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# REGULATORY APPROVAL PROCESS FOR MEDICAL DEVICES IN INDIA, USA & EUROPEAN UNION

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## ABSTRACT

Today millions of patients depend on medical device based treatment for the management and diagnose of several diseases. Quality and safety of device is depends upon the regulatory guidelines. Therefore a law containing adequate guidelines of rules and regulations are required for monitoring the entry of such devices into the use in public health. The regulations define requirements of medical device design, development and manufacture to ensure that products reaching market are safe and effective. Presently in India regulatory body CDSCO is governing regulation for regulation of devices which with time, amendment introducing in the law will provide safety assurance to public health. The United States has long had the world's most successful medical device (or med tech) industry, with the European Union (EU) serving as its largest export market. The trading bloc's reputation for relatively timely market approvals has long benefited these U.S. manufacturers. However, the EU's soon-to-be- implemented Medical Device Regulation (MDR)—an overhaul of the previous med tech regulatory regime—may present a number of obstacles for U.S. and other med tech firms that could limit their access to a critical market. The present review discuss about the classification of medical devices and regulations aspects in India, USA and European Union.

**KEYWORDS:** Medical classification, Regulatory, License, Marketing, European Union (EU).

## 1. INTRODUCTION[1]

A medical device is any instrument, apparatus, appliance, software , material used alone or in combination intended for use in diagnosis and treatment purpose to prevent and cure disease. Medical devices differ according to their indications and use. Medical device is a vast system which categorized the products starting from the therapeutic devices with medical uses such as wound healing, or clogged arteries to highly modified computerized medical technologies and diagnostic medical devices. To ensure the safety, efficacy and effectiveness and useful medical technologies and also increase the uniformity between the national medical device regulatory system the Global Harmonization Task Force (GHTF) was developed in 1992 by five members mainly European Union, Unites States, Australia, Japan and Canada where surveillance was between the study groups. GHTF defined a medical devices as any instrument, apparatus, implement, machine, appliance, implant, software material, or any other article which is used for several purposes like diagnosis, monitoring, treatment of any kind of disease or any kind of injury. The medical devices are used to sustain the life of the individual, support the anatomy or replacement of any kind of process, control of the conception and disinfection of medical devices in hospitals and other places, provide the information regarding the sample kits, reagents, chemical used for cleansing, calibrators and software data by means of in vitro examination of particular specimens derived from the human body and which does not achieve its action intended action by pharmacological, metabolic, or immunological means but which may be used in such ways. Medical devices include a wide variety of products such as medical gloves, bandages, contact lenses, disinfectants, X-ray equipment, pacemakers, dialysis equipment, incubators and heart valves.

Regulatory practices are critical determinants of the overall ability of firms producing medical devices (medtech) to sell their goods competitively in a given country. Regulations shape market access for foreign producers and influence decisions about pricing products within these market.

The United States has the world's largest medtech industry, by sales, and the European Union (EU) has long been its largest export market. The success of U.S. medtech firms in Europe has largely stemmed from an understanding of EU regulations. Further, the EU has enjoyed a reputation for having one of the world's most timely paths to market for medtech goods. However, on April 5, 2017, the European Parliament and Council released stricter regulatory requirements in the form of its updated Medical Device Regulation (MDR), which will

replace the current EU Medical Device Directive (MDD) next year. The MDD, which has been in force for over 20 years, governs the approval of medical devices for introduction into the EU market, as well as of the certified bodies that certify regulatory approval of medical device firms.

Slated to enter into force on May 26, 2020, the MDR is expected to restructure how the EU approves medical devices. It will affect a wide range of steps in the process, from submission of clinical trial data for lower-risk medical products and conformity assessment procedures to labeling requirements and post-market surveillance of products. This article explores the potential challenges facing U.S. medtech firms as they attempt to navigate the MDR.

