Research Article: A Comparative Analysis of Medical Device Regulations: Insights into Regulatory Frameworks in India, United States of America and Europe

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Abstract:

Medical devices are essential tools in modern healthcare, enabling accurate diagnosis, effective treatment and improved patient outcomes. As their usage expands, the need for stringent regulatory oversight becomes critical to ensure safety, efficacy and quality. This research article presents a comparative study of medical device regulations in India, the United States of America (USA) and the European Union (EU), three major global markets with distinct regulatory systems. All three regions follow a risk-based classification approach where higher-risk devices require more stringent controls. The USA adopts a centralized system under the FDA's Centre for Devices and Radiological Health (CDRH) with streamlined approval pathways like 510(k), Premarket Approval (PMA) and De Novo classification. The EU operates under the Medical Device Regulation (MDR 2017/745) emphasizing conformity assessments by Notified Bodies, Unique Device Identification (UDI) and post-market surveillance via EUDAMED. India's Central Drugs Standard Control Organization (CDSCO) governs medical devices through the Medical Device Rules (MDR) 2017. The study analyses regulatory elements such as application procedures, clinical evaluation, quality management systems, import-export protocols and change management. It highlights major similarities and differences, identifies challenges in compliance and explores pathways for global regulatory harmonization. The findings help manufacturers, regulators and other stakeholders better understand medical device regulations and support easier global market access through simpler and more consistent rules.

Keywords: Medical Device, Manufacture, Import, 510(k), CE mark.

1.0 Introduction:

A medical device is formally defined by the World Health Organization as "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 specific medical purpose and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, but which may be assisted in its intended function by such means." (1)

The WHO states that medical devices can be used for one or more of the following particular purposes:

- Disease diagnosis, monitoring, therapy, and/or amelioration
- Identification, mitigation, monitoring, prevention, treatment, or payment for an injury
- Study, replacement, or encouragement of any anatomical region or physiological process
- Life's foundation and nourishment
- Controlling conception
- Sanitizing medical devices. (2)

Medical Devices are regarded as a critical component of Health Systems the benefits they can provide continue to grow as they are required to prevent, diagnose, and rehabilitate illnesses and diseases in a safe and effective manner. The steps involved in Medical Devices manufacturing, regulation, planning, assessment, acquisition, and management are complex but necessary to ensure their quality, safety, and compatibility with the settings in which they are used. There are an estimated 2 million different types of medical devices on the global market today, divided into around 7000 generic device groupings. The worldwide medical devices market was valued at roughly $488.98 billion in 2021 and is expected to reach an amazing US$718.92 billion by 2029. The rising prevalence of chronic diseases, combined with healthcare providers' increased emphasis on diagnosing and treating diseases earlier, is leading to an increase in the number of patients undergoing diagnostic and surgical procedures, which is encouraging companies to improve, develop, and create new innovative medical advancements. (2)

Medical device manufacturers play an important role in public health and the global economy. Further, the manufacturing of medical devices is very tightly controlled by regulatory authorities. The medical device industry is one of the most regulated industries; it is regulated by laws that govern the safety and performance of devices across their life time, in their pre- and post-market lifecycle. Regulated manufacturing industries operate under government laws and regulations, while unregulated manufacturing industries do not operate under government rules and laws. (3)

Advancement in medical technology is one of the key steps in achieving the target goals in health care. The availability of highly sensitive and specific diagnostic techniques has helped in decreasing the incidence of diseases (e.g., decrease in incidence of carcinoma cervix among females). Further, diagnosis of diseases has become more accurate and quicker. Also, these have provided treatment alternatives for cardiovascular, orthopaedic, endocrinology, and oncologic diseases (e.g., use of insulin infusion pumps). All these have helped in achieving a healthier and longer life of people. World over, the technological advancement has helped the disabled people lead an independent life, contribute to the community, study and work similar to the rest of the population. (4)

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. (5)

2.0 Materials & methods:

For this research article, the authors used source of data from specific data base like Pub-Med (US National Institutes of Health) is a recognized and respected web site for medical related articles on the usage of medical devices. (https://pubmed.ncbi.nlm.nih.gov/), Google Scholar provides a simple way to broadly search for scholarly literature. From one place, you can search across many disciplines and sources: articles, theses, books, abstracts and court opinions, from academic publishers, professional societies, online repositories, universities and other web sites. Google Scholar helps you find relevant work across the world of scholarly research (https://scholar.google.com/), The Cochrane Library is a collection of databases in medicine and other healthcare specialties provided by Cochrane and other organizations (https://www.cochranelibrary.com/) and various general and special websites & search engine shall be used e.g., Google, internet search, Official website of FDA and for planned searches has used which act as databases / registers for medical devices

3.0 Results and Discussion:

3.1 INDIA:

India, officially the Republic of India, is a country in South Asia. It is the second most populous country, the seventh-largest country by area, and the one of the most populous democracy in the world.

Table 1: Country profile of India

Regulatory Authority	Central Drug Standards Control Organization (CDSCO)
Capital	New Delhi
Largest city	Mumbai
Area	8.55m sq km (3.3m sq miles)
Language	22 languages
Currency	Indian rupee
Population	1.35 billion

The Indian market is among the top twenty in the world by market size and fourth in Asia after Japan, China and South Korea. The industry in India is largely dependent on imports around 75%, with local manufacturers contributing to the lower end of the value chain.

The Indian medical device industry followed Drug and Cosmetic Act 1940 and Rules 1945 which is ambiguous, complex and lacking transparency till when Medical Device Rules 2017 was passed and came into effect from 1 January 2018. The MDR 2017 (Medical Device Rules 2017) is in conformity with the Global Harmonization Task Force (GHTF) framework and it was drafted with the intention to distinguish medical devices from pharmaceuticals for improved and well-defined regulations. (6)

The Central Drug Standards Control Organization (CDSCO) is regulatory body for approval of medical devices in India, under MHFW. Draft copy of "Medical Devices Rules, 2017" was released by government of India 31st January, 2017. The main focus of these rules is to achieve highest standard of medical devices with assurance of quality and safety of it. To have access of safe and effective medical devices, it is classified on risk basis (Refer table No. 2 Medical device classification in India)

Table 2: Medical Device Classification in India (7)

Class	Level of risk	Examples
Class A	Low risk	Surgical Dressing, Tongue depressors, and Non-invasive devices.
Class B	Low to Moderate risk	Catheters, Nebulizers, Blood pressure monitors, and Thermometers.
Class C	Moderate to High risk	Catheters, Bone fixation plates, and Surgical drapes.
Class D	High risk	Implantable devices and Heart valves

For a person to manufacture or import medical device in India, a company should hold a valid whole sale license in in Form 20B or 21B to be an authorized Indian agent or should have established a local manufacturing site in India. The wholesale drug license application – Form 19 (Two applications are made) is submitted to and granted by individual State Licensing Authorities. (7,8) The applicants are required to submit the documents for grant of fresh licenses as per the checklist for State of Maharashtra on FDA Maharashtra official Portal. (9)

SUGAM Portal Registration:

The applicant needs to register their company in SUGAM portal (Online system for medical device) in order submit applications online for manufacture or Import and Copy of Manufacturing License or Wholesale Licenses (Form 20B & Form 21B) is mandatory for registration and gets approval in 14 days. (10)

Before applying for a manufacturing license, the applicant has to first obtain Test license in form M.D 13, in order to manufacture small amount of medical device which can be used to generate testing and stability data.

