INDIA MEDICAL DEVICES & EQUIPMENT MARKET ENTRY & BUSINESS ESTABLISHMENT

Frequently Asked Questions

A Primer for Japan-Based International & Multinational Companies

Overview

India is emerging as one of the most significant growth markets globally for medical devices, healthcare equipment and diagnostics. For Japan-based international and multinational companies, the Indian market presents substantial commercial opportunities across import, distribution, hospital procurement, technology partnerships, contract manufacturing, assembly operations, and long-term local manufacturing investment. The trade and investment relationship between India and Japan is further strengthened by the India–Japan Comprehensive Economic Partnership Agreement (**CEPA**), 2011, which establishes a framework for enhanced bilateral trade, investment, and economic cooperation. Among other benefits, CEPA provides preferential tariff treatment for eligible products, including many medical devices, subject to requisite compliances.

However, entering the Indian market requires careful navigation of a sophisticated and evolving legal, regulatory, tax, and commercial landscape spanning medical device approvals, customs and trade regulation, foreign investment and exchange control laws, corporate structuring, transfer pricing, indirect taxation, government incentives, labour compliance, and sector-specific manufacturing regulations.

This FAQ is intended to provide Japan-based medical device manufacturers, healthcare technology companies, exporters, distributors, and investors with a practical overview of the principal legal, regulatory, tax, and structuring considerations relevant to establishing, expanding, and commercialising operations in India, while also highlighting common risk areas, compliance expectations, and strategic considerations that typically arise during the India market entry process.

SECTION A — Understanding India's Medical Devices & Equipment Market

Q1. What impact does the India–Japan Comprehensive Economic Partnership Agreement (CEPA), 2011 have on a Japanese company selling medical devices into India?

The Comprehensive Economic Partnership Agreement (**CEPA**), 2011 between India and Japan, provides a framework for preferential trade and investment between the 2 (two) countries. For Japanese medical device manufacturers and exporters, CEPA offers customs duty benefits on eligible products and facilitate greater market access into India, subject to compliance with conditions provided therein.

- Preferential Tariff Treatment: Annexure 1 of CEPA provides for tariff concessions on a wide range of goods traded between India and Japan. Most medical devices fall under the B10 category of CEPA and subject to the applicable schedule commitments (such as submission of a valid certificate of origin evidencing Japanese origin), the medical products and devices may qualify for reduced customs duties upon import into India.
- Enhanced Market Access: By reducing tariff barriers and promoting bilateral trade, CEPA facilitates access for Japanese manufacturers seeking to supply medical devices to India's growing healthcare sector.
- Rules of Origin Compliance: To avail preferential tariff treatment under CEPA, imported products must satisfy the applicable rules of origin requirements and should be accompanied by the prescribed certificate of origin. Japanese manufacturers should therefore assess their supply chains and manufacturing processes to ensure that the relevant origin criteria are met.
- Supply Chain Optimisation: Companies that manufacture, assemble or source components across India and Japan may be able to structure their supply chains to take advantage of CEPA's preferential trade framework, subject to compliance with applicable customs and origin requirements.

Note: The availability and extent of tariff concessions under CEPA depend on the specific customs classification of the medical device and India's applicable tariff commitments under CEPA. Product-specific analysis is therefore recommended before relying on preferential treatment.

SECTION B — Regulatory Approvals: Getting Your Products Licensed in India

Q2. What is the legal and regulatory framework governing medical devices and equipment in India?

India's regulatory framework for medical devices is governed by the following laws and regulations, administered by the Central Drugs Standard Control Organization (**CDSCO**) under the Ministry of Health and Family Welfare and primarily includes:

Law / Body	Role
Drugs and Cosmetics Act, 1940 (DCA)	The Parent legislation under which medical devices are regulated as "drugs". It provides the legal basis for regulation, import, manufacture, and sale. Further, DCA empowers the Central Government to notify any device as a "medical device".
Drugs and Cosmetics Rules, 1945	Subordinate Rules under the DCA, which govern import, manufacture, licensing, and distribution of drugs and medical devices. These Rules continue to apply to medical devices, to the extent not superseded by MDR 2017.
Medical Devices Rules, 2017 (MDR 2017)	Primary regulatory framework for medical devices (effective from 1 January 2018). It provides for risk-based classification (Class A–D) and regulates licensing, import, manufacture, clinical investigation, post-market surveillance, and unique device identification.

Law / Body	Role
Medical Devices (Amendment) Rules, 2020	This Amendment expanded the ambit of coverage of MDR 2017 to all devices meeting the definition of a medical device, from 1 April 2020, and mandates registration with the CDSCO.
CDSCO	National Regulatory Authority under the Ministry of Health & Family Welfare. It acts as the Central Licensing Authority for medical devices and maintains SUGAM portal for processing of digital applications related to import license.
State Licensing Authorities (SLAs)	SLAs are the designated authorities for grant of manufacturing license for Class A and Class B medical devices.
Bureau of Indian Standards (BIS)	The BIS Act provides for the legal framework for mandatory certification, hallmarking, and conformity assessment of goods, processes, and systems to ensure quality, safety, and consumer protection. Where such certification is compulsory for a particular medical device, compliance with the same is mandatory.
National Pharmaceutical Pricing Authority (NPPA)	Regulates the ceiling price of notified medical devices under the Drugs (Prices Control) Order, 2013. Prices for non-notified devices remain market determined.

Q3. How are medical devices and equipment classified in India, and why does classification matter?

India uses a four-tier risk-based classification system under the Medical Devices Rules, 2017, modelled on the International Medical Device Regulators Forum (**IMDRF**) framework:

Class	Risk Level	Examples	Import License Authority
A	Low risk	Non-measuring and non-sterile devices	Exempted from license requirement and governed by Rule 19J of MDR 2017 requiring registration on the Online System for Medical Devices.
		Sterile or Measuring	Application to be filed with CDSCO in Form MD-14 and license received in Form MD-15.
B	Low–moderate risk	Hypodermic needles, suture needles, reusable surgical instruments, thermometers	Application to be filed with CDSCO in Form MD-14 and license received in Form MD-15.
C	Moderate–high risk	Haemodialysis machines, ventilators, CT scanners, infusion pumps	Application to be filed with CDSCO in Form MD-14 and license received in Form MD-15; longer timeline.
D	Highest risk	MRI machines, pacemakers, implantable cardiac defibrillators, LINACs, active implantable devices	Application to be filed with CDSCO in Form MD-14 and license received in Form MD-15; strictest requirements.

Classification matters because it determines: (a) the documentation required; (b) whether clinical data from India is needed; and (c) the timeline and cost of approval. Further, depending on the class of medical device,

obtaining an import license in Form MD-15 typically takes 9 months, based on the documentation and review of the same by the authorities.

Q4. What is the step-by-step process for overseas manufacturers in obtaining an import license to sell medical devices or equipment in India?

