

## Medical Devices Regulation in United States of America, European Union and India: A Comparative Study

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### Abstract

In order to market any medical device, marketing authorization from Regulatory authority is required. The process of gaining authorization is complex, multistep and requires review of information by competent authorities. Upon scrutinizing the information furnished by Manufacturer, marketing authorization is granted by the concerned Regulatory authority. In the USA, manufacturers are required to apply to United States Food and Drugs Application (USFDA) for Marketing Authorization. There are two types of applications in USA; 510 (k) and Pre-Market Application (PMA). In EU, National Authorities give approval for marketing medical devices. A system of third party compliance is followed, where Notified Bodies (Third Party) ensure Quality Assurance, pre and post approval. In India, Central Drugs Standard Control Organization (CDSCO) approves devices for sale and import. Medical Devices are regulated under CLAA scheme. The Drug Controller General of India (DCGI) is the central licensing authority for medical devices. This paper attempts to capture information on regulations of Medical Device in three regions namely; USA, EU and India and compare provisions of Market authorization in the respective regions, and further, for the readers, make this complex subject easier to grasp.

**Keywords:** Medical devices; Marketing authorization; USA; EU; DCGI; IMDRF

### Abbreviations:

USFDA: United States Food and Drug Administration; EMA: European Medicine Agency; USA: United States of America; EU: European Union; RRA: Regional Regulatory Authority; GHTF: Global Harmonization Task Force; PMA: Premarket Approval; QSR: Quality System Regulations; CFR: Code of Federal Regulations; CDER: Centre for Drug Evaluation and Research; CBER: Centre for Biologics Evaluation and Research; CDRH: Centre for Device and Radiological Health; OCP: Office of Combination Product; MDUFA: Medical Device User Fee Act; IMDRF: International Medical Device Regulators Forum; STED: Summary of Technical Documentation; IDE: Investigational Device Exemption; NB: Notified Body

### Introduction

The advent of 1950s and 1960s saw tremendous technological advances thereby giving a fillip to innovation in the field of Pharmaceutical and Medical Device Industry. Today these Industries are estimated to worth billions of dollars. Medical Devices have enhanced the quality of healthcare at our disposal by making diagnosis, prevention and treatment of diseases and serious health conditions, easier and efficient. It is worth mentioning that development of Medical Devices, vis-a-vis, Pharmaceuticals is less expensive and time consuming. The GMP requirements are by far less stringent than Pharmaceuticals.

However, with passage of time, enhanced technology has become increasingly complicated and intricate, so much so, that it has several times circumvented the understanding of Medical Professionals,

Device developers and Regulators. These parties often encounter problems in understanding deficiencies and gaps in the development process consequently resulting in Patient injuries, adverse events (serious or non-serious) and even deaths, and leaving room for Public Hazard. Thus, it is clear that there is a need for effective regulation to be put on devices being circulated in the International and National commerce.

The Regulations of Medical Devices is vast and rapidly evolving field that is often complicated by legal and technical issues, for instance information on patent status, market approvals in other regions as a legal requirement, safety and efficacy data, engineering aspects etc. for technical requirements. Various Regional Regulatory Authorities (RRAs) have come up with regulations from time to time.

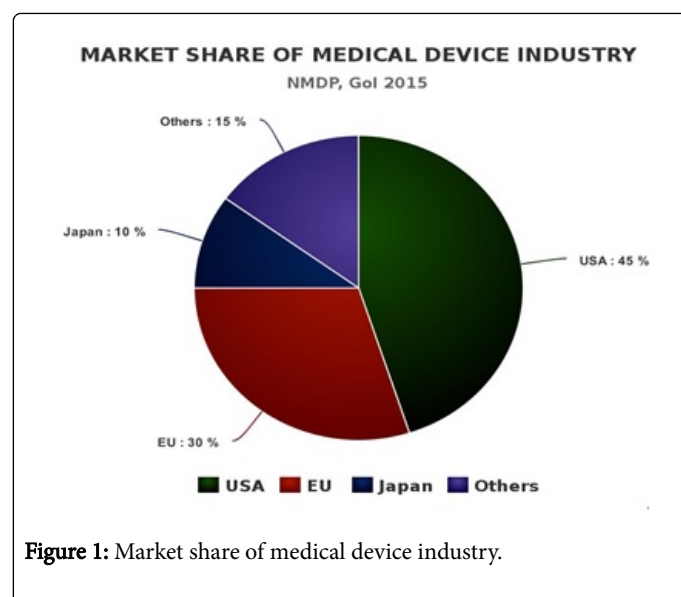
The USFDA put regulations in place in 1976, through Medical Device Amendment in the Food, Drugs and Cosmetic Act of 1938.