Quality Management System (QMS):

Fifth Schedule of Medical Device Rules,2017 to be implemented for finished medical devices for purpose of design, development, production, packaging, labelling, monitoring, installation and maintenance of the device.

Procedure to get Test License for Testing Purpose of Manufacturing medical Device: M.D Form 13:

The application in M.D Form-12 is sent to Central Licensing Authority (CLA) using SUGAM portal, to manufacture small quantity of medical devices for the purpose of testing. The CLA, after enquiry and review, issues a test license in Form MD-13 if satisfied, or may refuse the application within thirty days of the application date. (11,12)

Manufacturing License Procedure:

To manufacture Class A or Class B medical devices, manufacturer has to submit Form 3 or 4 application through SUGAM to manufacture device to the State Licensing Authority (SLA) with the necessary fee. All the documents submitted in SUGAM should also be submitted in paper copy to SLA.

Any individual who desires to market a medical device of Class C or D shall submit a request in SUGAM for issue of license in Form 7 or loan license in Form 8 to manufacture device to CLA with the prescribed fee.0[36,38] Paper copy submission of documents is not required for Class C & D device.

All documents shall be uploaded in SUGAM Portal, in pdf format and each file should not be more than 10mb. Assessment of the manufacturing facility by an authorized notified body is required before grant of the license (Refer Annexure V for notified body list in India). Manufacturing site of Class B, C & D devices should assure the compliance of Quality Management System and audit inspection is followed by regulatory body to issue license.39 For Class C & D device a team with at least two Medical Device Officers with or without a notified body will audit the premises. The audit report shall be shared to the CLA within 30 days of audit.

Once the examination of documents is done by SLA which proved to be compliance with regulatory requirements, manufacturer issues manufacturing license for class A and B devices in MD-5 form and in MD-6 Form in case of manufacturing loan license. For class C and D devices examination of documents is completed followed by inspection report. Once the compliance to regulatory requirements is proved, manufacturer issues license for manufacturing in Form MD-9 and in MD-10 Form in case of manufacturing loan license. (12)

Consolidation of import license and registration certificate:

Before the dawn of the MDR 2017 era, a manufacturer or his authorized agent who wishes to import a medical device into India, needs a registration certificate in Form 41 and import license in Form 10 on a mandatory basis

But the MDR 2017 has eliminated the need for registration certificate for the registration of the foreign manufacturers, their products and its manufacturing facilities. The basic requirement to import a medical device to India is to obtain is to obtain an import license in Form MD-15. which is to be applied via an authorized agent in Form MD-14 along with the prescribed fee and documents. This has made the import process less complicated than before. (6)

Procedure to obtain import license for medical device:

A. Import of medical device:

   Any individual who needs to import medical device should have foreign enterprise holding Indian subsidiary or appoint an authorised Indian agent in order to access Indian medical device market.

For foreign enterprise holding Indian subsidiary or appointment of an authorised agent: -

Power of Attorney (POA) is given to import medical device on behalf of the foreign enterprise and Indian embassy or equivalent personnel should authenticate POA.

B. Application for Grant of Import License:

Form MD-14 application shall be made according to the checklist.

Only an agent having valid wholesale license of medical device should send an application to issue import license to the CLA in Form MD-14 for obtaining import license. CLA may initiate an examination of production facility by a notified body. The applicant pays the expenditure of the inspection by CLA at overseas manufacturing site. (13)

C. Grant of Import License:

After verifying documents and depending on the audit report, the CLA may issue license in Form MD-15 or deny license with reasons within 9 (nine) months

Devices having Free Sale Certificate (FSC) issued by U.S, Australia, Japan, Canada, or the European Union Countries, import license may be issued without conducting clinical investigation in India.

Class C and D devices imported from other countries can enter Indian market only after safety and effectiveness of device is established through clinical investigation. In case of

Class B devices published safety and performance data and a FSC issued from the country of origin is sufficient to obtain import license.

Validity of an import license is for a total of 5 years from issued date.

Medical Device Testing Laboratory (MDTL):

The CLA, when the application for import of medical device is made, may ask the applicant to get the device which is to be imported be tested in one of the MDTL to access the safety of the device. MDTL issues certificate of test or evaluation in M.D Form-31. (14)

Table 3: Factsheet for Manufacturing of medical device in India

Product	Medical Device except in-vitro diagnostic device (IVD)
Country of Filing	India
Regulating Agency	CDSCO • CLA – Central Licensing Authority • SLA – State Licensing Authority
Regulating Ministry	Ministry of Health & Family Welfare (MoHFW)
Guideline	1) Medical Device Rules, 2017 2) The Drugs and Cosmetics Act, 1940 and rules 1945.
Regulatory Classification	Risk based classification of medical devices other than in vitro diagnostic medical devices, governed by the intended purpose of the device.
Mode of application	Online submission through - Online System for Medical Device (SUGAM) & Hardcopy Submission (SLA)

Agency	Input form	Output form	Validity	Turn Around Time
CDSCO & SLA	M.D 3 - Manufacturing License (Class A & B)	M.D 5	5 years and can be renewed there after	6 – 9 months
CDSCO & SLA	M.D 4 - Manufacturing Loan License (Class A & B)	M.D 6	5 years and can be renewed there after	1-2 months
CDSCO (CLA)	M.D 7 Manufacturing License (Class C & D)	M.D 9	5 years and can be renewed there after	6 – 9 months
CDSCO (CLA)	M.D 8 - Manufacturing Loan License (Class C & D)	M.D 10	5 years and can be renewed there after	2- 3 months
CDSCO (CLA)	M.D 12 - Manufacturing License for the purpose of testing	M.D 13	3 Years	1-2 months
Fees	As Given in second schedule of MDR-2017: - • Class A & B license for Site is Rs. 5,000 & Rs.500 for each additional item of Device or each unique type of device. • Class C & D license for Site is Rs. 50,000 & Rs.1000 for each additional item of Device or each unique type of device. • Test License to manufacture for clinical investigations or testing is Rs. 500 per product.			