The import licensing process for a foreign manufacturer involves the following steps in sequence:

1. Appoint an Authorised Indian Agent: A foreign manufacturer must mandatorily designate an Indian entity as its regulatory agent in India i.e., the Authorised Agent. Such authorised agent must have a license to manufacture for sale or distribution or wholesale license for sale or distribution or registration certificate in Form MD-42 under MDR 2017. Further, a power of attorney is required to be signed with the Authorised Agent. The agent must countersign all documents submitted in the application, bear significant regulatory liability, and interface with CDSCO on the manufacturer's behalf.

2. Verify device classification: Confirm the device class using CDSCO's classification list (See Q3).

3. Compile the technical documents: Prepare and collate the documentation required to support the import application. This varies subject to the class for which application is being made, but primarily includes:

   (a) a notarised copy of overseas manufacturing site or establishment and a Free Sale Certificate (**FSC**) issued by the national regulatory authority or equivalent competent authority of the country concerned;
   (b) notarised copy of Quality Management System certificate or Full Quality Assurance certificate in respect of the manufacturing site;
   (c) self-attested copy of valid wholesale licence or manufacturing licence issued;
   (d) a copy of latest inspection or audit report carried out by Notified bodies or National Regulatory Authority or Competent Authority within last 3 years, if any;
   (e) Constitution details of domestic manufacturer or authorised agent;
   (f) Site or plant master file as specified;
   (g) Device master file as specified; and
   (h) BIS Certification for certain devices, subject to the type of medical device. This is to be affirmed by the Authorised Agent as to whether the application of the medical device requires such mandatory BIS Certification, etc.

4. Submit applications for import license: Applications for import licenses are to be made on the SUGAM Portal via Form MD-14 along with the prescribed fees under MDR 2017 and the relevant documents.

5. CDSCO review and queries: CDSCO typically issues queries at multiple rounds and may order evaluation or testing, if required. Accordingly, one must engage an authorised agent proactively to respond within timelines.

6. Grant of License: Upon approval, an import license in Form MD-15 is issued. This license is product and manufacturer specific. Each brand/model requires a separate fee and license. In the event of rejection, the applicant may appeal to the Central Government within a period of 45 (forty-five) days. Upon receipt of such appeal, the Central Government may pass orders within 90 (ninety) days.

7. Post-license obligations: Register the Unique Device Identifier (UDI) with CDSCO, comply with labelling requirements as provided under Rule 44 of MDR 2017, maintain post-market surveillance records and report adverse events promptly.

Q5. Are there any devices or equipment categories that are currently exempt from licensing, or that have a simplified process?

Yes. The following categories have reduced regulatory burden:

- Class A (non-measuring, non-sterile) Medical devices: All Class A (non-sterile and non-measuring) medical devices are exempt from obtaining an import license under MDR 2017, subject to the condition that the manufacturer or importer shall make registration of such devices. Such classes can make a self-declaration on the SUGAM portal. Examples include basic bandages, certain non-sterile instruments.

- Devices for export only: These devices must still hold an Indian manufacturing/import license but are not subject to domestic sale requirements such as labelling requirements under MDR 2017. They are obligated to comply with destination country regulations.
- Devices for clinical investigation or demonstration: Application via Form MD-16 (import for clinical investigation) provides a separate pathway from commercial import licensing.
- Outsourcing sterilisation: Recently, the Drugs Technical Advisory Board has recommended that manufacturers outsourcing sterilisation to a licensed third-party facility may not require a loan license, provided they use a facility already licensed under Form MD-3/4 or Form MD-9/10. However, the said recommendation has not been notified as a gazetted amendment yet.

Q6. What are the labelling requirements for medical devices and equipment sold in India?

Labels on medical devices sold in India must comply with Chapter VI of MDR 2017. Key requirements include:

- Mandatory label elements: A few mandatory label requirements include the device name; name and address of manufacturer; name and address of Indian authorised agent/ importer (for imported devices); batch/lot number or serial number; date of manufacture; expiry/shelf-life date (where applicable); storage and handling conditions; sterility status and sterilisation method; CDSCO import license number and any specific warnings or precautions.
- Unique Device Identifier (UDI): Rule 46 of the Medical Devices Rules, 2017 requires medical devices to bear a Unique Device Identifier (UDI). However, implementation has been phased by risk class through CDSCO notifications. UDI requirements are currently mandatory for Class C and Class D medical devices, while implementation for Class B and subsequently Class A devices is being rolled out in phases according to CDSCO's implementation timelines.
- Instructions for Use (IFU): This must be provided for, and an electronic IFU (eIFU) is permitted in some cases.

Q7. What is 'Software as a Medical Device' (SaMD) and how is it regulated in India?

Software as a Medical Device (**SaMD**) refers to standalone software intended for a medical purpose such as diagnosis, prediction, prevention, monitoring, or treatment, without being part of a physical medical device. This includes AI-driven diagnostic tools, clinical decision support systems, or remote patient monitoring platforms and is a critical and newly developing regulatory area in India.

- Regulatory position: Under MDR 2017 read with the DCA, the definition of medical device is broad enough to include within its ambit, software that performs a medical function.
- CDSCO Draft Guidance on Medical Device Software: On 21 October 2025, the CDSCO issued draft guidance distinguishing SaMD (standalone medical software) from SiMD (software integral to hardware devices). The draft aligns with IMDRF framework.
- Classification: SaMD is classified into four risk classes (A–D) based on clinical significance and the severity of the healthcare context.
- Licensing: Manufacturing Licensing applications for Class A/B SaMD are to be made to the SLAs and Class C/D SaMD to the CDSCO. However, import licenses of all classes are to be made to the CDSCO.
- Applications: Medical device software is subject to the same quality management, safety, and post-market surveillance requirements applicable to other medical devices under MDR 2017.

SECTION C — Import, Customs, and Trade Regulations

Q8. What customs duties and import taxes apply to medical devices and equipment imported from Japan into India?

Japan is one of the most strategically important sources of medical equipment in India. About 27 Japanese healthcare companies have a notable presence in India, with 17 operating commercially through trade and 10 running manufacturing facilities. As of 2026, approximately 90% of Indian tariff lines for Japanese goods are at 0% or significantly reduced rates:

Charge	Typical Rate	Notes
Basic Customs Duty (**BCD**)	0% (under CEPA)	Most medical devices and equipment attract 0% BCD. However, some sub-components attract 7.5%, creating an inverted duty structure that paradoxically favours finished imports over domestic manufacturing.
Social Welfare Surcharge (SWS)	10% on BCD (0%)	Applicable on the BCD amount, not the assessable value.
IGST (Integrated Goods and Services Tax) on imports	5% or 12% or 18%	Replaces Countervailing Duty (**CVD**) and Special Additional Duty (**SAD**). Most medical devices attract 12% IGST; some attract 5% or 18%. IGST paid on import is generally creditable as Input Tax Credit (**ITC**) against output GST liability (see Q11).
Health Cess	5% on Assessable Value	Levied on specified medical devices since Finance Act 2020.
Customs Handling Fees / Port Charges	Variable	Port-specific and costs 1–3% of Cost, Insurance, and Freight (**CIF**) value.
Total effective duty burden (indicative)	Approx. 10 to 15%	Varies significantly by HS code and device category. IGST is recoverable as ITC; BCD, SWS, and Health Cess are not.