The European Commission, of EU regulates Medical Devices through Medical Device Directive, 93/42/EEC of 1993. The Member states follow the directives of EU with modifications as per pertinent rules and obligations.

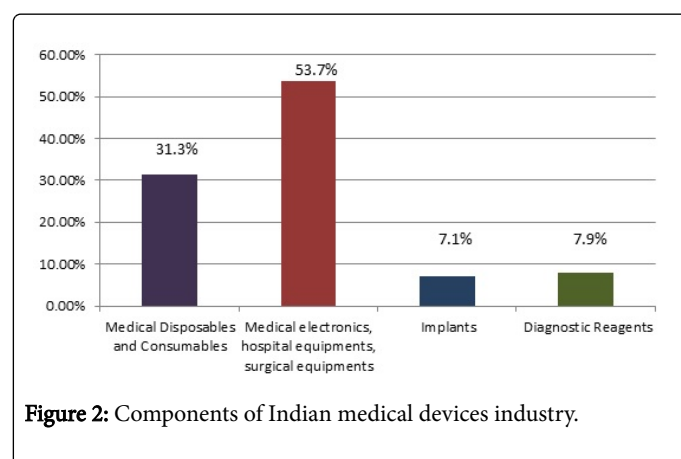
The CDSCO, Government of India, regulates a handful of devices under Central License Approval Authority scheme (CLAA), called Notified Devices. Government of India is mulling changes to extant regulatory apparatus.

### Current Global Trends in Medical Device Industry

The global market for medical devices is estimated over \$ 220 billion for the year 2015. The United States of America, with about 45% market share is the dominant market for medical devices followed by European market share of 30% and Japan with share of 10% and other 15% includes markets of Asia Pacific and Latin America (Figure 1).



Medical devices sector in India is relatively small as compared to the rest of the manufacturing industry, though India is one of the top twenty markets for medical devices in the world and is 4th largest market in Asia after Japan, China and South Korea. Although accurate data and figures are not available on the subject, an educated guess would place the sector at about Rs. 30,900 crores in production terms [1-6]. Medical Device Industry in India is predominantly import driven accounting for over 65% of the total market (Figure 2).



Some of the top medical devices companies by revenue (in no particular order), 2017, in India include [7]:

- Johnson & Johnson.
- General Electric Co.
- Medtronic Inc.
- Siemens AG.
- Baxter International Inc.

## Procedure of Marketing Authorization in the United States of America

In the United States of America, Medical Devices are regulated by Food and Drug Administration (FDA). FDA's Centre for Devices and

Radiological Health (CDRH) is responsible for regulating firms who manufacture, repackage, re-label, and/or import medical devices sold in the United States.

A system of Device classification is followed in the US. Devices are classified into Class I, II or III. Each device is assigned to a panel (Cardiovascular, Anaesthesiology etc.). The panel determines the Class and special controls and exemptions applicable to the device.

General Controls include:

- Establishment Registration by manufacturers, distributors, repackages and re-labellers,
- Medical Device Listing with FDA of devices to be marketed,
- Manufacturing the devices in accordance with Good Manufacturing Practices,
- Labelling medical devices in accordance with the labelling regulations, 21 CFR 801 or 21 CFR 809,
- Medical Device Reporting of adverse events as identified by the user, manufacturer and/or distributor of the medical device.

Special Controls may include:

- Adherence to performance standards, guidance documents,
- Implementation of post-marketing surveillance measures,
- Special labelling.

The FDA has established classifications for approximately 1,700 different generic types of devices and grouped them into 16 medical specialties referred to as panels. Each of these generic types of devices is assigned to one of three regulatory classes based on the level of control necessary to assure the safety and effectiveness of the device. The Devices are placed in Class I, II or III. All the classified devices are available on the website of FDA.

Class I devices are defined as non-life sustaining and present minimal harm potential to user. These devices are typically simple in design, manufacture and have a history of safe use. Their failure poses no risk to life and hence are subject to general control and require least regulations, these devices have to comply with Quality System Regulations (QSR) laid in 21 CFR Part 820 and labelled according to 21 CFR Part 821. Although most are exempt from 510 (k) pathway and some are even exempt from QSR. For example tongue depressors are exempt from 510 (k) but stethoscopes are not.

Class II medical devices are devices where General Controls are not sufficient to assure safety and effectiveness and existing methods/standards/guidance documents are available to provide assurances of safety and effectiveness. In addition to compliance with General Controls, Class II devices are required to comply with Special Controls.