Table 4: Factsheet for importing medical device to India.

Product	Medical Device except in-vitro diagnostic device (IVD)
Country of Filing	India
Regulating Agency	CDSCO • CLA – Central Licensing Authority • SLA – State Licensing Authority
Regulating Ministry	Ministry of Health & Family Welfare (MoHFW)
Guideline	1) Medical Device Rules, 2017 2) The Drugs and Cosmetics Act, 1940 and rules 1945.
Regulatory Classification	Risk based classification of medical devices other than in vitro diagnostic medical devices, governed by the intended purpose of the device.
Mode of application	Online submission through - Online System for Medical Device (SUGAM)

Agency	Input form	Output form	Validity	Turn Around Time
CDSCO (CLA)	M.D 14- Import Licence	M.D 15	5 years and can be renewed there after by paying fee	6-9 months
CDSCO (CLA)	M.D 16- Import Test Licence for Testing Purpose	M.D 17	5 years and can be renewed there after by paying fee	1-2 months
Fees	As Given in second schedule of MDR-2017: - • Class A Import license for Site is U.S $ 1000 & U.S $ 50 for each additional item of Device or each unique type of device.			

	• Class B Import license for Site is U.S $ 2000 & U.S $ 1000 for each additional item of Device or each unique type of device. • Class C & D Import license for Site is U.S $ 3000 & U.S $ 1500 for each additional item of Device or each unique type of device. • Fee for Import license for test or evaluation is U.S $ 100 • Inspection of the overseas manufacturing site is U.S $ 6000

3.2 UNITED STATES OF AMERICA (USA):

USA is the world's third largest country in size and nearly the third largest in terms of population. Located in North America, the country is bordered on the west by the Pacific Ocean and to the east by the Atlantic Ocean. Along the northern border is Canada and the southern border is Mexico.

Table 5: Country profile of USA

Regulatory Authority	United States of Food and Drug Administration (USFDA)
Government	Federal Government of the United States
Capital	Washington, DC
Area	9.8 Million Sq. Km (3.8 Million Sq. Miles)
Largest City	New York City
Language	English
Currency	US Dollar
Population	340 Million

Classification based on Risk (21 CFR 860):

Medical device risk classification was created by federal legislation (Federal Food, Drug, and Cosmetic Act, section 513). Medical device regulations are developed according to the relative risk of the equipment and are divided into classes. Regulatory classes I, II, and III are used to group devices according to the degree of control required to ensure a reasonable degree of safety and efficacy.

Class I devices are governed by the fewest regulations, and Class III devices are governed by the most stringent regulations. As the device class moves from Class I to Class II to Class III, regulatory constraints increase. (7)

Table 6: Classification of Medical Devices

Class	Risk Level	Required Submission	Examples
I	Low risk	Registration only unless 510(k) specifically required	Bandages, Tongue depressors.
II	Moderate risk	510(k) notification unless exempt • IDE possible	Powered wheelchairs, Infusion pumps.
III	High risk	PMA application • IDE probable	Pacemakers, Implantable defibrillators.

People involved in production and distribution of devices in U.S. have to register their facility annually by providing required information online, this includes submitting detailed list of marketed device, place of manufacturing, distribution site details and this process is known as establishment registration.

The manufacturers have to determine the right classification and appropriate regulatory controls applicable to their products by navigating the FDA website and check which of the 16 medical specialty panels and subgroup applies to the device. (15)

513(g) Program - If the manufacturer is unable to classify device, then clarification and advice regarding classification can be obtained from FDA by paying a user fee and placing a request for classification of the device. (16)

Registration and Listing of Device:

Medical device companies must register and pay the annual Device Facility User Fee (DFUF) online

Details relating to registration and listing are provided online and shall complete annual registration by paying user fee at the Device Facility User Fee (DFUF) website in the last quarter of every fiscal year.

Registration – The company (establishment) registers with the FDA.

Listing – The company lists all the medical devices they make or handle.

FURLS [FDA's Unified Registration and Listing System] or DRLM [Device Registration and Listing Module] is used for providing registration and listing information.

Issuance of Registration number does not denote device is cleared and can be marketed in U.S. it only confirms the company has registered.

A device listing number and importer registration are required to import medical devices into the U.S. (17)

Quality Management System (QMS):

Except few Class I devices all class of device are required to adopt and execute QMS that complies with the FDA Quality System Regulation (QSR) of 21 CFR Part 820.

513(g) Program –

If the applicant cannot determine the appropriate device classification, applicant can Request for Classification (513(g)) of the device. There is a 513(g) User Fee - $ 7,301. This program gives FDA view on the category of the device and required regulations that may apply to the proposed device. (18)

Agency view on the applicant's request is based on the information provided in the application and in part, FDA evaluation of the generic type of device to which the applicant device is classified into. It also explains whether such a device requires a PMA, 510(k) or neither is required to sell the product. Generally, product code for the device is given only for devices that are exempt and not for a 510 (k). (19)

5.2.5 Types of Applications for Medical Devices:

1 IDE
2 Premarket Notification 510 (K)
3 Pre-Market Approval

1. 21CFR Part 812 -IDE (Investigational Device Exemption):

An experimental device may be used in a clinical study under an investigational device exemption (IDE) to collect the safety and efficacy data required to support an FDA Premarket Notification 510(k) submission or Premarket Approval (PMA) application. A clinical research project involving a device with a high level of risk requires permission from both the FDA and the Institutional Review Board (IRB) before it can begin. Just before the investigation begins, the IRB permission is necessary for experiments using equipment that isn't too dangerous.

The following conditions must be met before devices that do not yet have marketing approval can be clinically evaluated:

1. An investigational plan approved by an institutional review board (IRB). If the study involves a significant risk device, the IDE must also be approved by FDA;
2. Informed consent from all patients;
3. Labeling stating that the device is for investigational use only;
4. Monitoring of the study and;
5. Required records and reports. (7,20)

2. Premarket Notification/510(K):

510 (k) is not a form. It is a request submitted to the FDA to prove that the device placed in the market is safe and effective. The FDA does not "approve" a 510(k) submission but instead "clears" the device for sale. It is achieved by proving that the device is substantially equivalent to a device that is approved device in US and that is not subject to PMA. (21)

Applicants must evaluate their device against a similar FDA approved device, which was legally marketed in US. A device which was previously cleared under 510 (k), a product which has been lawfully marketed before amendments, a device that was originally a high-risk device but later down classified to Class II or I can also be used for comparison as a predicate device.

