section

2. First branch: is the product an IVD?

Before using the general medical-device classification lookup, decide whether the product is an **In Vitro Diagnostic Medical Device (IVD)**. IVDs use the Part II classification parameters of the First Schedule and have a separate CDSCO section and online classification provision.

STEP A	If it is an IVD
	Use the dedicated CDSCO IVD section and its classification resources. Do not use the general non-IVD path as a substitute.
	→ Open CDSCO In Vitro Diagnostics → Open CDSCO Public Notices
	Important: This Navigator's main path below is for non-IVD medical devices.

STEP B	If it is not an IVD
	Continue to Section 3 and use the non-IVD classification path.
	→ Open CDSCO Medical Device & Diagnostics

3. How to use this Navigator — exact click path

This section is deliberately specific. Each step tells you **where to go, what to click, what to look for, and what to record**. The aim is to avoid leaving the user to search the CDSCO website without direction.

START

Define the device + intended use.
Write down the device name and the manufacturer's intended use before searching. Use the labelling, IFU/eIFU and relevant promotional material as applicable. Then continue to the CDSCO risk-classification information.

→ MDR 2017 — official CDSCO page

→ CDSCO Medical Device & Diagnostics

STEP 1	Open CDSCO's Medical Device & Diagnostics section
	Go to the CDSCO Medical Device & Diagnostics page. On that page, scroll down to the heading **Approved Data**. Under Approved Data, CDSCO lists **Risk Classification Approved Device Details** and a separate **Risk Classification Approved Device Class A (NSNM) Details** entry.
	→ Open Medical Device & Diagnostics → Open Risk Classification Approved Device Details directly → Open Class A (NSNM) lookup directly
	Important: Do not stop at the Medical Device & Diagnostics landing page; the risk-classification lookup is the next destination.

STEP 2	Search the CDSCO risk-classification lookup
	The direct lookup page is titled **Risk Classification of Medical Devices under the MDR, 2017**. Use **Show All Categories** when you do not yet know the category. Use the search field to search the device/common device name or a relevant term. If a matching record appears, record the **Device Category, Device Name and Risk Class** shown by CDSCO.
	→ Open the CDSCO risk-classification lookup → Open the CDSCO online-system home
	Important: MIIMD does not assign or infer the class. Record the classification shown by CDSCO.

STEP 3	If the lookup is not enough, find the relevant category publication
	Open CDSCO's **Public Notices** page. Search for the device's **clinical/function area** and the classification notice title. Use the exact category title listed in Section 4 of this Navigator. For example, CDSCO has category publications for Dental, Gastroenterology, Neurological, Respiratory, Software, Cardiovascular, Interventional Radiology and others.
	→ Open CDSCO Public Notices → Open CDSCO Medical Device & Diagnostics classification source
	Important: Search by device function/clinical area rather than relying only on a brand name.

3. How to use this Navigator — continued

STEP 4	Check publication date and status
	Once you find a classification publication, check its **release/publication date**. Then check whether it is a final classification publication or a draft/open-comment document. Do not treat a draft as the final classification position.
	→ Open CDSCO Public Notices
	Important: CDSCO describes classification information as dynamic and subject to revision.

STEP 5	Device still not found? Use the official unlisted-device route
	If the device cannot be located in the published classification information, do not guess the risk class. Open CDSCO **Notifications** → **Circulars** and locate **S. No. 22**: *New provision for Risk Classification of Medical Devices on the CDSCO Online System for Medical Devices*, released **05 Dec 2025**. Then use the CDSCO Online System for the applicable risk-classification route.
	→ Open CDSCO Circulars → Open CDSCO Online System for Medical Devices
	Important: The circular concerns the Risk Classification Module for medical devices other than IVDs.

STEP 6	Verify the current position before acting
	Return to CDSCO's online risk-classification information and the latest relevant publications. Check whether a later category-specific publication exists. Use the verified CDSCO position—not an old copy, third-party summary or MIIMD inference—for regulatory or licensing decisions.
	→ Open CDSCO Risk Classification Approved Device Details → Open CDSCO Class A (NSNM) lookup → Open CDSCO Public Notices

THE DECISION PATH

Define device + intended use → Check IVD/non-IVD → CDSCO Risk Classification lookup → Category-specific publication if needed → Check date + final/draft status → If not found, use unlisted-device route → Verify current CDSCO position → Then act

What you should record before leaving the Navigator

- Device/common name used for the search.
- Manufacturer-stated intended use.
- CDSCO category identified.
- Risk class shown by CDSCO, if published.
- Exact CDSCO source document and publication date.
- Whether the source is final or draft/open-comment.
- Any later publication or online entry that changes the position.