For medical devices specifically, the picture is favourable because most products fall under Chapters 90 (medical/optical), 30 (medicaments), and 28 (chemicals) i.e., categories where India committed to substantial duty reduction:

Product Category	HSN	MFN BCD (RoW)	India-Japan CEPA BCD
MRI machines, CT scanners	9018.13 / 9022.12	7.5%	**0%**
X-ray apparatus	9022.14 / 9022.19	10-15%	**0%**
Endoscopes (Olympus, Pentax, Hoya)	9018.19	7.5%	**0%**
Ultrasound machines	9018.12	7.5%	**0%**
ECG, patient monitors (Nihon Kohden, Fukuda)	9018.11	7.5%	**0%**
Dialysers, dialysis machines (Nipro, Terumo)	9018.90	7.5%	**0%**
Catheters, stents (Terumo)	9018.39 / 9021.90	7.5%	**0%**
Orthopaedic implants	9021.10 / 9021.31	7.5%	**0%**
Hearing aids	9021.40	0%	**0%**
IVD reagents (Sysmex)	3822	10%	**0% or phased**
BP monitors, glucometers (Omron)	9018.19 / 9027	7.5%	**0%**
Surgical instruments	9018.31 / 9018.32	7.5%	**0%**

IGST will continue to apply as it is a domestic tax (not a trade measure) and is outside the CEPA's scope. However, reduction in BCD will still have significant impact on IGST as the base for calculation of IGST also includes BCD. An illustrative table is provided below:

Duty Component	Rate (MFN)	Amount (INR)	Rate on CEPA	Amount (INR)
Assessable Value	—	1,00,00,000 (approx. USD 105,842)	—	1,00,00,000 (approx. USD 105,842)
BCD	7.5%	750,000 (approx. USD 7,938)	0%	0
Health Cess	5% on Assessable Value	5,00,000 (approx. USD 5,298)	5% on AV	5,00,000 (approx. USD 5,298)
SWS	10% on BCD	75,000 (approx. USD 794)	0% on BCD (becomes nil because BCD is nil)	0
Sub-total (AV + duties)	—	1,13,25,000 (approx. USD 119,866)	—	1,05,00,000 (approx. USD 1,11,135)
IGST	5%	5,66,250 (approx. USD 5,993)	5%	5,25,000(approx. USD 5,557)

Total landed duty	—	18,91,250 (approx. USD 20,017)	—	10,25,000 (approx. USD 10,848)
Effective duty rate	~19%		~10%	

For the benefits to be available, Rules of Origin implemented through the Customs (Administration of Rules of Origin under Trade Agreements) Rules, 2020 (**CAROTAR**) need to be complied with. The Japanese issuing bodies are Japan External Trade Organization (**JETRO**) and authorised Japan Chambers of Commerce and Industry (**JCCI**).

Whereas earlier a stamped Certificate of Origin from the exporting country's chamber was largely treated as conclusive, CAROTAR has shifted the burden: a basic level of due diligence on the part of an importer to satisfy itself that the claimed originating criteria have been met and that mere submission of a Certificate of Origin may not be sufficient. Recently, a March 2025 amendment also replaced the term "Certificate of Origin" under CAROTAR with the broader term "Proof of Origin."

For Japanese medical device imports, this means the Indian importer cannot simply rely on the Certificate of Origin, they must maintain records demonstrating the bona fide Japanese origin of the goods. For MNCs (Japanese subsidiaries' Indian arms), this is easier; for distributor-led imports, this needs structured documentation cooperation with the Japanese exporter.

For hospitals importing complete medical device packages for new/expansion projects under approved heads, the Project Imports Regulations, 1986 allow concessional BCD (currently 7.5%) on the entire bundle. Thus, while CEPA continues to dominate, but Project Imports gives an additional pathway for mixed-origin bundles.

Q9. What is the HS code classification system in India and how does one find the right code for a product?

India uses the Harmonised System of Nomenclature (**HSN**) for customs classification, aligned with the WTO Harmonised System but with Indian-specific sub-classifications at the 8-digit level. Correct HS code classification is critical because it determines: (a) the applicable customs duty rate; (b) whether BIS QCOs apply; (c) eligibility for CEPA preferential tariffs; and (d) IGST rate (similar HSN applicable under GST as well).

- Chapter 90 of the Indian Customs Tariff: Most medical instruments, apparatus, and equipment fall under Chapter 90 (HS 90.xx). Specific headings include: 9018 (instruments and apparatus for medical use); 9019 (mechano-therapy, massage, psychological aptitude-testing apparatus); 9021 (orthopaedic appliances; splints; artificial parts of body; hearing aids; pacemakers); 9022 (X-ray and radiation apparatus); 9027 (instruments for physical or chemical analysis).
- Chapter 84 and 85: Some equipment with both medical and industrial applications (e.g., certain centrifuges, pumps, electronics) may be classified under Chapter 84 (machinery) or Chapter 85 (electrical equipment), with different duty rates.
- IVD Reagents and Consumables: Typically, under Chapter 38 (miscellaneous chemical products) or Chapter 30 (pharmaceutical products).
- Software (SaMD): Currently classified under service codes for GST purposes, however this is an evolving position.

Q10. Are there any import restrictions, prohibitions, or mandatory certification requirements that apply to medical devices entering India?

Yes, in addition to obtaining the CDSCO import license under MDR 2017, certain regulatory approvals and compliance requirements are mandatory for market entry, including the following:

- Refurbished / Second-Hand Equipment: CDSCO has stated that import of refurbished/ second hand medical devices for commercial sale is not permitted for commercial sale under the current regulatory regime.
- Hazardous Materials: Devices containing radioactive materials, certain lithium batteries, or certain chemicals are subject to additional approvals from the Atomic Energy Regulatory Board (AERB) and/or the Ministry of Environment, Forest and Climate Change (MoEFCC), subject to the nature of risk.
- Clinical investigation devices: Devices imported for clinical trials or demonstration (not commercial sale) require prior approval in application Form MD-16 from CDSCO.

- Import of samples: Small quantities for demonstration or testing purposes require a separate CDSCO permission via an application in Form MD-16.

Q11. What is GST and how does it apply to medical devices and equipment sold in India?