The device(s) legally sold against which equivalence of new device is evaluated is known as the predicate device(s). Claiming of SE (Substantially Equivalent) does not say that the device(s) must be the same of that of a 510(k) applicant’s device.

SE is established for aspects like: Safety, effectiveness, performance, material of construction, intended use, resources, labelling, biocompatibility and other relevant aspects of the device. Also, an applicant can claim SE against a device which is no longer being marketed in the US.

Substantial Equivalence:

A 510(k) requires demonstration of substantial equivalence to another legally U.S. marketed device.

A device is substantially equivalent if, in comparison to a predicate it:

- has the same intended use as the predicate; and
- has the same technological characteristics as the predicate; or
- has the same intended use as the predicate; and
- has different technological characteristics and does not raise different questions of safety and effectiveness; and
- the information submitted to FDA demonstrates that the device is as safe and effective as the legally marketed device.

A device may not be marketed in the U.S. until the submitter receives a letter finding the device substantially equivalent. If FDA determines that a device is not substantially equivalent, the applicant may:

- resubmit another 510(k) with new data,
- request a Class I or II designation through the De Novo Classification process
- file a reclassification petition, or
- submit a premarket approval application (PMA). (22)

Product Codes:

These are the three coded letters, which is used by the agency in order to track and identify similar devices. This number is also useful for the 510(k) application submitters to search for an appropriate predicate device. (23)

De Novo Classification process:

De Novo is an FDA process used to classify new medical devices that do not have a similar (predicate) device but are low or moderate risk (Class I or II).

When is De Novo Used:

- If a company submits a 510(k) but no existing predicate device is found, the device is considered "new".
- If the device is not high-risk (Class III) and can be safely regulated as Class I or II, the company can apply for De Novo classification. (24)

510 (k)s have to be submitted in two copies to the FDA. One of the copies is submitted in an electronic format also known as eCopy and a hard copy submission. An eCopy is submitted along with a printed copy of the signed cover letter and the complete paper submission is submitted. (25)

Application is submitted to the Office of the Device Evaluation (ODE) which is part of the FDA's Centre for Devices and Radiological Health (CDRH). 510(k) applications are usually made when introducing a device for the first time by the manufacturer or when a device which was previously cleared has change in indications for its use or by making major modifications for the device.

Types of 510(k) Submissions:

1. Traditional 510(k):

Highly depends on the proof of substantial equivalence to a predicate device Used when:

- Introducing a new device with a predicate device available for comparison.
- Making significant modifications to an already cleared device.

2. Abbreviated 510 (k):

Mostly depends on the use of available of special regulation, guidance documents, and accepted standards. Used when:

- The device follows FDA-recognized standards or guidance documents.
- Submit a summary report showing compliance with recognized FDA guidance, standards, or special controls.
- Faster review if all guidelines are followed correctly.

3. Special 510(k):

When a modification to a device does not disturb the known use or the scientific aspects of the device. Used when:

- Making minor modifications to an already cleared device (e.g., design, labelling, or manufacturing changes).
- The modifications must not affect safety or effectiveness.
- Must reference the previously cleared 510(k) number of the original device.

Pre-Market Approval (PMA):

Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices.

Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of Class III devices.

Therefore, these devices require a premarket approval (PMA) application under section 515 of the FD&C Act in order to obtain marketing approval. Some Class III pre amendment devices may require a Class III 510(k).

PMA is the most stringent type of device marketing application required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).

The regulation governing premarket approval is located in Title 21 Code of Federal Regulations (CFR) Part 814, Premarket Approval of Medical Devices. A Class III device that fails to meet PMA requirements is considered to be adulterated under section 501(f) of the FD&C Act and may not be marketed. (26)

Import of Medical Device:

The FDA verifies and enforces legal requirements regarding medical devices to ensure that imported medical devices meet with relevant U.S. laws. The FDA's CDRH division oversees the Medical Device program. Imported devices should be in compliance all the relevant law applicable to both U.S Bureau of Customs and Border Protection (CBP) and FDA.

Foreign Manufacturers of Medical Devices:

A foreign manufacturer is a manufacturer located outside of the United States. Foreign manufacturers must meet applicable U.S. regulations in order to import a device into the U.S.

The basic regulatory requirements include:

- Establishment registration
- Medical Device Listing
- Quality System
- Premarket Notification [510(k)], unless exempt, or Premarket Approval
- Labeling
- Medical Device Reporting. (MDR)

US agent is mandatory for initial registration procedure and for updating procedure. FDA inspection is carried out for confirmation of regulatory requirements and in case of adverse drug events reporting.

Import Process:

All medical devices imported into the United States (U.S.) must meet the regulatory requirements of both the U.S. Bureau of Customs and Border Protection (CBP) and FDA. Products that do not meet FDA regulatory requirements may be detained upon entry.

CBP administers the Tariff Act of 1930 as amended. The primary duties include: assessment and collection of all duties, taxes, and fees on imported merchandise, administering and reviewing import entry forms, enforcing CBP and related laws, and administering certain

navigation laws and treaties. FDA and CBP have an agreement for the cooperative enforcement of the Food, Drug, and Cosmetic Act, Section 801, Title 21 U.S.C. 381.

An entry for an FDA regulated product that is filed with CBP, will also be electronically submitted to FDA for review. An importer or customs broker is required to submit required entry information to CBP through the Automated Commercial Environment (ACE) system.

The required entry information includes:

- country of origin

- importation product code, which is a combination of the FDA panel code and FDA product code
- importer product description
- manufacturer
- shipper
- applicable affirmations of compliance codes

The HTS code is a classification code used to provide the applicable tariff rates and statistical categories for items imported into the U.S. For questions and guidance on tariff rates, please contact your local CBP Port of Entry. (27)

Table 7: Factsheet for medical device for U.S.