**Overview of Medical Device Regulations**

Globally, nearly all major markets apply a risk-based classification system to regulate med tech goods, similar to the structures recommended by the Global Harmonization Task Force (GHTF), a voluntary international association that was aimed at harmonizing international medical device standards. Specifically, the GHTF recommended dividing medical devices into four categories—A, B, C, and D—based on the relative harm they potentially pose to patients; regulatory requirements were ideally supposed to become stricter in accordance with the relative device risk (figure 1).6 Though the GHTF was disbanded in December 2012, it has since been replaced by the International Medical Device Regulators Forum (IMDRF), which adheres to the recommendations of its predecessor.

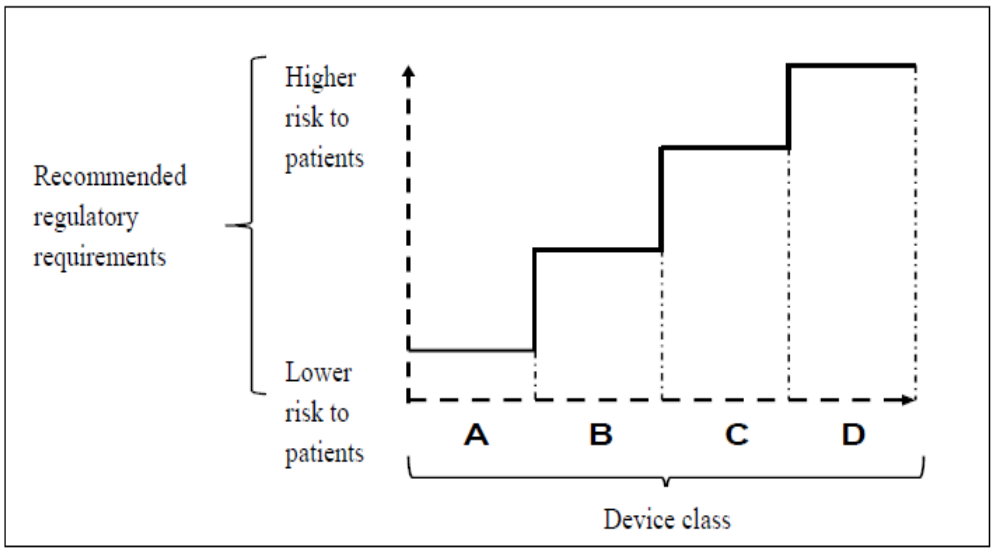


**Fig. 1: Classification of Medical Devices.**

## 2. MEDICAL DEVICE CLASSIFICATION IN INDIA[2-4]

Medical devices are categorized on the basis of their medical uses or technical model and manufacturing point. But medical devices have been classified by the regulatory authorities according to their safety and efficacy and quality standards to be set around the world. Different criteria are used to determine the risk, affected body system, effectiveness, and other local and systemic effects.

1. Notified medical devices,
2. Non notified medical devices,

1. Notified medical devices;

- Class A,
- Class B,
- Class C,
- Class D.

**CLASS A-** These medical devices are subjected to general controls and referred as low risk devices. Class 1 is subjected to regulatory control. In this category mainly it contains the banned devices, replacement, refund, good manufacturing practices, repair, and notification. Class 1 devices are not used in preventing any impairment to the human health. These are mainly exempt from premarket notification. These articles are basically simpler approach than other one.

Examples;- Surgical instrument, Toothbrush, Examination gloves, Elastic bandages.

**CLASS B**- This class mainly includes the general control and specific controls. It requires more regulatory control than

Class 1 These are referred as the low medium risk devices. These need certification by the notified body. These are performed as indicated without causing harm to patient or user. These include special requirements, post marketing surveillance.

Examples- sterile items surgical gloves, urinary catheters, stomach tubes, needles, tracheal tubes etc.

**CLASS C**- these devices are referred as the medium high risk devices, they need certification by the notified body for the design and manufacturing of medical devices. They follow the quality management system.

Examples blood bags, condoms, non absorbable sutures, anesthesia machine, contact lens care products.