India's Goods and Services Tax (**GST**) is a comprehensive indirect tax that replaced multiple earlier levies (VAT, CST, service tax, excise duty) from July 2017. For a foreign company selling medical devices in India, whether through an Indian subsidiary, distributor, or directly, GST is the primary domestic indirect tax:

- GST rates for medical devices and equipment: GST was levied at four different slabs 0%, 5%, 12%, or 18% depending on the product. Most medical devices attracted 12% GST. Life-saving devices and certain equipment attracted 5%. Some non-medical supplies bundled with devices may attract 18%. However, a recent reform with effect from September 2025 has further consolidated the tax slabs as follows:

Category	HSN / Services Accounting Code (SAC)	GST Rate (post-Sept 2025)	Pre-reform Rate (post 18 July 2022 and pre-Sept 2025)
Diagnostic imaging — MRI, CT, X-ray, ultrasound, mammography	9018 / 9022	5%	12–18%
Ventilators, BiPAP, oxygen concentrators	9019	5%	12%
Medical oxygen	28044010	5% (effectively Nil for hospital supply)	12%
PPE — surgical/N95 masks, surgical gloves, gowns	6210 / 4015 / 6307	5% (most medical grade)	5–12%
IVD reagents, test kits, diagnostic kits, glucometers, strips	3822 / 9027	5%	12%-18%
Wadding, gauze, bandages, dressings, syringes, needles	3005 / 9018	5%	12%
Orthopaedic implants, artificial joints, fracture appliances	9021	5%	5% (unchanged)
Hearing aids	9021.40	Nil (0%)	0% (unchanged)
Dental equipment, drills, dental chairs, dental instruments	9018.41 / 9018.49	5%	18%
Hospital beds, stretchers, operating tables, medical furniture	9402	18%	18% (unchanged)
Spectacles, contact lenses, frames	9001/9003/9004	5–18% (varies)	5–18%

Category	HSN / Services Accounting Code (SAC)	GST Rate (post-Sept 2025)	Pre-reform Rate (post 18 July 2022 and pre-Sept 2025)
Software / SaMD / SaaS (incl. PACS, RIS, AI diagnostic software)	SAC 998314 / 997331	18%	18% (unchanged)

- Input Tax Credit (ITC): GST continues to adopt the principles of value-added taxation and consequential, credit mechanism. In other words, GST paid on purchases (including IGST paid on imports) can be credited set-off against GST collected payable on sales, provided the recipient is GST-registered and the supply is for a taxable supply in furtherance of business purposes.

- GST Registration: Any entity (including a foreign entity with a fixed establishment in India) supplying goods or services with annual turnover above INR 40 lakhs (approx. USD 42,337) (INR 20 lakhs (approx. USD 21,169) for services) must register for GST. There may be other exceptional circumstances where registration under GST may be compulsory.

- IGST on imports: Imports are subject to IGST (at the same rate as domestic supply). This IGST is fully creditable as ITC by the Indian importer.

SECTION D — Business Structures: When and How to Establish a Presence in India

Q12. What are the options for a Japanese company to sell medical devices in India, and when should it remain export-only versus establishing a presence in India?

A Japanese company has four broad structural options, each suited to a different stage of market development:

Structure	How It Works	Best Suited For
Export-Only (via Indian Distributor)	Japanese company sells to an independent Indian distributor who holds the import license as the authorised agent and stocks, sells and provides services in India.	Early-stage market testing; low-volume, high-value capital equipment; when local presence is not yet commercially justified and testing of demand before committing capital.
Liaison Office (LO)	A representative office established with approval from Reserve Bank of India (**RBI)** that can only undertake market research, promotion, and communication with no commercial activity or revenue generation.	Regulatory monitoring, relationship building and market intelligence gathering. Not suitable for revenue generation or commercial contracts.
Wholly Owned Indian Subsidiary (WOS)	A private limited company incorporated in India under the Companies Act, 2013 which would be 100% owned by the Japanese parent company. It can trade, import, assemble, manufacture, invoice, and sign contracts in India.	Suitable when commercial volumes justify a local presence; when tender participation is important and when post-sale service is critical. This is the most suitable vehicle for long-term purposes.
Joint Venture (JV) with Indian Partner	A private limited company jointly owned by the Japanese company and an Indian partner. Brings local manufacturing,	Suitable for when local manufacturing or assembly is planned; when government hospital penetration requires local credentials and when

Structure	How It Works	Best Suited For
	distribution, regulatory relationships, and government access.	technology transfer is part of the strategy.

The progression typically follows: Export → Liaison Office (optional) → Wholly Owned Subsidiary → Joint Venture/Manufacturing. The decision at each stage is driven by a combination of commercial, legal, tax, and regulatory considerations described in Q13–Q16.

Q13. How does a Japanese company incorporate a Wholly Owned Subsidiary (WOS) in India? What are the key steps and requirements?

Incorporating a private limited company in India as a WOS of a foreign entity involves the following steps:

1. Name reservation: File the proposed company name on the Ministry of Corporate Affairs portal. The name must comply with the statutory naming rules of Companies Act, 2013 and its applicable rules (Companies (Incorporation) Rules, 2014).
2. Digital Signature Certificate (**DSC**): All proposed directors must obtain a DSC from the certifying authority for the purposes of affixing their digital signature to all the necessary documents.
3. Director Identification Number (**DIN**): Each director must hold a DIN and apply for the same at the time of incorporation.
4. Incorporation filing (SPICe+ form): File the integrated SPICe+ form on the MCA portal and attach the Memorandum of Association (**MoA**), Articles of Association (**AoA)** and subscriber and Director details. Once successfully incorporated, the company shall receive its Certificate of Incorporation.
5. FDI approval (if applicable): 100% Foreign Direct Investment (**FDI**) is permitted under the automatic route for medical devices, i.e. no prior government approval is required. The investment must be reported to the RBI within 30 days of receipt of funds via the FIRMS portal.
6. PAN and TAN: Permanent Account Number (**PAN**) and Tax Deduction and Collection Account Number (**TAN**) from the Income Tax Department, are automatically obtained upon incorporation of company and are reflected in the Certificate of Incorporation
7. Goods and Services Tax (GST) registration: Register for GST on the GST portal before commencing taxable supply.
8. Import–Export Code (IEC): Obtaining an IEC from the Directorate General of Foreign Trade (DGFT) is mandatory for any entity engaging in import or export.
9. Set up under MDR 2017: The Indian WOS will now act as the authorised agent (or appoint a regulatory affairs firm) and obtain fresh import licenses in the WOS's name as per the due process set out in Question 4.

Other factors, to consider include:

- Minimum number of directors: At least 2 directors for a private limited company and at least 1 out of them must be a resident Indian Director (resident in India for at least 182 days during the financial year) are required.
- Share capital: No minimum paid-up capital requirement for a private limited company in India.
- Timeline: Typically, 3–6 weeks for incorporation, longer if name issues arise or FDI reporting is complex or in case of any other comments from the registrar of companies (RoC).

Q14. What is a Joint Venture (JV) structure and when is it preferable to a Wholly Owned Subsidiary?