Product	Medical Device
Country of Filing	United States (US)
Regulating Agency	US Food and Drug Administration
Regulating Ministry	U.S. Department of Health and Human Services (HHS)
Regulatory Classification	Medical device
Regulatory Department	The Center for Devices and Radiological Health (CDRH)
Application Form	No forms for 510 (k)
Regulatory Pathway	510 (k), PMA
Regulations	21 CFR 807 Subpart E , FD&C Act
Types of 510(k) Submissions	Traditional, Abbreviated and Special 510(k)
Mode of Submission	Hard copy and eCopy
FDA User Fee Type	MDUFA IV
510 k Fees	$24,335
PMA Fees	$540,783
Annual Establishment Registration Fee	$9,280
Medical Device User Fee Cover Sheet	Form FDA 3601
Review Timeline	90 days

3.3 EUROPE (EU):

Europe is a continent located entirely in the Northern Hemisphere and mostly in the Eastern Hemisphere. It is bordered by the Arctic Ocean to the north, the Atlantic Ocean to the west, Asia to the east, and the Mediterranean Sea to the south. It comprises the westernmost part of Eurasia.

Table 8: Country profile of EU

Regulatory Authority	European Medicine Agency (EMA)
Capital	Brussels
Area	10.8 million km2
Largest City	Istanbul
Language	24 languages
Currency	Euro
Population	74.14 crores

All requirements for a medical device to be marketed are given in the European Commission Regulation (EU) No. 2017/745, known as the Medical Device Regulation (MDR) with current latest version of 10/01/2025 66; it's a new set of regulations that replaces the older directives for medical devices and the transition period ends in 26 May of 2021. (28)

History of change from MDD to MDR:

Medical Device Directive (MDD):

The MDD (Council Directive 93/42/EEC), often referred to as MDD or 93/42/EEC, was introduced in 1993 and appended in 2007 by 2007/47/EC. For more than 25 years the MDD served as the most important regulatory document for medical device registration in Europe. This directive like all other directives was trans posed into national law by the EU Member States. As most of these laws directly referred back to the directive, the MDD defined the "essential requirements" and prerequisites to market medical devices in the EU.

The main objectives of the MDD were to ensure the free movement of medical devices in Europe and to allow only safe products that meet EU-uniform requirements.

Medical Device Regulation (MDR):

The MDR (Regulation (EU) 2017/745 on medical devices) was released in May 2017 and replaced the MDD (and the directive for Active Implantable Medical Devices (AIMD)).

The main intent of the MDR is to ensure a high standard of safety and quality for medical devices that are produced in, or supplied to, member countries of the EU.

Change from MDD to MDR:

The MDR entered into force (and was partially applicable) on 26 May 2017 and included a transition period of three years.

Due to the Coronavirus Disease 2019 (COVID-19) pandemic, the mandatory date of application of the MDR was postponed by one year. So, the start of the complete application of the MDR was 26 May 2021. This implies that as of 26 May 2021, medical devices can no longer be certified according to the MDD.

For the placement of medical devices on the market the transition period from MDD to MDR ends on 26 May 2024. However, medical devices already placed on the market may continue to be made available until 27 May 2025. (29)

Figure 1: Transition timelines from MDD to MDR

Major Changes in MDR:

The most important changes introduced by the MDR are as follows:

- Notified bodies (NB), manufacturers and importers will have to be registered (MDR certificate)
- Installation of a scrutiny procedure for NBs (Class IIb and III devices)
- Technical documentation (Annex II) must be updated continuously

- Labelling requirements have been massively increased
- Clinical investigations and evaluations are regulated according to more than 20 articles
- A Unique Device Identification (UDI) will be required
- The EUDAMED Database will be extended:
    1. Access to competent authorities, manufacturers, Notified Bodies and the public
    2. Display of certificates, vigilance reports, clinical investigations, and PMCFs
- Harmonized Evaluation of high-risk devices.68

In general, all devices placed on EU market must meet essential requirements and must be CE marked. Last stage of approval of device is placing CE mark on the device, and it indicates the requirements of the MDR regulation have been met.

Not all classes of medical devices are subjected to same control system; level of control depends on the type of device classification. For class I devices, conformity assessment process can be completed by the manufacturer and the CE mark can be placed without involvement of notified bodies due to low level risk associated with the device. Involvement of notified bodies is mandatory for class IIa devices. For class IIb and III which pose high risk, notified bodies should be involved right form the design and manufacture of the device. Following a successful audit by a notified body, which ensures the required regulations have been met, a CE certificate for the device is presented and manufacturer can place CE mark on their device. (30)

Table 9: Medical Device Classification in Europe

Class	Level of risk	Examples
I non-sterile	Low risk	Volumetric urine bags, tongue depressors
I Sterile	Low/medium risk	Bandage dressings, scalpels
IIa	Medium risk	Syringes, nebulizers
IIb	Medium/high risk	Defibrillators, hemodialyzers, incubators, lung ventilators
III	High risk	Heart monitors, breast implants, bioactive implantable devices, IUDs

Medical Device nomenclature and identification:

Among the innovation that have been introduced with the MDR there is the obligation to implement two system for the identification and traceability of MDs. These are the European Database on Medical Devices (EUDAMED) and the Unique Device Identification (UDI) system. (31)

Before placing a device on the market applicants have to comply with Regulation (EU) 2017/745 and need to register in “European Databank on Medical Devices (EUDAMED)” and provide information relating to the economic operator as well as information relating to the device. (32)

European database on medical devices (EUDAMED):

The European Database on Medical Devices, named EUDAMED, has been set up to support the traceability and enhance the transparency, including the information for the public and for healthcare professionals with regard to the devices placed on the market, to the economic operators, to the notified bodies and about the clinical investigations of Medical Device. (33)

In EUDAMED will have to be present the UDI of all the devices on the market. Indeed, in this database must be registered all the devices that must be placed on the market in the European Union. Other information to be included in the database are the information relating to conformity assessment, notified bodies, certificates relating to both clinical investigations and post-market surveillance. (34)

In MDR the reference article is Article 33 “European database on medical devices” which defines the purposes of EUDAMED, and the electronic systems include on it relating to the registration of devices, of the economic operators, of the notified bodies, of the clinical investigations, on vigilance and post-market surveillance, UDI-database. (35)

According to Article 33, EUDAMED database should contains:

- Electronic system for registration of devices referred to in Article 29(4);
- UDI-database referred to in Article 28;
- Electronic system on registration of economic operators referred to in Article 30;
- Electronic system on notified bodies and on certificates referred to in Article 57;
- Electronic system on clinical investigations referred to in Article 73;
- Electronic system on vigilance and post-market surveillance referred to in Article 92;

After the data entered in EUDAMED is verified, the regulatory authority will acquire a "Single Registration Number (SRN) and will issue it to the applicant. SRN is required while submitting applications to a notified body and for accessing EUDAMED. Device manufacturers except micro and small enterprises are needed to appoint a person responsible for regulatory compliance.