**CLASS D**: General controls and specific control with premarket approval. These are referred as the high risk medical devices. These devices required premarket approval to ensure the device effectiveness and safety. These devices usually sustain human life. It is useful in preventing impairment of human health or risk of injury (Figure 1).

Examples;- pacemakers, vascular grafts, angioplasty catheters. Heart valves, implantable defibrillator.

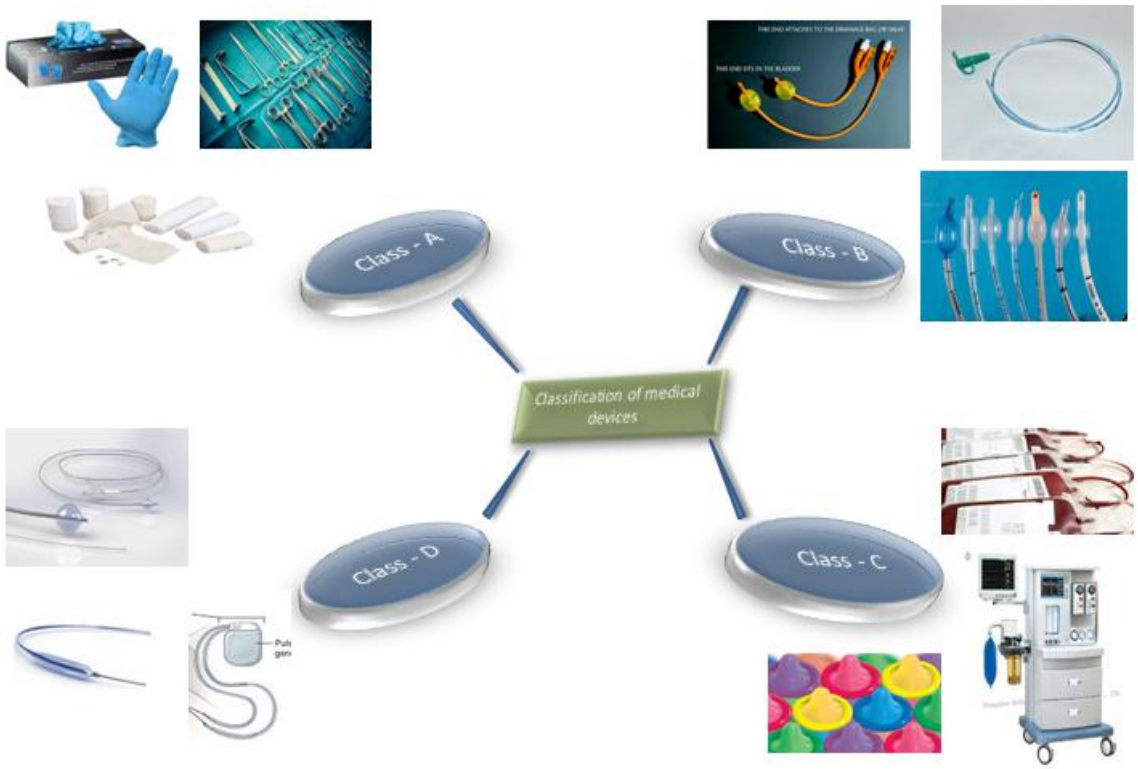


**Fig-2-Examples of Medical Devices.**

**2. Non notified medical devices**

The following products are regulated as drugs (Non Notified Medical Devices) under Drugs and Cosmetic Act & Rules as follows;-

1. Blood Grouping Sera
2. Ligatures, Sutures, and Staplers
3. Intra Uterine Devices (CU-T)
4. Condoms

5. Tubal rings
6. Surgical Dressing
7. Umbilical tapes
8. Blood/blood Component bags

- The list of medical devices with their date of notification is explained in Table 1 which has been regulated by Ministry of Health and family welfare Govt. of India.

