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THE COMPARISON OF MEDICAL DEVICE REGULATIONS IN INDIA WITH USA, EU: AN QUALITATIVE STUDY

[1]Tulshidas Ramdas Maske, [2]Dr. Nilesh Ware,

[1]Dept. of Technology Management, Defence Institute of Advanced Technology (DU),DRDO, Pune, India

[2]Assistant Professor, Dept. of Technology Management, Defence Institute of Advanced Technology (DU),DRDO, Pune, India

Abstract : Safe, effective, and of high-quality medical devices are necessary for a well-functioning healthcare system. By 2025, The market for medical devices worldwide is anticipated to be worth $797 billion [1]. In the medical regime, the effectiveness and safety of medical equipment are crucial factors. The authorization process is intricate, multistep, region-specific, and requires assessment by notified bodies. The notified bodies approve marketing licensing/authorization after critically investigating the technical documentation submitted by the Manufacturer.

For quality patient care, there needs to be a balance between innovation and regulations. Manufacturers must submit an application for marketing authorization to the US Food and Drug Administration (USFDA) in the USA [2]. National notified bodies, EMA, and RA of member states must all approve the marketing of medical devices in the European Union[3]. Medical device manufacturing, import, and sales in India are authorized by the Drug Controller General of India (DCGI), a central licensing authority (CLA) under the Central Drugs Standard Control Organization (CDSCO).

This paper aims to review medical device regulations in these three nations, namely the USA, the EU, and India, and to compare regulatory requirements across these three areas as well as their potential influence on innovation market.

***Keywords*:** Regulatory affairs, FDA, MDR, EU MDR, CDSCO, CE Marking, Patient safety, Good Regulatory Practices

1) INTRODUCTION

The Global Harmonization Task Force (GHTF) has developed the standardized definition of medical devices as in (GHTF document SG1/N029R11) [4], The term "medical devices" as used under section 3 of the Drugs and Cosmetics Act of 1940 (23 of 1940) includes:

"all devices like instruments, apparatus, appliances, implants, material, or articles used alone or in combination, including software or an accessory, intended by its manufacturer to be used especially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of:

- Diagnosis, prevention, monitoring, treatment, or alleviation of any disease or disorder;
- Diagnosis, monitoring, treatment, alleviation, or assistance for, any injury or disability;
- The investigation, replacement or modification, or support of the anatomy or of a physiological process;
- Supporting or sustaining life;
- Disinfection of medical devices; and control of conception" [5].

Though having the second-largest population, India still imports all the medical devices it needs, About 80% of the national's medical devices are still imported. In India, imports dominate the medical device industry [6].

The following top 10 global healthcare corporations all gained their positions in the "*Forbes Global 2000* rankings for 2020 [7]:

Medtronic ranks #1

Johnson & Johnson #2

Abbott #3
Philips #4
GE Healthcare #5
BD #6
Siemens Healthineers #7
Cardinal Health #8
Stryker #9
Baxter #10 " [7].

Medical device companies should establish and maintain an effective medical device lifecycle planning and quality management system (QMS) that includes establishing user needs, regular quality assurance inspections, and a functioning CAPA process that ensures and addresses product non-conformance events for end users.

Four categories are used to segment the global market for medical devices: device type, expenditure type, end-user-based, and region based. This paper will emphasis on segmentation based on geography:

- Asia Pacific region: China, India, Japan, South Korea;
- North America: USA; South Africa: Brazil;
- Western Europe region: Germany, UK;
- Middle East; European Union: Russia;
- Africa.

The regulatory process of India, USA, and Europe is overviewed below.

2) NEED OF THE STUDY

The comprehensiveness of regulatory processes are an effort to control and elevate healthcare end users. A multistakeholder group aspiring to bring new, innovative, and effective medical devices to market is the metaphorical 'a valley of death' in which most products get failed before being commercially marketed. Regulatory process envy from developing ideas to clinical uses and most of the country's regulatory amendments are designed for patient safety. The intended use of the device is a key factor determining the further review process. In the emerging era, telehealth has critically uplifted patient care during COVID-19 but there is a need of appropriate internal discussion between government bodies, industry, researcher's innovators for reboot risk assessment to improve medical products transition to patient care.
This review study attempted to:

- Summary of medical device regulations in USA, EU and India
- Review a comparative analysis of the regulations governing the manufacture of medical devices in India, the USA, and the EU.
- To assess and propose suggestions for useful growing demands for innovators and the community of the medical business