4. Classification List Navigator — current and recent material

Use this section as a shortcut to the most recent classification material identified on the current CDSCO Medical Device & Diagnostics / Public Notices pages. **"Latest identified" means the latest publication located by MIIMD in the reviewed CDSCO sources as of 20 September 2026; it is not a CDSCO phrase.**

Material	Document date	Status / CDSCO listing	Official link
Oncology	02 Jan 2026	Latest identified	Open direct PDF
Radiotherapy	26 Nov 2025	Latest identified; CDSCO Public Notices release date: 27 Nov 2025	Open direct PDF
Interventional Radiology	26 Nov 2025	Latest identified; CDSCO Public Notices release date: 27 Nov 2025	Open direct PDF
Class A — non-sterile & non-measuring	31 Oct 2025	Latest identified	Open direct PDF
Cardiovascular + Neurological	01 Apr 2025	Draft / stakeholder comments	Open draft PDF
Merged existing Medical Devices risk-classification	01 Jan 2025	Consolidated reference; check later publications	CDSCO notice S. No. 111

Important about the dates: The current CDSCO Public Notices index lists the Radiotherapy and Interventional Radiology notices with a **release date of 27 Nov 2025**. The classification documents themselves are dated **26 Nov 2025**; this Navigator records the document date in the date column and retains the CDSCO release date in the status field.

Important about the merged classification: CDSCO's current Public Notices index identifies **S. No. 111 — Merged existing Medical Devices risk-classification — 01 Jan 2025**. The direct legacy PDF endpoint could not be independently re-verified in this final check, so the link intentionally goes to the official Public Notices index and identifies S. No. 111 rather than using an uncertain direct URL.

The January 2025 merged classification is useful as a consolidated reference, but later category-specific publications can supersede or update information for a category. Always check the later category-specific material and current online lookup.

→ Open the current CDSCO Medical Device & Diagnostics source page

→ Open the current CDSCO Public Notices index

5. Other category-wise classification lists identified by CDSCO

These are earlier category-specific classification publications identified on CDSCO's current Public Notices page. The table gives the exact CDSCO S. No. and release date shown by CDSCO. Where an exact historical PDF endpoint was re-verified, the link goes directly to that PDF. Otherwise, the link opens the official Public Notices index so the reader can locate the notice by S. No. or title.

CDSCO release date	CDSCO release date	S. No.	Open
Oncology	11 Oct 2022	188	CDSCO notice S. No. 188
Dental	10 Oct 2022	189	Direct PDF
Surgical Instruments	09 Sep 2022	195	CDSCO notice S. No. 195
Rehabilitation	04 Aug 2022	197	Direct PDF
Obstetrical & Gynecological	03 Jun 2022	204	Direct PDF
General Hospital	16 Mar 2022	210	CDSCO notice S. No. 210
Neurological	28 Sep 2021	225	CDSCO notice S. No. 225
Gastroenterology	27 Sep 2021	227	Direct PDF
Personal Protective Equipment	13 Sep 2021	230	CDSCO notice S. No. 230
Nephrology & Renal Care	13 Sep 2021	232	Direct PDF
Operation Theatre	13 Sep 2021	233	Direct PDF
Pain Management	13 Sep 2021	229	Direct PDF
Software	13 Sep 2021	231	CDSCO notice S. No. 231

How to use an index-linked entry: Open the official Public Notices page and use your browser's Find function (Ctrl+F / Cmd+F) for the S. No. or the exact category title. This is safer than relying on an unverified legacy PDF filename.