Table 1- Notified Medical Devices with their date of notification , indication , and medical class division

| Name of device | Date of notification | Indication | Type of medical class division |
|---|---|---|---|
| Disposable hypodermic Syringes | 17-03-1989 | Used to inject liquid or gases into body tissues | Class 2 |
| Disposable Hypodermic Needles | 17-03-1989 | Used in treating shock | Class 2 |
| Disposable Perfusion Sets | 17-03-1989 | Cardiac Surgeries | Class 2 |
| In vitro Diagnostic Devices for HIV, HBsAG & HCV | 27-08-2002 | Provide information for diagnosis and monitoring | Class 2 |
| Cardiac stents | 06-10-2005 | Used in Angioplasty | Class 2 |
| Drug Eluting Stents | 06-10-2005 | Prevents fibrosis and used in angioplasty procedure | Class 3 |
| Catheters | 06-10-2005 | Hip Fracture repair, dementia | Class 1 |
| Intra Ocular Lenses | 06-10-2005 | Cataract surgery | Class 2 |
| I.V Cannulae | 06-10-2005 | Administer intravenous fluids | Class 2 |
| Bone Cements | 06-10-2005 | Implant fixation | Class 2 |
| Heart Valves | 06-10-2005 | To maintain the unimpeded forward flow through heart. | Class 3 |
| Scalp Vein Set | 06-10-2005 | Used for venipuncture | Class 2 |
| Orthopaedic Implants | 06-10-2005 | To support damaged bone | Class 2 |
| Internal Prosthetic Replacements | 06-10-2005 | Used for elbow replacement , for fixation of spine [11]. | Class 2 and 3 |

## 3. CLASSIFICATION OF MEDICAL DEVICES IN US AND EUROPEAN UNION[3-5]

**TABLE 1 Risk Classification of Medical Devices in the United States and Europe**

| United States | European Union |
|---|---|
| Class I: low risk of illness or injury, e.g., gauze, toothbrushes | Class I: low risk; e.g., sterile dressings, gloves |
| Class II: moderate risk of illness or injury, e.g., suture, needles | Class IIa: low-medium risk; e.g., surgical blades, suction equipment<br>Class IIb: medium to high risk; e.g., ventilators, some implants, radiotherapy equipment |
| Class III: significant risk of illness or injury; e.g., pacemakers, implantable defibrillators | Class III: high risk; e.g., drug-eluting cardiac stents, pacemakers, implantable defibrillators |

### Importance of Medical Devices

Medical devices must be able to meet the standards and should be designed in a specific way so that patient health and safety can be achieved. Population of India was a big factor for the

growth rate of medical device due to the patients health care, increased awareness among people regarding healthcare facilities and health insurance policy. Regulation of medical devices in India is done as drugs by the Drug Controller General Of India (DCGI) AND Central Drugs Standards Control Organization (CDSCO). Medical devices must be able to meet the standards and should be designed in a specific way so that patient health and safety can be achieved. The compliance and conformation procedures for Class A medical devices can be done by the manufacturer itself but ISO along with Bureau of Indian Standards (BIS) will issue the notified bodies for the conformity procedures of Class B and Class C. Notified bodies will be responsible for the examination of the device whether they are able to meet the ISO standards. Medical devices must have Indian Conformity Assessment Certificate mark, after conformation of standards by the notified bodies and they will be able to placed directly into the market. Schedule M-III (Quality Management System deals with the design, development, storage, production, management, and distribution of medical devices) is responsible for the import of medical devices in India. International Organization for Standardization (ISO) is responsible for the requirements of QMS and organization needs to submit demonstration of medical devices and services to meet customer needs and requirements. The Ministry of Health and Family Welfare, Government of India in 2009 notified an amendment that tends to strengthen the law against counterfeit medical devices in India.[3] Pharmacist can play a major role in the regulation of medical devices in India. Pharmacy personnel should be actively involved in the standards documentation to ensure that the materials, process are fit for the purpose.