A Joint Venture in India is typically structured as a private limited company (or occasionally a limited liability partnership (LLP)) jointly owned by the Japanese company and one or more Indian partners. The JV structure is suited to the following scenarios:

- Manufacturing or assembly: Access to government incentives (e.g., Product Linked Incentive schemes), state-level benefits, and procurement preferences are stronger when there is an Indian manufacturing partner bringing local regulatory approvals, established manufacturing infrastructure, and workforce.

- Distribution network: A strong Indian distribution partner may bring an established hospital network, regulatory relationships, and geographic reach that a WOS would take years to build.
- Government relations: Some government procurement preferences, and access to Medical Device Park allocations, are more easily obtained with an Indian co-promoter.
- Technology transfer: The Japanese company may transfer technology to a JV while the Indian partner contributes manufacturing, land, local regulatory approvals, and distribution.

Key JV structuring considerations:

- Shareholding: JV agreements should clearly specify the Japanese company's shareholding (typically 51–74% for operational control) and the Indian partner's contribution (cash, land, licenses, distribution).
- Board composition: Clearly define board seats, quorum, reserved matters requiring higher majority or unanimity (e.g., IP transfers, key appointments, business plan changes).
- IP protection: The JV agreement must clearly delineate whether IP is licensed or assigned, royalty payment terms, usage structure and post termination rights.
- Non-compete and lock-in: Essential to prevent misuse of technical know-how by the Indian partner.
- Exit mechanisms: Clauses such as Tag-along, drag-along, put/call options, right of first refusal and right of first offer, are critical to manage deadlock and exits scenarios.

Q15. What is a Liaison Office (LO) and when is it the right structure?

A Liaison Office (also called a Representative Office) is a limited-purpose presence that allows a foreign company to maintain a physical presence in India for specific permitted activities only and without generating revenue or conducting commercial business in India.

- Permitted activities: Market research, promotion of parent company's products and services, acting as a communication channel between parent and Indian customers, collecting information and promoting technical/financial collaborations.
- Not permitted: Signing commercial contracts in its own name, invoicing, collecting revenue, importing goods in its own right, or manufacturing.
- Application: Applications from foreign companies for establishing a LO shall be considered by the AD Category-I bank as per the guidelines given by RBI. The validity period of an LO is generally for 3 (three) years, and such validity may be extended.
- Annual compliance: An Annual Activity Certificate (**AAC**) must be filed with the Authorised Dealer bank and a copy to the Directorate General of Income Tax (International Taxation), New Delhi.
- Funding: The LO is funded entirely by remittances from the foreign parent. It cannot generate revenue in India.

The LO is appropriate for a Japanese medical device company that wants to build physical relationships, attend conferences, support CDSCO regulatory activities, and gather market intelligence, without committing to a full commercial structure. It is often a transitional step before WOS / JV incorporation.

Q16. What are the key direct taxes applicable to an Indian Wholly Owned Subsidiary or JV of a Japanese medical device company?

The principal direct tax applicable to an Indian company (WOS or JV) is Indian corporate income tax levied under the Income-tax Act, 2025 (**ITA 2025**), which replaces the erstwhile Income-tax Act, 1961 (**ITA 1961**):

Tax / Levy	Rate (AY 2026-27 / Tax Year 2026-27)	Notes
Corporate Income Tax - domestic companies - concessional regime	22% + 10% surcharge + 4% cess = effective 25.17%	Under Section 200 of the ITA 2025) (erstwhile Section 115BAA of the ITA 1961) -optional lower rate for companies foregoing certain deductions

Tax / Levy	Rate (AY 2026-27 / Tax Year 2026-27)	Notes
Corporate Income Tax -new manufacturing companies (Section 201 of the ITA 2025) (erstwhile Section 115BAB of the ITA 1961)	15% + surcharge + cess *15% tax rate is only applicable on income from manufacturing operations	For new companies incorporated on or after 1 Oct 2019 and commencing manufacturing before a specified date - optional lower rate for companies foregoing certain deductions. *Specified date for the purpose of this Section is 31 March 2024
Standard corporate tax rate (companies not opting for concessional rates)	30% + surcharge + cess	Newly incorporated companies prefer the concessional tax rates under Section 200/ 201 of the ITA 2025 (erstwhile Section 115BAA/ 115BAB of the ITA 1961).
Minimum Alternate Tax (MAT)	14% of book profits + surcharge + cess	Not applicable if the company opts for Section 200/ 201 of the ITA 2025 (erstwhile Section 115BAA/ 115BAB of the ITA 1961).
Dividend Distribution Tax	Abolished (Finance Act 2020)	Dividends are now taxable in the hands of shareholders.
Capital Gains Tax (updated per Finance Act 2024, effective 23 July 2024)	LTCG (listed equity): 12.5% (on gains exceeding INR 1,25,000 (approx. USD 1,323) LTCG (unlisted): 12.5% (no indexation benefits) STCG: 20% (listed equity) / slab rates (unlisted) *Plus surcharge and cess at the applicable rates	-

Taxation of Income received by Japanese Parent Companies from Indian WOS or JV

The following table sets out the applicable tax rates and withholding tax obligations in respect of key categories of income earned by a foreign company from its Indian WOS or JV.

Income Type	Applicable Rate	Taxability and Tax Deduction at Source (TDS)
Dividend/ Royalty/ Fees for Technical Services/ Interest income on moneys borrowed in foreign currency	20% (plus applicable surcharge and cess) As per Section 207 of the ITA 2025 (erstwhile Section 115A of the ITA 1961)	Such income shall be taxable in the hands of the Foreign Company at rates specified in this table or such other lower rate as prescribed under the relevant DTAA (see Q18) The Indian JV/WOS shall withhold taxes as per the above rates at the time of accrual / payment whichever is earlier.

Income Type	Applicable Rate	Taxability and Tax Deduction at Source (TDS)
Capital Gains on sale of Indian WOS or JV shares	LTCG (listed equity): 12.5% (on gains exceeding INR 1,25,000 (approx. USD 1,323) LTCG (unlisted): 12.5% (no indexation benefits) STCG: 20% (listed equity) / slab rates (unlisted) *Plus, surcharge and cess at the applicable rates	Such income shall be taxable in the hands of the Foreign Company at rates specified in this table or such other lower rate as prescribed under the relevant DTAA (see Q18) The Indian JV/WOS shall withhold taxes as per the above rates at the time of accrual / payment whichever is earlier.

- **Tax Deduction at Source (TDS):** Indian companies shall withhold tax at source on payments to resident and non-resident parties. Key TDS rates applicable to medical device businesses: professional fees (10%), rent (2% or 10% depending on the nature), salaries (slab rates), payments to non-residents (varying rates, subject to DTAA).
- **Goods and Services Tax (GST):** The WOS/JV shall collect GST from customers and remit it to the government. GST registration is mandatory above the turnover threshold (see Q11).
- **Transfer Pricing:** All transactions between the Indian WOS/JV and the Japanese parent (including product imports, management fees, royalties, loans) shall be at 'arm's length' basis and are subject to Indian Transfer Pricing rules under Sections 161-173 of the ITA 2025 (erstwhile Sections 92-92F of the ITA 1961). This is a major compliance area - See Q19.