Special Controls may include:

- Special labelling requirements,
- Mandatory performance standards, both International and United States,
- Post-marketing surveillance,
- FDA medical device specific guidance.

Information on Class II exempt devices is located within the device regulation, 21 CFR 862 through 892. Devices falling in these class are cleared for sale only through 510 (k) regulatory pathway, where the applicant demonstrates that the 'Device' is substantially equivalent to an existing device called, 'Predicate device' and Clinical Trials may be

required for devices falling in this class. The information required in a 510 (k) submission is defined 21 CFR 807.87.

Class III devices usually support or sustain human life, are of substantial importance in preventing impairment of human health, or present a potential unreasonable risk of illness or injury to the patient. Devices falling in this class have to demonstrate safety and efficacy through Clinical Trials.

For Class III medical devices, sufficient information is not available to assure safety and effectiveness through the application of General Controls and Special Controls. Typically a Pre-Market Approval (PMA) submission to the FDA is required to allow marketing of a Class III medical device. Section 515 (c) (1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) specifies the required contents of a PMA.

Some devices falling in Class III includes replacement heart valves, PTCA balloons, implanted cerebella stimulators, Pacemaker. These devices mandatorily require Phase IV trials data. A few Class III medical devices are required to only have a 510 (k) cleared by the FDA to be marketed.

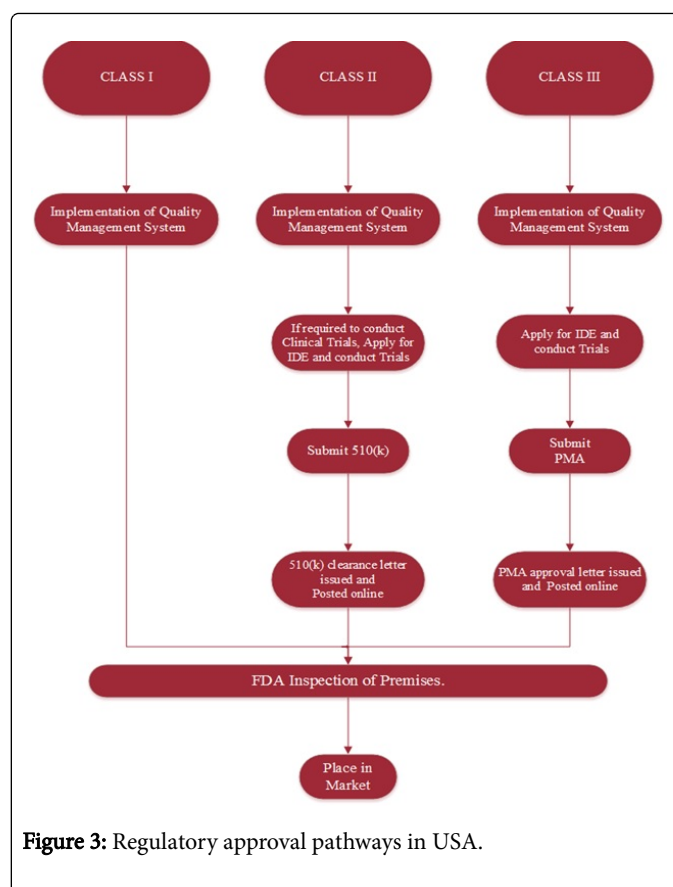
Manufacturers are required to submit their application for review. Depending on the complexity of the new or modified medical device, the FDA Review of a 510 (k) submission takes between 20 and 90+ days. The more complex the changes or comparison required to support the safety and effectiveness of the new or modified medical device, the longer the FDA review process.

The FDA has a statutory 180-day review cycle for PMA applications. Often PMA applications require medical advisory board review prior to the FDA granting approval to market the medical device. A facility inspection verifying the manufacturing systems present to manufacture the medical device is usually performed prior to FDA PMA approval. FDA approval of a PMA often requires significantly more than 180 days [4].

The FDA reviews the application (510 (k) or PMA) and if satisfied with, data posts online a 510 (k) clearance letter or PMA Approval Letter. Following which a device could be marketed in the USA. Any changes to constitution of device shall be informed to FDA through supplement filing as per the prescribed timelines.