The electronic system is available from December 1st, 2020, useful for EU manufacturers, competent authorities and importers to register to the EUDAMED themselves, to provide necessary information and to obtain Single Registration Number (SRN) for each actor role. The SRN is made of three different parts (Figure 23). The first part is a two-letter country code for the actor (e.g., CH for Switzerland), the second part is the two-letter abbreviation of the actor's role (e.g., IM stay for Importer) and the third part is a 9-digit number code. (34)

Figure 2: Single Registration Number (SRN)

Unique Device Identification:

According to Article 2 of MDR, UDI is "a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market" (36)

The main objective of UDI system is to allow greater traceability of devices from the manufacturer to the end user, through the entire supply chain, described above. The identification code may also be used to improve incident reporting, safety corrective actions, surveillance by authorities, and to participate in the reduction of medical errors and in the detection of falsified devices. (34)

According to Article 27 of MDR is responsible for defining in detail the key features of the UDI code. In particular, in that article, it is said that the UDI code includes two distinct parts UDI-DI and a UDI-PI:

- The UDI-DI refers to a model of device and it is also used as the access key to information stored in a UDI database. It helps to distinguish if medical device is for example an artificial limb or a plaster. Whenever a change on the original performance safety and interpretation of data is made, the UDI-DI code must change.

- The UDI-PI identifies the unit of device production and it may include one or more of the following parts: serial number, lot number, software identification, manufacturing date, expiry date. (31,37)

It is placed on the label of the device or on its packing in text format or bar code. (33)

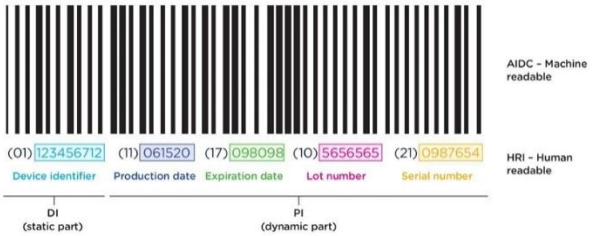

Figure 3: UDI Example

The manufacturer shall obtain a basic Unique Device Identification (UDI-ID) from the issuing authority before marketing device in EU. Details to the UDI database and assigning of basic UDI-ID shall be completed before the manufacturer send application to a notified body.

EU Declaration of Conformity:

According to Article 19 of MDR The EU declaration of conformity, written and signed by the manufacturer, is a document that attests to compliance of the device under examination with Regulation 2017/745. Also, compliance with any other Union legislation and Common Specifications is declared if the device is in line with those requirements. (37)

Annex IV of MDR provide the content of EU Declaration of conformity such as:

- The declaration of conformity is written in the official language of the Member State where the device is made available. The document contains the name, the trade name, and the single registration number (SNR) of the manufacturer and information regarding the device, including its name, UDI-DI, and risk class.
- Sometimes, additional information for the unambiguous identification of the product is reported, such as a photograph or a product code. Furthermore, when a NB is in charge of the certification procedure, the EU declaration of conformity reports the NB's name and a description of the conformity assessment procedure. (38)

Technical Documentation for Medical Device According to MDR 2017/745:

The term technical documentation is a generic term for product documentation, which gives the evidence, that a medical device conforms to the Regulation, meeting the general safety and performance requirements.

Technical documentation is a core part of the process of approval of medical devices. Without this documentation, a product cannot be approved because the manufacturer cannot perform the conformity assessment procedure with his medical device. Therefore, it is of great importance to maintain a technical documentation compliant with the standard.

No matter the class of the medical device, a technical documentation must always be available. In particular, for the technical documentation must comply with the requirements of the authorities in order to obtain CE conformity for their medical device. Products of simple Class I devices conformity assessments shall only be carried out by manufacturers without the intervention of any notified body, Class Is, Im, Ir need comply in parts with the requirements of the notified body, products of the class IIa, IIb and III must comply completely.

The information to be included in a technical documentation is listed in Annex II "Technical documentation" and it includes:

- Device description and specification, including variants and accessories.
- Information to be supplied by the manufactures.
- Design and manufacturing information.
- General safety and performance requirements.
- Benefit-risk analysis and risk management.

- Product verification and validation, in particular pre-clinical and clinical data. (34,39)

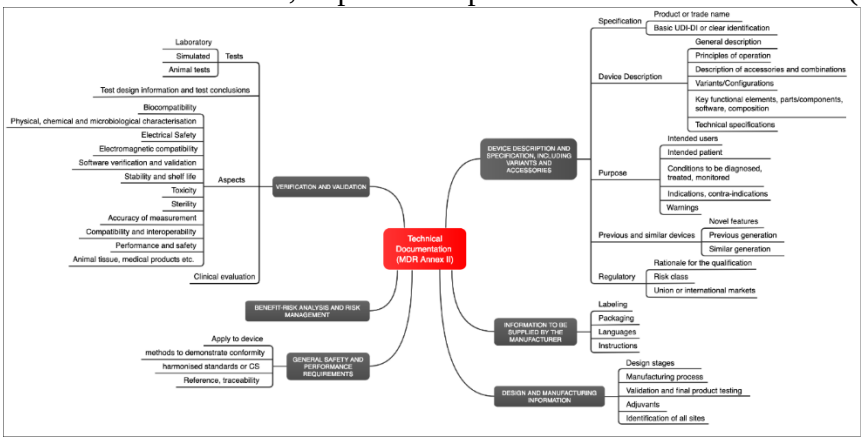

Figure 4: MDR specifies the requirements for the technical documentation in Annex II

Quality management system:

- According to Article 10 of the MDR requires manufacturers of products to set up, document, use, maintain, update and continuously improve a quality management system.
- Quality management encompasses all parts and elements of the organization that deal with the quality of processes, processes and products. To comply with MDR regulations, the Quality Management System (QMS) controls the required structure, responsibilities, procedures, processes, and management resources.
- Implement Quality Management System (QMS) to all the medical device manufactured in EU. The QMS will include a regulatory compliance plan including conformity assessment methods and a way for handling system modifications.
- Plan including conformity assessment methods and a way for handling system modifications. The post-market surveillance is done according to the post-market surveillance plan and it should be part of the manufacturer's QMS. (39)

Conformity Assessment Procedures:

A conformity assessment procedure must be undertaken by the manufacturer before the device is put in service or in the market. Where the conformity assessment involves a notified body, the manufacturer should submit an application for certification to a notified body of its choosing. Manufacturers shall conduct an assessment the device as per procedures set out in Annex IX to XI of MDR.71 (Refer Annexure XV The conformity assessment procedures set out in Annex IX to XI of MDR. (40)

Depending on the risk class and features of the device, there are different pathways to be followed.