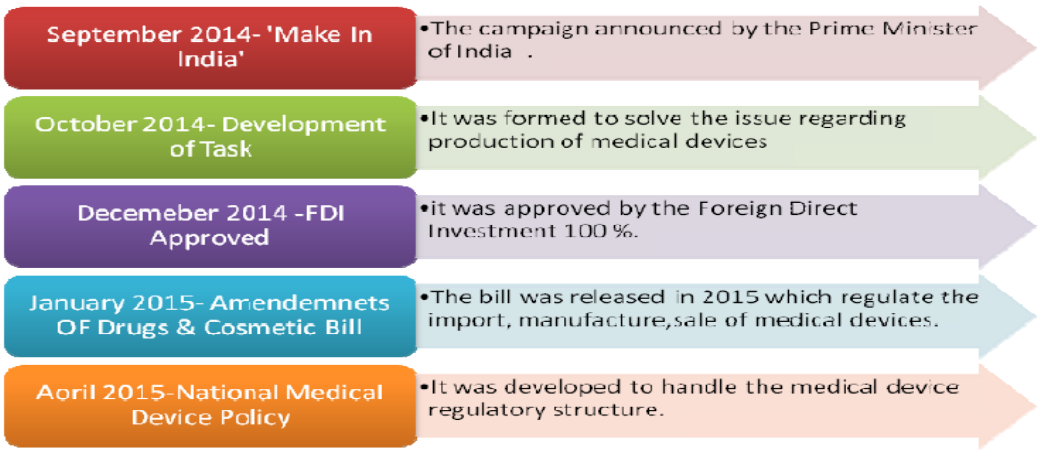


Figure 2- Regulatory framework of medical devices according to 'Make In India ' campaign.

## 4. REGULATORY FRAMEWORK FOR MEDICAL DEVICES IN INDIA[5-7]

India has emerged as one of the leading markets for pharmaceutical products. Increase in the private healthcare infrastructure, widening rural markets, and inclusion of newer technologies have placed healthcare as an independent sector in India. With privatization of healthcare, the medical devices sector is growing too. In order to regulate the import, manufacture, distribution and sale of drugs and cosmetics, the Drugs and Cosmetics Act, 1940 ("D&C, Act") was introduced in India in 1940. However, no separate legislation/regulation has been enacted for regulating the import, manufacture, distribution or sale of medical devices in India till date by the Government of India.

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The Central Drugs Standard Control Organization (CDSCO) is the key medical regulatory organization in India. Since 2006, both the Indian Department of Science and Technology and the Ministry of Health and Family Welfare have sought to completely restructure the regulations for the medical devices. Till date, neither of these attempts has been successful. Medical device market is quite diverse which includes medical and diagnostic equipment; medical implants like heart valve and cardiac stents, pacemakers, cannulae, knee joints; and lower end plastic disposables, blood bags, IV sets, syringes etc. There is a growing awareness about health issues within India, an increasing demand for quality care at affordable prices, further the Indian Healthcare industry is in a steady growth trajectory and is expected to grow in the next few years.