### Steps for marketing approval in USA

1. Classify Medical Device.
2. Implement Quality Management System (GMP Requirements).
3. Submission of Clinical Trial data, If Applicable (Investigational Device Exemption (IDE)).
4. Submission of Marketing Approval Application (510 (k) Premarket Notification, Premarket Approval Application).
5. FDA 510 (k) Clearance Letter or PMA Approval Letter.
6. FDA Quality system inspection of Manufacturing Facility.
7. Medical Device Listing in FURLS System.
8. Establishment Registration in FURLS System (Figure 3).



**Figure 3:** Regulatory approval pathways in USA.

### Procedure of Marketing Authorization in European Union

In EU, there is decentralized procedure of marketing authorization as no single body regulates Medical devices. A system of third party compliance is followed. Notified Bodies are the third party that issue Quality Assurance certificates and ensures post approval compliance to Quality Management System (QMS).

Medical Devices are regulated by Medical Devices Directive, which consists of three directives that regulate the safety and marketing of medical devices in Europe. The three directives are:

- Medical Device Directive (MDD 93/42/EEC),
- Active Implantable Medical Device Directive (AIMDD 90/42/EE),
- *In vitro* Diagnostic Medical Device Directive (IVDMDD 98/79/EC).

These directives are regularly updated. The directive 93/42/EEC has been thus far, amended five times. The last amendment was 2007/47/EC, which came into effect in March 2010.

A system of product classification is followed in EU, whereby Medical Devices are classified into classes I, IIa, IIb and III, depending upon the risk involved with usage of device. The criteria for class determination are laid in Annex IX of MDD 93/42/EEC. These criteria take into account the following:

- Duration of contact,
- Invasiveness of device,
- Source of Energy of device,

- Active Principle of Device, if used in combination, as for Drug Eluting Coronary Stents.

Some examples of devices and their class are:

Class I: Blood Pressure Cuff, Hospital Bed;

Class IIa: Hearing aid, X ray diagnostic equipment;

Class IIb: Ventilator, Blood bags;

Class III: PTCA balloon, Drug Eluting Coronary Stent.

It is worth mentioning that all devices which are of human blood derivative and or utilizing animal tissues or derivative fall in Class III.

All devices used for contraception or the prevention of transmission of Sexually Transmitted Diseases are in class IIb, unless implantable for long term invasive devices which fall in Class III. Medical devices intended for recording of X-ray diagnostic images are in Class IIa.

Medical Devices cannot be placed on European Market without conforming to the strict safety requirements of EU. A device must bear CE mark, except for Custom-made devices; Devices for clinical investigation, health protection-urgent unusual circumstances; humanitarian use and In-house use.

Devices are labelled as per Annex I of Council Directive 93/42/EEC in national language and use of appropriate symbols is recommended. Conformity assessment of the Device is performed by a Notified Body.

Technical Documentation should be submitted to the NB for assessment. Documents are accepted in IMDRF format (STED) or as per Notified Bodies Medical Devices (NB-MED) recommend document (NB-MED/2.5.1/Rec 5) 'Technical documentation'. STED and NB-MED format include comprehensive information on device.

The Notified Body is effectively responsible for pre-market evaluation of medical devices. They monitor all aspects of the evaluation from manufacturing process to post-market surveillance.

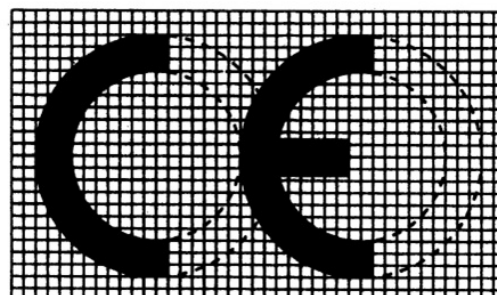
They review all data (including clinical data), conduct regular inspections (including impromptu on-site inspections) and collect reports regarding safety. Adverse event reporting to the Competent Authority is mandatory for the manufacturer. Once a device is reviewed and deemed acceptable, it receives the CE marking [8].

Once NB clears a device, manufacturer can declare conformity and place the device in market. An NB can conduct surprise audit to ensure conformance to QMS by the Manufacturer. Documents must be kept at disposal of Competent Authority for five years (Fifteen Years for implantable Devices).

The timelines for gaining approval differs for different class of devices, complexity of design and risk to the user with use of device. After being approved for marketing class I devices' validity is indefinite and for Class II and III devices validity is for 3 years.

Any change in the constitution of device, thereafter, has to be informed to the Notified Body as per prescribed timelines (Figures 4-8).