1. Class I devices:

Manufacturers of class I devices, except for custom-made and investigational ones, after having prepared the technical documentation, follow a self-conformity assessment. They evaluate the device compliance on their own and, if the device fulfils the requirements of Regulation 2017/745, they submit the EU declaration of conformity.

If devices of class I are sterile, have a measuring function, or are reusable surgical instruments, manufacturers have also to undergo the QMS evaluation.

2. Class IIa, IIb, and III devices:

Manufacturers of devices belonging to classes IIa, IIb, and III are subjected to a conformity assessment procedure that involves a NB and is based on the assessment of the QMS and technical documentation.

The documentation to be submitted for the evaluation of QMS includes the documents related to PMS, the clinical evaluation plan, the organization of the company, the procedures related to the design, manufacturing, testing, and validation of the device. The QMS assessment could be performed within

an audit and, if conformity is respected, an EU QMS certificate is released. To verify that manufacturers continue to maintain a QMS in line with the one certified, the NB performs an audit at least every 12 months. Moreover, once every 5 years, the NB could carry out an audit without any announcement.

The NB also examines the technical documentation related to Annex II and III and may ask the manufacturers to perform additional tests to prove conformity with GSPR. Moreover, they analyse the clinical evaluation performed by manufacturers and for this purpose, they could involve an expert panel. In the end, they provide a final report about the documentation assessment and, if conformity is satisfied, an EU technical documentation certificate is released.

3. Additional procedures:

Special dispositions are needed when devices under examination are:

- class III implantable devices,
- class IIb active devices administering a medicinal product,
- devices incorporating a medicinal substance,
- devices consisting of animal or human origin, or their derivatives.

4. Custom-made devices:

For custom-made devices, manufacturers have to follow the conformity procedure set out in Annex XIII.

5. Investigational devices:

The requirements to be observed are those for devices under clinical investigation. (41)

Notified bodies play a vital role in the approval process as they are responsible for ensuring that medical devices put on the EU market follow all the necessities of the class assigned in MDR and documents should be as per an official language decided by that Member State.

Competent authorities should be informed about all the device certifications obtained by notified bodies. The certificates issued by the notified bodies shall be in a language recommended by the Member State. Notified bodies may restrict use of medical device in certain category of patients and manufacturer has to take follow up of it.

CE marking of Conformity:

The CE marking of conformity is the unique symbol indicating compliance with Regulation 2017/745. and it is affixed on devices before placing them on the market.

The manufacturer and the authorized representative are the only two figures who can affix this symbol.

The CE marking is put visibly on the device. Only when it is not possible to affix the symbol on the device, due to its shape or intended purpose, it can be placed on the packaging. (42)

Figure 5: CE mark symbol

1 Regulatory process for Conformité Européene (CE) marking:

- The MDR has a transition period of 4 years and will fully apply from May 2021. Medical devices must comply with the Medical Device Regulation (MDR) in order to obtain CE Marking certification.
- Appoint a responsible for regulatory compliance who have expertise in medical devices.

- Determine the regulatory classification of the device using annex VIII (Classification rules) of the MDR.
- Implement Quality Management System as per annex IX of the MDR, which is similar to ISO 13485.
- Prepare a Technical file / Design Dossier as per annex II of MDR.
- Obtain UDI for the device from competent issuing authority.
- Manufacturer who does not have establishment in a state, the device can only be placed in EU if the manufacturer designates a sole EU Authorized Representative (EC REP).
- EC REP name and address should be placed on device label.
- SRN from EUDAMED should be obtained.
- Declaration to the EU regulations should be prepared, the manufacturer shall predict accountability for compliance with the MDR.
- Manufacturer EC REP should submit an application for certification to a designated notified body of its choice and QMS, technical file or design dossier must be examined by a notified body each year to ensure ongoing compliance with the MDR.
- CE marking certificate for device and ISO 13485 certificate will be granted for firm and manufacturer now can place CE marking on the device.
- Perform clinical evaluation and PMS activities to maintain certification.
- Facility audited each year to ensure compliance with MDR, CE marking certificate will be invalidated if the audit fails.
- CE marking certificate usually valid for period indicated by NB but not exceeding 5 years and are reviewed during annual ISO 13485 audit.

Import into EU:

When a manufacturer is not recognized in member state, the product can only marketed in EU if the manufacturer designates a EC REP. Importers should place only such devices which are CE marked and are in compliance with the current regulation and “EU declaration of conformity” of the device is given. The product is labelled accordingly and accompanied by the instructions for its use and the manufacturer assigns an UDI-ID on the device. Importers should always have a copy of EU declaration.

A post-market surveillance system shall be planned, created, recorded, implemented, maintained and updated for each device in a manner proportional with the risk class and suitable to the type of product.

General obligations of importers:

Place only such devices for which manufacturers and Authorized representative are present and devices are CE marked and are in compliance with the current regulation. EU declaration is signed, required device labelling information along with importers details and UDI information (if applicable) is present on the label.

Importers must maintain a log book to note down complaints, recalls and withdrawals of the device. Importers should always have a copy of the EU declaration of conformity. (43)

Authorized Representative (AR):

When a manufacturer is unidentified in a member state, the device can only be placed in E.U if the manufacturer appoints an AR and the responsibilities include:

- Review of “EU declaration of conformity” and other necessary technical documents.
- Verify if the device is registered and as an UDI-ID if applicable.
- Inform manufacture about complaints and reports from healthcare or authorities.

Table 10: Factsheet for medical device for E.U

Product	Medical Device
Country of Filing	European Union (EU)
Regulating Agency	Europe Medicine Agency (EMA)
Regulatory Classification	Medical device
Regulatory Department	National competent authorities
Application Form	Conformity assessment application to notified bodies
Regulatory Pathway	CE mark certificate
Regulations	Regulation (EU) 2017/745
Mode of Submission	Online submission to Common European Submission Portal (CESP)
Review Timeline	3 to 12 months

3.4 COMPARISON:

Table 11: Comparison of regulation and requirements for medical device in India, USA and EU.