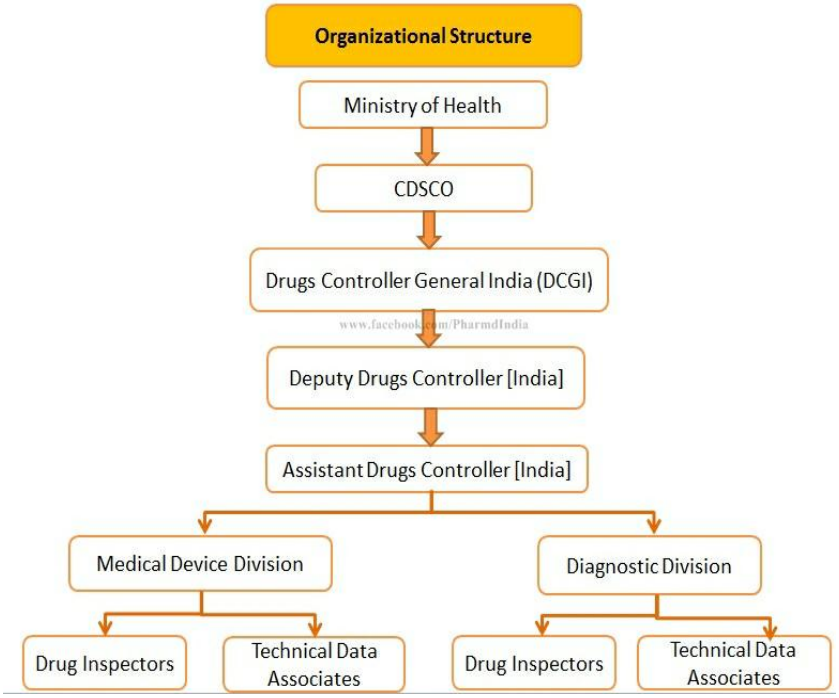


**Fig-4-Regulations of medical devices in India.**

## 5. MEDICAL DEVICES APPROVAL PROCESSES IN THE UNITED STATES AND EU[7]

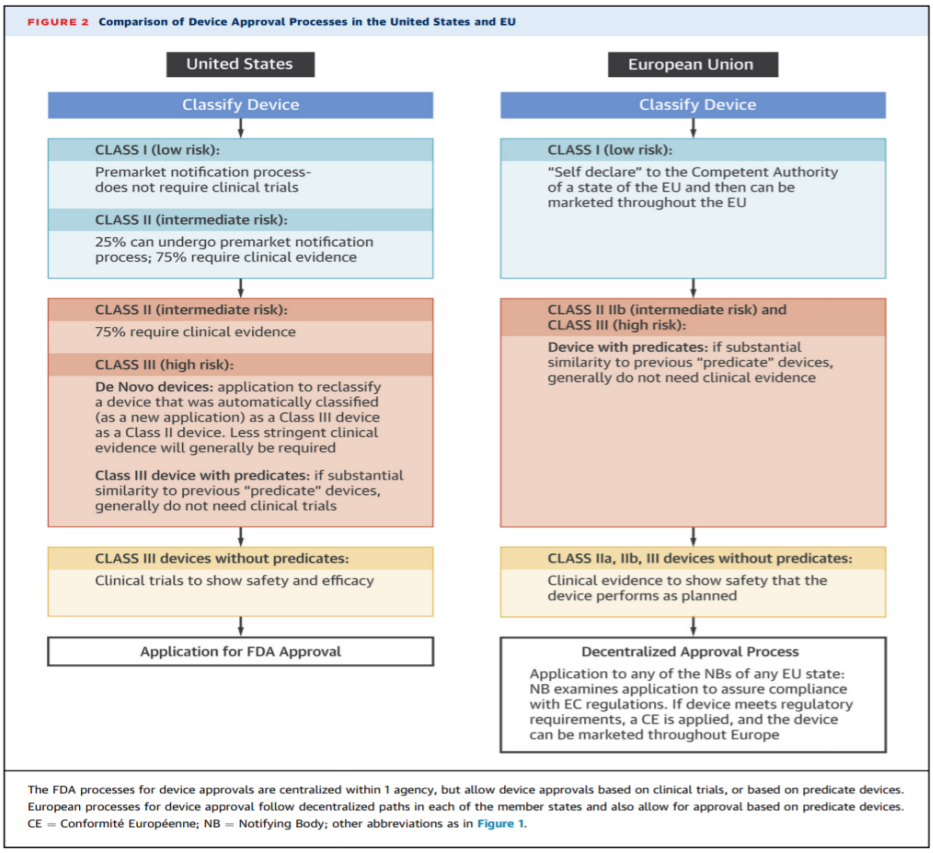


**Fig. 5: Medical Devices Approval Processes in The United States and European Union.**

## 6. CONCLUSION

Regulatory guidelines required for approving new medical devices must provide effective pathways for innovators but also ensure the safety of patients. The major purpose of making rules and regulations stringent for medicinal devices is to provide safety to public health. It is the responsibility of these regulatory authorities to ensure that the companies abide to the rules and regulations to safeguard public health. The article helps the readers to find knowledge about the regulatory approval process for medical devices in India, USA & European Unions.

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