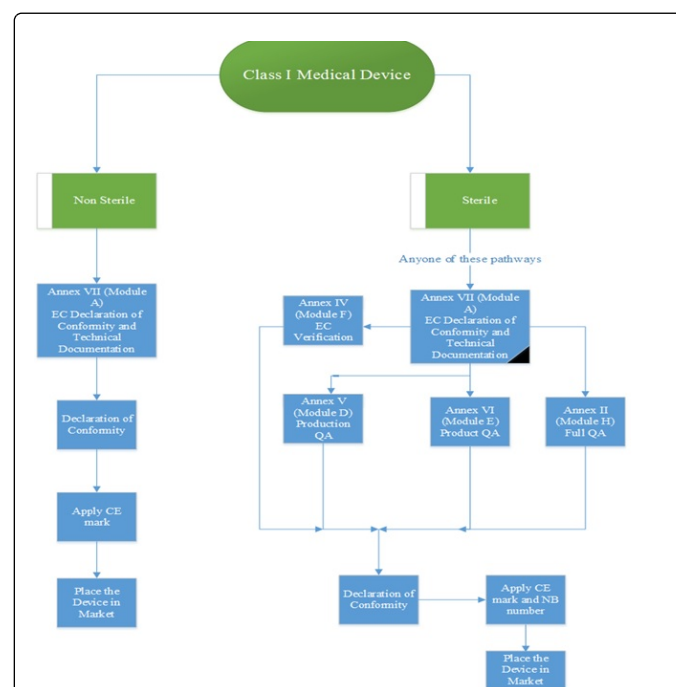
The CE conformity marking shall consist of the initials 'CE' taking the following form:



**Figure 4:** CE mark.

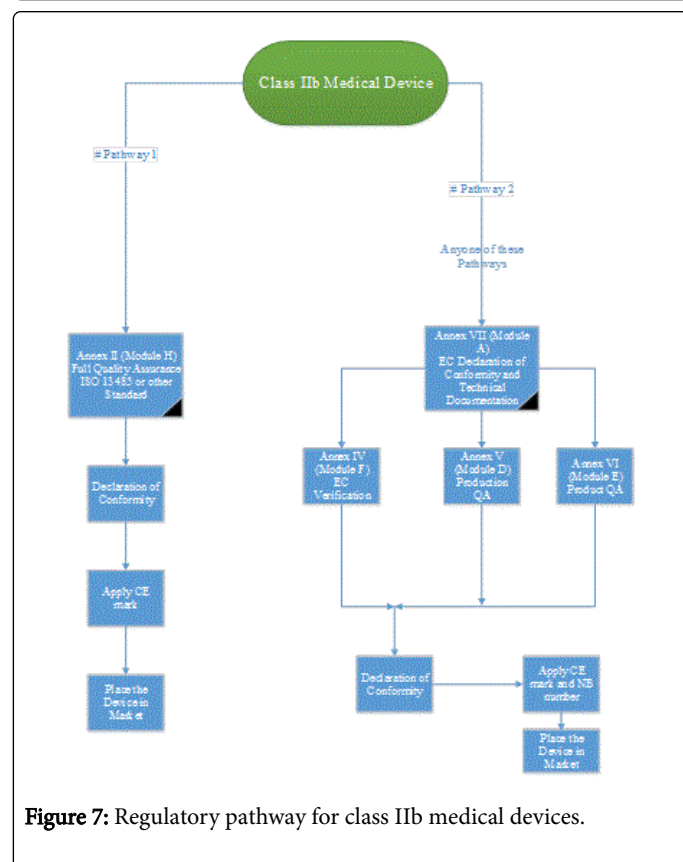
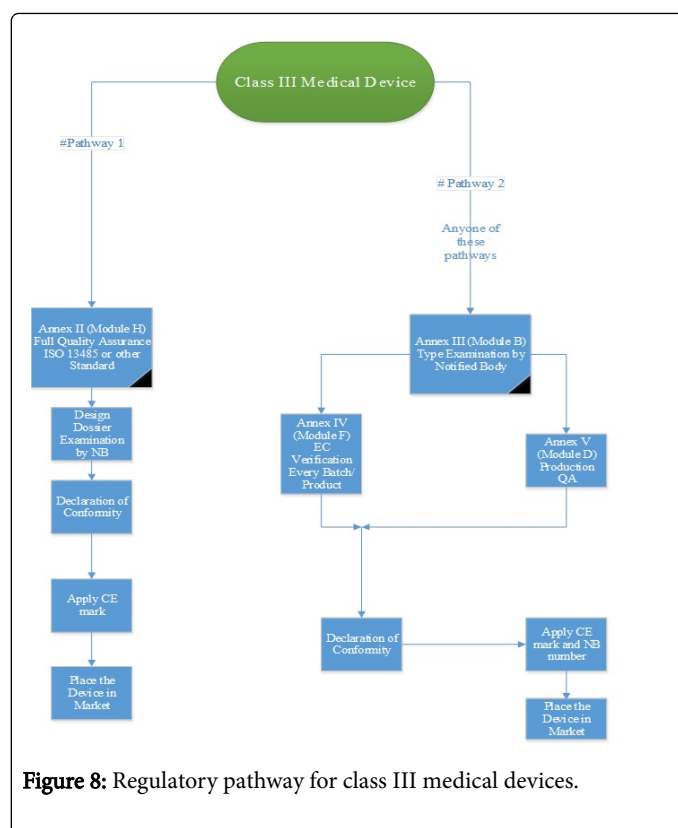
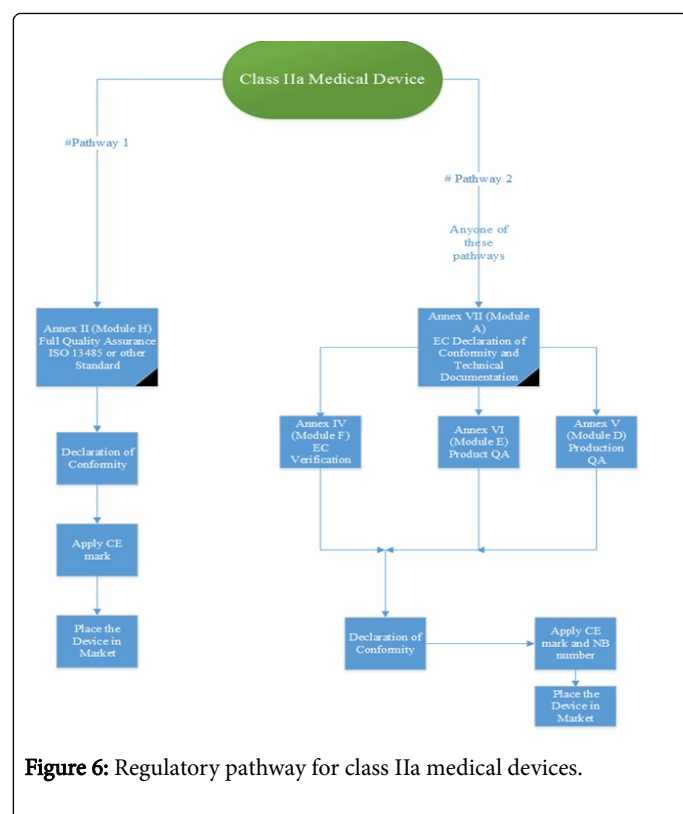
### Steps for marketing approval in Europe