5. Other category-wise classification lists — continued

Category	CDSCO release date	S. No.	Open
Pediatrics & Neonatology	23 Aug 2021	244	CDSCO notice S. No. 244
Urology	23 Aug 2021	243	CDSCO notice S. No. 243
(CDSCO release date	09 Aug 2021	246	Direct PDF
Radiotherapy	06 Aug 2021	248	CDSCO notice S. No. 248
Respiratory	06 Aug 2021	249	Direct PDF
ENT	06 Aug 2021	250	CDSCO notice S. No. 250
Cardiovascular	26 Jul 2021	251	Direct PDF
Interventional Radiology	26 Jul 2021	255	Direct PDF
Physical Support	26 Jul 2021	254	Direct PDF
Dermatological & Plastic Surgery	26 Jul 2021	256	CDSCO notice S. No. 256
Anesthesiology	12 Jul 2021	258	CDSCO notice S. No. 258

Do not read the 2021–2022 list as automatically current. The purpose of this section is navigation. A category may have a later CDSCO publication. For example, Radiotherapy and Interventional Radiology have newer classification documents dated 26 Nov 2025 (listed by CDSCO with a 27 Nov 2025 release date), and Oncology has a newer 02 Jan 2026 publication. Use the recent-material table first and then the older category list when needed.

→ Open the CDSCO Public Notices index

6. Supporting official CDSCO resources

These links are included because classification questions often become confused with other regulatory concepts. Use the resource that matches the question rather than treating every CDSCO page as interchangeable.

Resource	Why open it	Official link
Medical Devices Rules, 2017	Core rules and amendments	Open official source
CDSCO Medical Device & Diagnostics	Main medical-device regulatory information page	Open official source
Risk Classification Approved Device Details	Online non-IVD risk-classification lookup	Open official source
Risk Classification Class A (NSNM) Details	Dedicated online Class A NSNM lookup	Open official source
CDSCO Public Notices	Dated classification notices and drafts	Open official source
CDSCO Circulars	Circulars including the unlisted-device Risk Classification Module	Open official source
CDSCO Online System for Medical Devices	Online medical-device system	Open official source
CDSCO Medical Device FAQ	FAQ including classification questions	Open official source
Medical Device Software Guidance 2026	Current software-specific guidance listed by CDSCO on 21 Jul 2026	Open official source
Medical Device Grouping FAQ	Grouping is separate from classification	Open official source
Regulatory Pathway under MDR-2017	Post-classification pathway reference	Open official source
CDSCO In Vitro Diagnostics	Separate IVD classification/regulatory section	Open official source

7. Common mistakes to avoid

• **Searching only by brand name:** classification information is generally organised around device/category concepts and intended use.

• **Guessing the class:** A–D labels alone are not enough; use the CDSCO-published classification or official route.

• **Treating a draft as final:** check whether the notice is a draft/open-comment item.

• **Using an old category list without checking later publications:** CDSCO states classification information is dynamic.

• **Confusing classification with grouping:** grouping is a separate regulatory concept.

• **Confusing classification with notified/regulated status:** these are related but not interchangeable questions.

• **Assuming EU MDR or US FDA classification carries over to India:** Indian classification must be checked under the Indian framework.

• **Assuming absence from one online lookup proves the device is unregulated or non-compliant:** absence from a particular lookup is not, by itself, proof.

8. Final verification checklist

1. I have defined the device and manufacturer's intended use.

2. I have confirmed whether the product is an IVD or non-IVD medical device.

3. I checked the CDSCO online risk-classification lookup.

4. I checked the relevant category-specific CDSCO publication where necessary.

5. I checked the publication date and whether a later category-specific publication exists.

6. I confirmed whether the source is final or draft/open-comment.

7. If the device was not listed, I used the official CDSCO unlisted-device route rather than guessing.

8. I have recorded the exact CDSCO source used.

9. I have re-verified the current position before taking a regulatory/licensing action.

MIIMD SOURCE NOTE

This resource was prepared using official CDSCO material reviewed by MIIMD on **20 September 2026**. The links are intended to take the reader directly to the relevant official page or document. For legacy category publications where a stable exact PDF endpoint was not independently re-verified during this final build, the link intentionally opens the official CDSCO Public Notices index and the exact S. No. is provided.

MIIMD DISCLAIMER

MIIMD — Make in India Medical Devices is a healthcare technology ecosystem platform focused on discovery, visibility and information related to India's medical-device industry. This resource is an information-navigation aid. It is not a substitute for the Medical Devices Rules, official CDSCO notifications, circulars or guidance, regulatory filings, decisions of competent authorities, or professional regulatory advice.

Explore the next layer

Once a device/category is understood, the natural next questions are: What products exist? Which Indian manufacturers make them? What technologies are available? Which ecosystem stakeholders may be relevant? This is where the MIIMD discovery layer can connect regulatory information to India's indigenous medical-device ecosystem.