SECTION E — Transfer Pricing, Double Tax Treaties, and Cross-Border Payments

Q17. What is 'Permanent Establishment' (PE) risk and why should a Japanese company manage it carefully?

Permanent Establishment (**PE**) is a concept under international tax law and India's Double Taxation Avoidance Agreements (**DTAAs**) that determines when a foreign company has sufficient presence in India to be taxed in India on business profits even without incorporating an Indian entity.

PE risk arises for Japanese medical device companies in the following common situations:

- Fixed Place PE: If the Japanese company's personnel operate from a fixed location in India (e.g., an office, warehouse, or a customer's premises) regularly and habitually, even informally, the Japanese company may have a PE. This could make its Indian-source profits taxable in India at the full corporate tax rate.

- Agency PE: If an Indian distributor or agent is 'dependent' on the Japanese company (e.g., operates exclusively or mainly for the Japanese company, has authority to conclude contracts on its behalf), the Japanese company may have an Agency PE in India.

- Liaison Office PE (in case if the Japanese company puts up a Liaison Office (LO) prior to forming a WOS or JV): If LO personnel go beyond permitted activities (market research) and begin concluding contracts or making decisions that bind the parent, the LO creates a PE.

An important development under Section 9(9) of ITA 2025 (erstwhile Explanation 2A to Section 9(1)(i) of ITA 1961) is the codification of Significant Economic Presence (**SEP**) as a form of business connection. A non-resident may be deemed to have a business connection in India on account of SEP if it: (a) has transactions in respect of any goods, services, or property in India exceeding INR 20 million (approx. USD 211,712); or (b) has a systematic and continuous soliciting of its business activities or engaging with users in India. While SEP exists in domestic law, it may be overridden where a beneficial DTAA applies and such treaty does not incorporate corresponding Nexus provisions.

PE exposure: If a PE is found to exist, India can tax the profits attributable to the PE at full corporate rates. This creates double taxation risk (also taxed in Japan) and significant compliance obligations, interest, and penalties if not managed proactively. The Indian tax authorities have adopted an aggressive stance on PE attribution in recent years. Simply allowing a dependent distributor to negotiate and conclude sales can create PE exposure.

Q18. Does a Double Taxation Avoidance Agreement (DTAA) exist between India and Japan, and how does it help?

India has entered into a DTAA with Japan. Key benefits under India-Japan DTAA include:

- Reduced withholding tax on dividends**:** Under India-Japan DTAA, dividends paid by the Indian subsidiary to the Japanese parent are subject to withholding tax at 10% (versus the standard 20% domestic rate).
- Reduced withholding tax on royalties and fees for technical services (**FTS**): Under India-Japan DTAA, royalties and FTS paid by the Indian entity to the Japanese parent are taxed at 10% in India (versus 20% domestic rate). Royalties may include IP licensing fees, software licensing fees, and technical know-how.
- Reduced withholding tax on interest**:** Interest on loans from the Japanese parent to the Indian subsidiary is taxed at 10% under India-Japan DTAA (versus 20% domestic rate for foreign companies).
- PE protection**:** DTAAs define the conditions under which a PE arises and limit India's right to tax where no PE exists providing legal certainty.
- Capital gains**:** DTAAs also address capital gains tax on disposal of shares in the Indian entity relevant on eventual exit.

Key compliance requirements to claim treaty benefits in India:

DTAA benefits do not apply automatically. The Japanese company shall hold a Tax Residency Certificate (TRC) from its home country, file Form 41 (erstwhile Form 10F) in India, provide a no PE Declaration and ensure that it satisfies the substance requirements to claim the DTAA benefits.

Form 41 shall be filed annually on the Indian income tax e-filing portal. Non-residents without a Permanent Account Number (**PAN**) in India are subject to higher withholding tax rates in India. Hence, Japanese companies regularly receiving income from India (royalties, technical fees, dividends) are strongly advised to obtain a PAN and maintain Form 41 compliance on an annual basis.

Q19. What are Transfer Pricing rules in India and how do they affect a Japanese company's Indian subsidiary?

Transfer Pricing (**TP**) refers to the rules governing the prices at which transactions occur between related parties (e.g., a Japanese parent company and its Indian subsidiary). India's TP rules under Sections 161 to 173 of the ITA 2025 (erstwhile Sections 92 to 92F of the ITA 1961) require that all 'international transactions' between associated enterprises be conducted at 'arm's length prices.'

For a medical device or equipment company, the following illustrative transactions between the Indian WOS/JV and the Japanese parent are subject to TP:

- Purchase of medical devices/equipment from the Japanese parent for resale in India (the most common and material transaction).
- Royalties or license fees paid to the Japanese parent for use of IP, trademarks, or software.
- Management fees or service charges paid to the Japanese parent for shared services (finance, HR, IT, legal).
- Loans from the Japanese parent (interest rates shall be at arm's length).
- Reimbursement of R&D costs.

Compliance requirements include:

- Form 48 (erstwhile Form 3CEB): Form 48 is required to be filed by every taxpayer that has entered into international transactions with associated enterprises during a tax year, irrespective of the value of such transactions. The taxpayer is mandatorily required to obtain and furnish an accountant's report

certified by an independent Chartered Accountant, which discloses the nature, value, and arm's length price of each international transaction.

- TP documentation or Local File: Local File is required in all cases where the aggregate value of international transactions exceeds INR 10 million (approx. USD 105,853). The taxpayer is required to maintain contemporaneous documentation that provides a detailed analysis of the functional, asset, and risk profile of the Indian entity, along with the selection and justification of the most appropriate transfer pricing method such as Comparable Uncontrolled Price (CUP), Transactional Net Margin Method (TNMM), Resale Price Method (RPM), Cost Plus Method (CPM) or Profit Split Method (PSM). This documentation shall also include a benchmarking study supporting the arm's length nature of the transactions.

- Master File: Master File requirements are triggered where the following conditions are satisfied conjunctively:

a. Consolidated group revenue exceeds INR 5,000 million (approx. USD 53 Million); and
b. Aggregate value of international transactions of the Indian WOS or JV exceeds INR 500 million (approx. USD 5.2 million), or INR 100 million (approx. USD 1.06 million) for transactions involving intangibles.

In such cases, the Indian WOS or JV is required to furnish a comprehensive overview of the global group's business operations, including its organizational structure, value chain, intangibles, and financing arrangements in Form 56 (erstwhile Form 3CEAA).

- Country by Country Reporting (CbCR): CbCR obligations arise where the consolidated group revenue of the multinational enterprise exceeds INR 64,000 million (approx. USD 677.5 million). In such scenarios, detailed jurisdiction-wise information relating to revenue, profits, taxes paid, number of employees, and tangible assets is required to be reported. The report is filed in Form 59 (erstwhile Form 3CEAD) by the ultimate parent entity or an alternate reporting entity, while Indian constituent entities are required to file an intimation in Form 58 (erstwhile Form 3CEAC) specifying the reporting entity.