3) COMPONENTS OF THE REGULATORY FRAMEWORK

The 67th World Health Assembly, which endorsed WHA 67.20, a regulatory system enhancement for medical devices, underlined the value of rigorous regulatory frameworks. The resolution states that "Regulators are an essential part of the health workforce," "effective regulatory systems are a vital component of strengthening the health system and contribute to better public health outcomes," and "inefficient regulatory systems themselves can be a barrier to access to safe, effective, and quality medical products." [4]

a) Elements of the regulatory framework

The terms "law," "regulation," "standards," and "guidelines" shown in Fig. 01 are used to establish the structure of the regulatory framework. Common procedures for GRP (10,13,14,30-WHO) are outlined through a review of available public documents in regulations of medical products are [12]:

- Legality
- Consistency
- Independence
- Impartiality
- Proportionality
- Flexibility
- Clarity

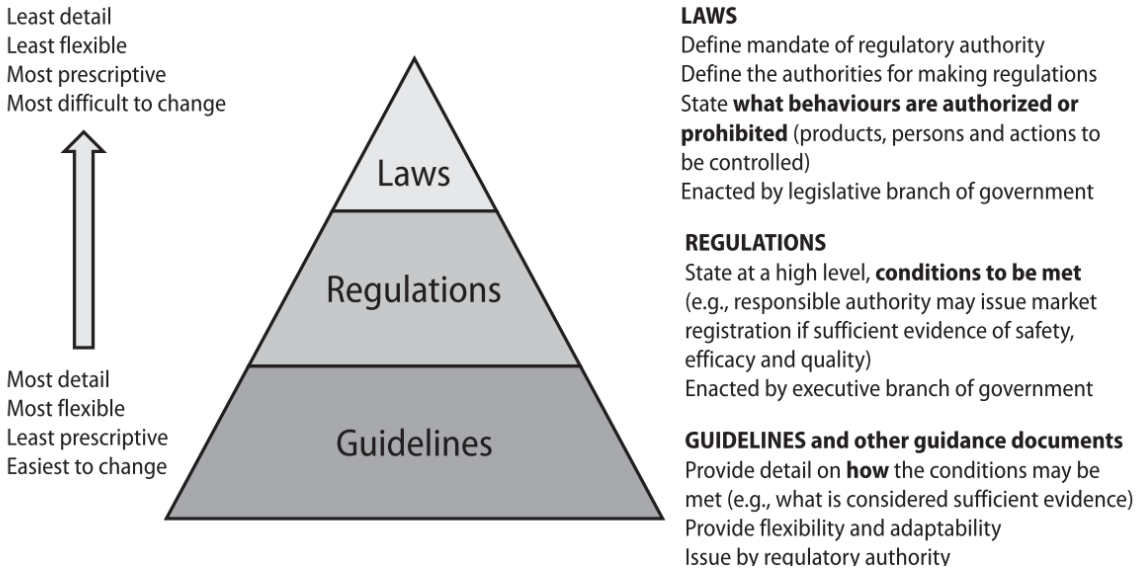

Figure 01. The architecture of a regulatory framework (TRS 1033-55th report of the WHO Expert Committee) [4]

b) Common stages of government regulations

The performance and reliability of medical devices into the market are influenced by three key factors: the product, use, and presentation framed by regulatory bodies. Fig. 02 indicates these crucial components.

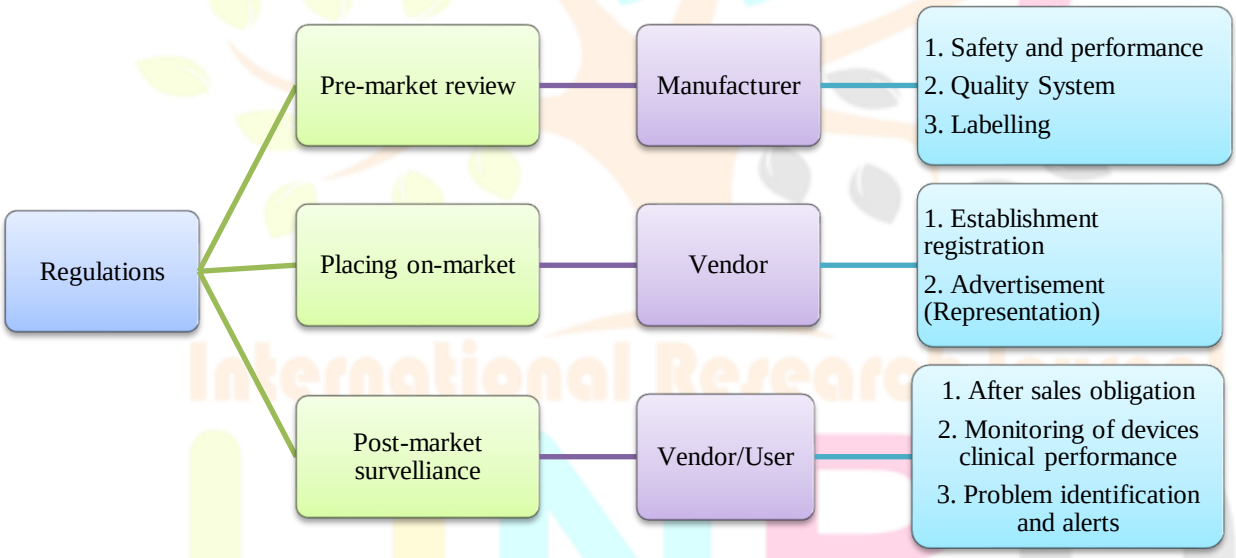

Figure 02. Critical elements for regulatory attention

4) United States of America – FDA QSR (21 CFR 820)