Features	India	USA	EU
Regulatory agency	Central Drug Standards Control Organization (CDSCO)	U.S. Food and Drug Administration (USFDA)	EMA Europe Medicine Agency and National competent authorities
Product	Medical Device	Medical Device	Medical Device
Regulations	Medical Device Rules, 2017	FD&C Act, 21 CFR Parts	Medical Device Regulation (MDR) 2017/745
Classification based on risk	A- Low risk B-Low-Mod risk C-Mod-High risk D-High risk	I-Low risk II- Moderate risk III-High risk	I non-sterile- Low risk I Sterile- Low risk IIa- Medium risk IIb- Medium/high risk III- High risk
Approval Pathways	Application in M.D Form-3 for Class A & B, M.D Form-7 for Class C & D for Manufacturing and M.D Form-14 for Import.	510(k) Clearance (Application for most of the Class II device and few class I and III devices.), PMA Approval (For Class III devices.), De Novo (medical devices that do not have a predicate device)	Application to Notified body for confirmatory assessment.
Mode of Submission	SUGAM portal (Online System for Medical Devices) + Hardcopy (Class A/B); Online only (Class C/D)	Hard Copy and eCopy Submission	Online Submission through CESP Portal (Common European Submission Portal)

Features	India	USA	EU
Database	Not Applicable	GUDID, Medical Device Database, FURLS (FDA Unified Registration and Listing System)/ Device Registration and Listing Module (DRLM).	EUDAMED
UDI	Effective from January 2022 (Under development; limited currently)	Global Unique Device Identification Database (GUDID) is well established. Direct marking of UDI on devices is mandatory from 24 September, 2022.	European database on medical devices (EUDAMED) UDI have to be assigned to all the devices sold in EU by May 2021
Quality Management System (QMS)	Mandatory for Class B, C, D devices as per 5th Schedule of MDR 201	Mandatory compliance to FDA's Quality System Regulation (QSR) 21 CFR Part 820	ISO 13485-based QMS required under MDR 2017/745
Conformity Assessment	Notified Body required for Class C/D	FDA site inspection for most manufacturers	Notified Body audit mandatory for IIa, IIb, III
Product Label Requirements	Basic labelling with manufacturer's details	Full labelling (21 CFR 801) including UDI code and IFU (Instruction for use)	Strong focus on labelling and language requirements under MDR
Clinical Investigation Requirement	Needed only for Class C/D unless FSC (Free Sale Certificate) is available.	Mandatory IDE for significant-risk devices	Clinical evaluation is mandatory for almost all classes
Post Market Surveillance	Event reporting through SUGAM Portal	MDR Reporting (21 CFR 803), MAUDE (Manufacturer and User Facility Device Experience) database.	Vigilance and PMS Plan reporting to EUDAMED
Timeline	6 to 9 Months	Most 510(k) applications in 90 days. For submissions received beginning in Fiscal Year 2019, average total is 120 calendar days.	3 to 12 months
Fees	1. Class A & B license for Site is Rs. 5,000 & Rs.500 for each additional item of Device. 2. Class C & D license for Site is Rs. 50,000 & Rs.1000 for each additional item of Device. 3. Class A Import License for Site is U.S $ 1000 & U.S $ 50 for each	1. 510(k) application- $24,335 2. PMA- $540,783 3. Annual Establishment Registration Fee- $9,280	Varies according to the notified bodies and member state.

Features	India	USA	EU
Validity	Valid in perpetuity, unless it's cancelled or surrendered. (Pay retention fee every 5 years)	Annual Establishment Registration. (Device must remain in compliance with FDA regulations to continue selling of device in the US market.)	CE Certificate valid for 5 years (NB audit required)

4.0 SUMMARY AND CONCLUSION:

The regulation of medical devices is a critical function to ensure that products entering the market are safe, effective and of assured quality. Each country has developed its own regulatory framework, shaped by its healthcare priorities, infrastructure and legal systems. This comparative study focused on India, the United States (USA) and the European Union (EU), three major regulatory jurisdictions with distinct approaches to medical device approval.

All three countries follow a risk-based classification system, wherein higher-risk devices undergo more rigorous scrutiny. Regardless of the classification, the implementation of a Quality Management System (QMS) is a mandatory requirement to ensure consistent product quality and compliance. The QMS typically includes risk management, documentation control, corrective and preventive actions (CAPA) and internal audits, ensuring that safety and performance standards are upheld throughout the product lifecycle.

In the USA, the regulatory authority U.S. Food and Drug Administration (FDA) follows a centralized approach through its Centre for Devices and Radiological Health (CDRH). The approval pathways include 510(k) for substantial equivalence, Premarket Approval (PMA) for high-risk devices and De Novo classification for novel devices. The FDA framework is known for its speed and efficiency offering the fastest approval timelines among the three, particularly the 510(k) pathway, which allows manufacturers to bring devices to market by demonstrating equivalence to a legally marketed device (predicate). This pathway reduces the burden of full clinical testing and accelerates market access, making the USA one of the most innovation-friendly regulatory environments

In the European Union, regulation is governed by the Medical Device Regulation (MDR 2017/745), replacing the older Medical Device Directive (MDD). The EU employs a decentralized system where conformity assessment is conducted by independent Notified Bodies. The MDR introduced several important changes including stricter clinical evaluation requirements, mandatory Unique Device Identification (UDI) and enhanced post-market surveillance (PMS). The MDR is considered one of the most robust regulatory systems globally, especially for high-risk devices, ensuring long-term patient safety, traceability and transparency via the EUDAMED database.

India, regulated by the Central Drugs Standard Control Organization (CDSCO) has modernized its framework with the Medical Device Rules (MDR) 2017. It introduced clear device classification (Classes A to D), streamlined licensing, digital submission via the SUGAM portal and recognition of foreign approvals from GHTF founding members. Despite these advances, India still faces challenges such as longer approval timelines and limited availability of local clinical trial facilities. However, the introduction of Notified Bodies, mandatory Quality Management System (QMS) certification and a stronger focus on post-market surveillance show India's clear efforts to align its medical device regulations with international standards.

An important differentiation lies in how device modifications are treated: while the USA allows for Special 510(k) submissions for minor modifications, India requires a fresh application even for small changes and the EU requires a notified body review depending on risk.

In all countries, the complexity and cost of regulatory compliance increase with the risk level of the device, and market authorization becomes more demanding. Post-market surveillance and adverse event

reporting mechanisms such as Manufacturer and User Facility Device Experience (USA), European Database on Medical Devices (EU) and SUGAM (India) play a crucial role in ensuring ongoing safety and performance after the device is approved.

In conclusion, this study shows that the USA provides efficient and well-organized regulatory pathways, the EU emphasizes thorough evaluation and transparency and India is actively improving its system to match global standards. As India continues to upgrade its regulatory framework, it has strong potential to become a leading centre for medical device innovation and manufacturing. Moving forward, adopting international best practices, avoiding unnecessary work and encouraging better co-operation between regulators and the industry will be key to achieving this goal.

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