Transfer pricing is the single most litigated area of Indian direct tax for multinational companies. The Indian Revenue Authority maintains a dedicated TP audit programme, and adjustments running into tens or hundreds of crores are not uncommon. An Indian subsidiary receiving medical devices from its Japanese parent at standard list prices without a documented TP study is highly exposed to audit risk from the first year of operations.

Certainty mechanisms available to reduce TP dispute risk:

- Safe Harbour Rules (Section 167 of ITA 2025, Section 92CB of ITA 1961): Under the Safe Harbour provisions, qualifying eligible transactions (IT/ITES services, R&D services, intra-group loans, and corporate guarantees) are automatically accepted as arm's length if the operating margin or rate falls within prescribed benchmarks. For example, a minimum operating margin of 15.5% on operating costs for all eligible IT service transactions, subject to the aggregate operating revenue of such transaction entered during the tax year does not exceed INR 20,000 million (approx. USD 211.7 million). Safe Harbour elections avoid TPO scrutiny and are particularly valuable for Indian subsidiaries providing back-office, sales support, or IT services to their Japanese parent.

- Advance Pricing Agreements (**APAs**) (Sections 168 and 169 of ITA 2025, Sections 92CC and 92CD of ITA 1961): APAs provide binding certainty on the Arm's length price or TP method for a period of up to five future years (and may be rolled back for up to four preceding years under Bilateral APA rollback provisions). For Japanese companies with significant recurring intercompany transactions (licensing, management fees, procurement, supply of medical devices), a Bilateral APA with the competent authority of the relevant Japanese member state provides the highest level of certainty and is strongly recommended.

SECTION F — When to Trade vs. When to Assemble or Manufacture in India

Q20. What government incentives are available for Japanese companies that choose to manufacture or assemble medical devices and equipment in India?

The Indian government has created a comprehensive incentive architecture to attract foreign investment into medical device manufacturing. Key schemes include:

Scheme	Key Benefit	Eligibility / Notes
Production Linked Incentive (PLI) Scheme for Medical Devices	Financial incentive of 5% on incremental sales of domestically manufactured devices, for 5 years (FY2022–23 to FY2026–27). Total outlay: INR 3,420 crore (approx. USD 362 Million).	Covers high value segments such as imaging (MRI, CT, mammography, C-arm, X-ray), radiotherapy, anaesthesia, cardio-respiratory, implants.
Income Tax Exemption for New Manufacturing Companies (Section 201 of the ITA 2025) (erstwhile Section 115BAB of the ITA 1961)	15% + surcharge + cess on income from manufacturing operations	A domestic company incorporated on or after 1 October 2019 that commenced manufacturing by 31 March 2024 is eligible. Japanese-owned parent companies that established Indian manufacturing subsidiaries within this window should confirm their eligibility and ensure compliance with all conditions for sustained application of this regime.
100% FDI via Automatic Route	No government approval required for full foreign ownership in medical devices manufacturing.	The Consolidated FDI Policy, 2020 explicitly permits this. This is the simplest entry route.
Medical Device Parks (Scheme for Promotion of MDP)	Subsidised common infrastructure: testing labs, cleanrooms, warehousing, utilities. Reduced capex for smaller manufacturers.	Parks in Tamil Nadu, Greater Noida, Madhya Pradesh and Himachal Pradesh. As of now, scheme is implemented through State Implementing Agencies in each state.
Scheme for Strengthening Medical Device Industry	INR 500 crore (approx. USD 53 million) scheme for manufacturing support for key components, skill development, clinical studies support, common infrastructure with an initial outlay for three years up to FY2026–27.	Targets technology depth gap beyond PLI. Application to be made to the Department of Pharmaceuticals.
Make in India — Government Procurement Preference (Public Procurement Order, 2017 as amended from time to time)	Under the order, 'local suppliers' who manufacture in India can receive an explicit purchase preference (typically 20% margin over imported equivalents) in public tender procurements, provided the minimum local content thresholds are met and the preference is specified in the tender document.	Applies to all procurement by Central and State government entities. Japanese companies that manufacture in India get a market access advantage as their India-made devices qualify for preference in government hospital procurement, CGHS tenders, and state health scheme purchases.
State-Level Incentives	Capital subsidy, land at concessional rates, power tariff concessions, SGST exemptions/refunds, employment incentives.	Varies on a state-to-state basis. Tamil Nadu, Andhra Pradesh, Karnataka, Gujarat, Maharashtra, Himachal Pradesh has active MedTech investment incentive programmes.

Q21. What are the key legal, labour, and compliance obligations that a manufacturing entity in India must meet that a trading entity does not?

Moving to manufacturing in India significantly increases the regulatory and compliance footprint. The key additional obligations include the following:

- CDSCO Manufacturing License: A separate application for domestic manufacturers is required. The manufacturing facility is inspected by CDSCO and Good Manufacturing Practice compliance is required.
- BIS License: If the manufactured device falls under a BIS Quality Control Order, a BIS licence for the manufacturing facility is required.
- Labour law compliance: India has on 21 November 2025 made effective the four Labour Codes, which consolidates 29 erstwhile central labour laws. The key obligations under these Labour Codes include minimum wage, provident fund (EPF), employee state insurance (ESI), gratuity, working conditions, working hours, maternity benefit, framework for standing orders, etc. However, it is pertinent to note that the compliance with respect to labour law is applicable to all entities carrying out business in India and engaging employees for the same.
- Environmental clearances: Some manufacturing facilities may require environmental impact assessment (EIA) and consent from the State Pollution Control Board (SPCB) under the Environment Protection Act, 1986, Water (Prevention and Control of Pollution) Act, 1974, and Air (Prevention and Control of Pollution) Act, 1981.

Q22. What is the Export Promotion Capital Goods (EPCG) scheme and how does it benefit a medical device manufacturer in India?

The EPCG Scheme, administered by the DGFT under the Foreign Trade Policy, allows an Indian manufacturer to import capital goods (machinery, equipment, tools) at zero customs duty, in exchange for an obligation to export a specified value of goods or services manufactured using those capital goods.

- Duty saving: Capital goods imported for medical device manufacturing attract BCD (typically 5–7.5%) plus IGST — the EPCG scheme eliminates the BCD and thereby, the Social Welfare Surcharge, providing significant capital cost savings.
- Export obligation: The company must fulfil an export obligation equal to 6 times the duty saved (CIF value of imports × duty rate × 6), within 6 years from the date of EPCG license grant.
- Applicability: Relevant for Japanese companies establishing manufacturing or assembly operations in India and planning to export to third markets (other than India). The obligation can be met through export of the finished devices, not just the product manufactured on the specific capital goods.