1. Determination of MDD that applies to the device.
2. Determine the Class using Annex IX.
3. Choose conformity assessment procedure/route.
4. Appoint an authorized representative located in Europe.
5. Audit of QMS and Technical Documents by Notified Body.
6. Register Device with Competent Authority of Member State.
7. Prepare Declaration of Conformity stating Medical Device complies with applicable Directive
8. Affix CE mark.
9. Place in Market.



**Figure 5:** Regulatory pathway for class I medical devices.





## Procedure of Marketing Authorization in India

The Government of India regulates medical devices through a specialized division called, Medical Device and Diagnostics Division, CDSCO, Ministry of Health and Family Welfare. Only a few Medical Devices and Diagnostic kits, called Notified Devices, are regulated under Central Licensing Approval Authority (CLAA) scheme for the purpose of Manufacture, Import, Sale and Distribution. Drug Controller General of India (DCGI) is the Central Licensing Authority.

The regulation of Notified Medical Devices is overseen by both, the central government and the state governments. Under the applicable regulatory framework, the functions of manufacture, import, distribution and sale of medical devices require licenses or permissions, as the case may be.

Import, manufacture, sale and distribution of Medical devices are regulated under Drugs and Cosmetics Act, 1940; and Rules, 1945. At present following notified Medical Devices are regulated under the Act (Table 1).

Further the following products are regulated as “Drugs” under Drugs and Cosmetics Act and Rules there under which are considered ‘Medical Device’ in the Country of Origin. This provision is ambiguous and inconsistent with Harmonized Standards of Medical Devices. Manufacture for sale of these products is regulated by the concerned State Drug Licensing Authority only [5].