The PLI (**Production Linked Incentive**) Scheme for Medical Devices, launched by the Department of Pharmaceuticals in July 2020 with an outlay of INR 3,420 crore (approx. USD 36.2 million), offers a 5% cash incentive on incremental sales of domestically manufactured devices over a 5 (five) year window (FY 2022–23 to FY 2026–27) to address India's 70-80% import dependence in this sector. It targets four high-value, import-heavy segments:

- cancer care/radiotherapy devices,
- radiology and imaging (including nuclear imaging),
- anaesthetics and cardio-respiratory devices (including renal care and catheters), and
- all implants including implantable electronic devices.

The scheme is restricted to greenfield projects and operates in two tiers (i) Category A for large manufacturers (incentive cap INR 121 crore (approx. USD 12.66 million)) and (ii) Category B for MSMEs (cap INR 40 crore (approx. USD 4.2 million)), administered through IFCI as the project management agency.

As of December 2025, 22 greenfield plants have been commissioned, production has started on 55+ devices including MRI, CT, and linear accelerators, and INR 157 crore (approx. USD 16.4 million) of incentives have been disbursed. The scheme closes for new applications in March 2027.

The PLI scheme is structured to incentivise manufacturing in India, so a foreign company exporting into India cannot directly claim it. But the scheme doesn't restrict foreign ownership or origin of technology, it only requires that the applicant be an India-registered entity producing in India. This allows a collaboration model to work. Further, 100% FDI is allowed in medical device manufacturing via the automatic route (no government approval needed, no non-compete restrictions), so structuring options are wide.

SECTION G — Key Risks, Common Mistakes, and Practical Guidance

Q23. What are the immediate next steps a Japanese medical device company should take after reading this FAQ?

The following concrete actions should be initiated immediately by the Japanese company intending to initiate export to India:

1. Appoint an Indian regulatory affairs firm / CDSCO authorised agent: This is the single most important first step while appointing an Authorised Agent. It is important to assess their relationships with the CDSCO, experience with product being exported to India, and clientele.
2. Commission an HSN code classification and duty mapping: Engage a licensed Indian Customs House Agent to classify your product portfolio under Indian HSN codes and compute the duty burden.
3. Instruct Indian legal counsel on corporate structure: Engage an Indian corporate law firm to advise on WOS vs. LO vs. JV, FDI rules, and incorporation requirements.
4. Engage Indian tax advisors on transfer pricing and DTAA: Appoint a tax firm early to structure intercompany arrangements correctly from the outset.
5. Check BIS Quality Control Orders: Verify whether any of your products are subject to mandatory BIS certification. This is a binary requirement and non-compliance stops imports entirely.
6. Identify the CDSCO classification for each product: Japan product categories must be mapped to Indian classes, and a formal classification verification can be taken up.
7. Assess PLI Scheme eligibility: If your product falls within PLI target categories and you are considering India manufacturing, apply early given scheme windows may close or be modified.
8. Begin distributor due diligence: Identify 3–5 Indian medical device distributors with relevant hospital networks and evaluate them rigorously before signing any agreement.

Glossary of Key Terms

Term / Abbreviation	Meaning
APA	Advance Pricing Agreement — a binding agreement between a taxpayer and the Indian tax authority (CBDT) on the transfer pricing methodology for specified transactions.
AERB	Atomic Energy Regulatory Board — regulates use of radiation sources, including medical X-ray and nuclear medicine equipment.
BCD	Basic Customs Duty — the primary import tariff levied on goods entering India.
BIS / QCO	Bureau of Indian Standards / Quality Control Order — BIS sets national standards; a QCO mandates BIS certification before import or domestic sale of specified products.
CDSCO	Central Drugs Standard Control Organisation — India's national regulatory authority for drugs and medical devices.
CEPA	Comprehensive Economic Partnership Agreement, 2011 entered between India and Japan
DCA	Drugs and Cosmetics Act, 1940 — parent legislation governing drugs, cosmetics, and medical devices in India.
DGFT	Directorate General of Foreign Trade — administers India's Foreign Trade Policy, including EPCG, Advance Authorisation, and IEC.
DTAA	Double Taxation Avoidance Agreement — bilateral tax treaty between India and another country to prevent the same income from being taxed twice.
EPCG	Export Promotion Capital Goods Scheme — allows duty-free import of capital goods against export obligation.
FEMA	Foreign Exchange Management Act, 1999 — governs cross-border transactions, FDI, and foreign currency flows in India.
FDI	Foreign Direct Investment — investment by a foreign entity in an Indian company or business.
FSC	Free Sale Certificate — a document from the competent authority in the country of manufacture confirming the device is lawfully marketed there.
GST / IGST	Goods and Services Tax — India's unified indirect tax. IGST is the form levied on imports and inter-state transactions.
HSN / HS Code	Harmonised System of Nomenclature — the international goods classification system used for customs and GST purposes.
IEC	Importer–Exporter Code — mandatory registration for any entity importing or exporting from India, issued by DGFT.
IMDRF	International Medical Device Regulators Forum — a voluntary group of international regulatory authorities harmonising medical device regulations globally.
ITC	Input Tax Credit — the credit a GST-registered entity can claim for GST paid on its purchases, offsetting against GST collected on sales.
IVD	In-Vitro Diagnostic device — a medical device used to perform tests on samples (blood, urine, tissue) outside the human body.
LO	Liaison Office — a limited-purpose representative office of a foreign company in India, permitted only for specified non-commercial activities.
MDR 2017	Medical Devices Rules, 2017 — the primary standalone regulation for medical devices in India.

Term / Abbreviation	Meaning
NPPA	National Pharmaceutical Pricing Authority — regulates ceiling prices of scheduled drugs and certain notified medical devices.
PE	Permanent Establishment — a tax concept determining when a foreign company has sufficient presence in India to be taxed on Indian-source profits.
PLI Scheme	Production Linked Incentive — a scheme providing financial incentives for incremental domestic manufacturing across specified sectors including medical devices.
SaMD	Software as a Medical Device — standalone software that performs a medical purpose. Regulated as a medical device under MDR 2017.
SLA	State Licensing Authority — state-level drug controller responsible for issuing manufacturing licenses for Class A and Class B medical devices.
TDS	Tax Deducted at Source — the Indian withholding tax system whereby the payer deducts tax before making payment to the recipient.
TP	Transfer Pricing — rules governing the prices of transactions between related parties (e.g., Japanese parent and Indian subsidiary).
TRC	Tax Residency Certificate — a certificate issued by the home country tax authority confirming the entity's tax residency, required to claim DTAA benefits.
UDI	Unique Device Identifier — a unique numeric or alphanumeric code for each medical device unit, required under MDR 2017 for traceability.
WOS	Wholly Owned Subsidiary — an Indian private limited company 100% owned by a foreign parent, incorporated under the Companies Act, 2013.

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Currency Note: All INR amounts in these FAQs are accompanied by an approximate USD equivalent in brackets, converted using the RBI Reference Rate for 24 June 2026, fixed at ₹94.48 per USD 1.

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