S. No	Name of the devise	Notification number	Date of notification
1	Disposable Hypodermic Syringes	GSR 365 (E)	17-03-1989
2	Disposable Hypodermic Needles	GSR 365 (E)	17-03-1989
3	Disposable Perfusion Sets	GSR 365 (E)	17-03-1989
4	<i>In vitro</i> Diagnostic Devices for HIV, HBsAG and HCV	GSR 601 (E)	27-08-2002
5	Cardiac Stents	S.O. 1468 (E)	06-10-2005
6	Drug Eluting Stents	S.O. 1468 (E)	06-10-2005
7	Catheters	S.O. 1468 (E)	06-10-2005
8	Intra Ocular Lenses	S.O. 1468 (E)	06-10-2005
9	I.V. Cannulae	S.O. 1468 (E)	06-10-2005
10	Bone Cements	S.O. 1468 (E)	06-10-2005
11	Heart Valves	S.O. 1468 (E)	06-10-2005
12	Scalp Vein Set	S.O. 1468 (E)	06-10-2005
13	Orthopaedic Implants	S.O. 1468 (E)	06-10-2005
14	Internal Prosthetic Replacements	S.O. 1468 (E)	06-10-2005

**Table 1:** List of notified devices.

### Items classified as drugs in India

- Blood Grouping Sera.
- Ligatures, Sutures, Staples.
- Intra Uterine Devices (Cu-T).
- Condoms.
- Tubal Rings.
- Surgical Dressing.
- Umbilical Tapes.
- Blood Component Bags, Blood Bags.

The Government of India, through CDSCO, published guidance documents in 2012 regarding marketing authorization of Medical Devices. In these documents the CDSCO outlined its expectation for grant of License for Import and Manufacture of Medical Devices. These Guidance documents are:

**CDSCO/MD/GD/CLAA/01/00:** Guidance Document on application for grant of License in Form-28 for Manufacture of Medical Devices in India under CLAA scheme.

List of items for Grant of License in Form-28 for Manufacture of Medical Devices in India as outlined in CDSCO/MD/GD/CLAA/01/00

- Covering Letter,
- Authorization Letter,
- A duly filled Form-27,
- Requisite Fee (License fee Rs. 6000/- and Inspection fee Rs. 1500/-),
- Constitution Details of firm,
- Approved Manufacturing Premises Plan/Layout,
- Full Details of competent and regular technical staff,
- Site Master File (SMF),

- Specific Environmental Requirements,
- Device Master File,
- Details of Standards,
- Promotional literature, package insert, device label etc.,
- ISO 13485:2003 Certificate (if any), CE mark (if any), any other approval (if any).

**CDSCO/MD/GD/IL/01/00:** Guidance Document on Common Submission format for Import License in Form 10 of Notified Medical Devices in India.

List of items for Common Submission Format for Import License in Form 10 of Notified Medical Devices in India as outlined in CDSCO/MD/GD/IL/01/00 (Table 2).

- Covering Letter,
- Authorization Letter,
- Duly filled Form-8,
- Duly filled Form-9,
- Requisite Fee,
- Duly attested (notarized) and valid copy of Wholesale License for sale and distribution of drugs and Manufacturing License, Under D&C Act by State Licensing Authority,
- Registration Certificate in Form-41 by CDSCO,
- Import License in Form-10 issued by CDSCO,
- Required documents as per registration certificate in Form-41 issued by CDSCO.

### Steps for Import License in India

1. Determine whether the device requires registration under D&C Act.

2. Grant India Agent Power of Attorney to manage registration in India.
3. File application for Device Registration with CDSCO through Form-40.
4. Device manufacturers new to India require Form-45 in support of Form-40.
5. Obtain Registration Certificate Form-41 from CDSCO, valid for 3 years.
6. Identify distributor in India (holding Forms 20B and 21B).
7. Apply for Import License using Form 8 & 9 [6, 9-12].

S. No	Point of Comparison	USA	European Union	India
1	Regulation Authority (s)	USFDA	EMA and RA of Member State	CDSCO
2	Classification Categories	Class I	Class I	Class A
		Class II	Class IIa	Class B
		Class III	Class IIb	Class C
			Class III	Class D
3	Regulatory Pathway	510 (K) application	Multiples pathways as described in flowcharts	Market Authorization application to Competent Authority
		Premarket Approval (PMA)		
4	Fees for available pathways	MIDUFA FY2017	Fee varies for Members State	Manufacturing License:
		510 (K) \$ 4,690		Rs 6,000/- License Fee
		PMA \$ 234, 495		Rs 1,500/- Registration Fee
				Import License:
				\$ 1,000/- Registration Fee
				\$ 5,000/- Inspection of Premises
5	Quality Management Systems requirement	21 CFR Part 820	ISO 13485 or as per applicable annex of 93/42/EEC	BIS 15575 or ISO 13485
6	Assessment of Technical Data performed by	USFDA	National Regulatory Authority	CDSCO
7	Establishment Requirement	Establishment Registration	Responsible person registration	Premises Registration
8	Medical Device Regulations	21 CFR Part 800	MDD- 93/42/EEC	Drugs and Cosmetics Act, 1940
		21 CFR Part 801		
		21 CFR Part 803		
		21 CFR Part 806		
		21 CFR Part 807		
		21 CFR Part 808		
		21 CFR Part 809		
		21 CFR Part 810		
		21 CFR Part 812		
		21 CFR Part 814		
		21 CFR Part 814	AIMDD- 90/42/EE	
		21 CFR Part 820		
		21 CFR Part 821		
		21 CFR Part 822		
21 CFR Part 830	IVDMDD- 98/79/EC			

		21 CFR Part 860		
		21 CFR Part 861		
9	Validity of License	Indefinite, unless revoked or product recalled	Validity of CE marking is Indefinite for Class I	
		Annual Establishment Registration is required	3 years for Class IIa, IIb and III	3 years from the date of approval, for Notified Devices
10	Labelling Requirements	As per 21 CFR Part 801	As per annex I	As per Drugs & Cosmetics Act, 1940
			93/42/EEC	GSR 703
11	Data Presentation (Electronic/Paper)	Electronic/Paper	Electronic/Paper	Paper/Electronic
12	Final Outcome of Review Process	Approval Letter (PMA)	CE mark	Import/Manufacturing License number
		Marketing Clearance 510 (k)	CE mark with NB number	
13	Timelines for Approval(months)	Class I (1)	Class I (1)	6-12 months for Notified Devices
		Class II (3-6)	Class II (3-6)	
		Class III (18-30)	Class III (9-15)	

**Table 2:** A comparative study of medical devices regulations applicable for USA, EU and India.

## Conclusion

The primary goal of the pre-marketing assessment process is to protect the safety of patients who will potentially benefit from a new device. It might be useful for regulatory agencies to develop regulatory apparatus for assessment of medical devices before granting permission to place a device in the market.

In USA, medical device regulation is performed by CDRH. Strict conformity to desired principles is required to obtain marketing authorization. 510 (k) and PMA are the regulatory pathways for obtaining marketing authorization in USA. The choice of regulatory pathway adopted by companies depends primarily upon the complexity of design, potential risk to health of user and safety of device.

In European Union, CE marking/certification is mandatory for any device to be marketed. Medical devices are regulated through Notified Bodies and National Authorities in a very novel fashion. The Notified Body ensures compliance to Quality and Safety standards and approves devices for CE marking, whereas marketing authorization is granted by Competent Authority of the member state.

In India, CDSCO regulates handful devices through gazette notifications. These devices are called notified devices. A few products are classified as drugs in India but are classified as devices in other countries. This system is not in consonance with international standards. Existent system appears to be rudimentary in character when compared to regulatory systems of USA and EU. Therefore, revamping of current regulatory system is required for administration of devices moving in commerce and creating harmonized standards of medical devices.

## Definitions

All the Regional Regulatory Authorities have defined Devices and components that they intend to regulate. These definitions mostly concur with one another. For the purpose of convenience we are considering IMDRF definition as it is widely accepted across the globe.

‘Medical device’ means any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease,
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- Investigation, replacement, modification, or support of the anatomy or of a physiological process,
- Supporting or sustaining life,
- Control of conception,
- Disinfection of medical devices,
- Providing information by means of *in vitro* examination of specimens derived from the human body.

And does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

**New medical device:** A new Medical Device is one which has no predicate device approved by Regulatory authority.

**Predicate device:** A Predicate Device means a device, first time and first of its kind, approved by Regulatory Authority.



**CE mark:** CE Mark, European Conformity is a conformity mark that all the devices must bear before they can be placed in the market in Europe.

**Authorized agent:** Is a person, firm or company appointed by the Manufacturer to undertake import for sale and distribution of Device in a country other than country of origin and to act as first point contact between Competent Authority (CA) and the Medical Device Company.

**Notified body:** Notified Body means a body corporate or other legal entity, notified by the RRA, as competent body to carry out the audit of manufacturing site, assessment, and verification of specified category of medical devices for establishing conformity with standards and other requirements, conduct post-market surveillance, and issue warnings and recalls for adverse events.

**Manufacturer:** Manufacturer means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

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