The U.S. Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) oversees medical marketplace in the country. According to FDA 2891- 21 CFR Part 807 [9], the establishment is obligated to register its premises and list its products/devices with the FDA. Table 1. lists the 21CFR820 subparts. Any foreign business that intends to import medical equipment into the United States must designate a U.S. authorized agent, who must be a U.S. citizen or possess a business location in the US.

Instead of depending on technologies and procedures, the FDA's classification system is based on the intention of the device and the level of risk it poses [2]. The FDA differentiates devices into three categories:

- "Class I- low risk of illness or injury (such as surgical gauze);
- Class II-moderate risk (such as sutures [10]); and
- Class III-support or sustain human life, are of substantial importance in illness/ injury" [2]. according to the FDA [2].

✓ General Controls include: -

- Marketing the devices in compliance with Good Manufacturing Practices;

- Establishment Registration by manufacturers, distributors;
- repackagers, and re-labelers;
- Medical Device Registration of Devices with FDA;
- Medical Device Reporting of adverse events as identified by the medical device's user, manufacturer and/or distributor;
- Labelling medical devices in accordance with the labeling regulations, 21 CFR 801 or 21 CFR 809" [14].

Subpart	Section
A	General Provisions
B	Quality Management Requirements
C	Design Controls
D	Document Controls
E	Purchasing Controls
F	Identification and Traceability
G	Production and Process Controls
H	Acceptance Activities

Subpart	Section
I	**Nonconforming Products**
J	Corrective and Preventive Action
K	Labeling and Packaging Control
L	Handling, Storage, Distribution and Installation
M	Records
N	Servicing
O	Statistical Techniques

Table 01. Summary of 21 CFR820 Sub-parts [2].

According to figure 3, classification of the devices, determines the regulatory control along and after the marketing process, which are significant considerations for the manufacturers.
Depending on the device's specifications and the variables affecting the submission for approval, one of three fundamental pathways followed to obtaining FDA marketing authorization for medical devices: "The three processes are the humanitarian device exemption (HDE) process, the PMA process, and the PMN procedure" [16].

5) European Union – Regulation (EU-MDR) 2017/745)

"Medical Device Regulation" (MDR) is a set of regulations and standards that govern the manufacture, distribution, and use of medical devices in the EU. The MDR was introduced in 2017 and became fully applicable in May 2021, replacing the previous Medical Device Directive (MDD). The MDR aims to improve the efficiency and reliability of medical devices, enhance transparency and traceability throughout the supply chain, and increase the notified bodies' role in the compliance evaluation process.. The MDR applies to all medical devices sold or distributed in the EU, regardless of their origin, and imposes new obligations on manufacturers, importers, and distributors of medical devices.

Since the 1990s, the EU has had "three comprehensive directives that address medical devices. These are:

- Active Implantable Medical Devices Directive 90/385/EEC;
- Medical Devices Directive 93/42/EEC; and
- In Vitro Diagnostic (IVD) Directive 98/79/EC."

In accordance with the specified articles indicated in table 02 [10], manufacturers must adhere to the EU Directive's standards in order to obtain the *Conformite Européenne (CE)* designation for medical devices.

Chapters	Section	Articles
I	Scope and definition	Articles 1 - 4
II	Making available on the market and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement	Article 5- 24
III	Identification and traceability of devices, registration of devices and of economic operators, a summary of safety and clinical performance, European database on medical devices	Articles 25- 34
IV	Notified bodies	Article 35-50
V	Classification and conformity assessment	Article 51-60
VI	Clinical evaluation and clinical investigations	Article 61- 82
VII	Post-market surveillance, vigilance and market surveillance	Article 83- 100
VIII	Cooperation between member states, medical device coordination group, expert laboratories, expert panels and device registers	Article 101-108
IX	Confidentiality, data protection, funding and penalties	Article 109-122

Table 02. Summary of Regulation (EU) 2017/745 chapters. [10].

The ordinance rules directed in MDD 93/42/EEC provide decision scale for manufacturers primarily for intended-use-based classification followed by modification or re-examine weather the product complies with risk-based classification.

5.1. Classification of Medical devices as per EU-MDR

The selection of an appropriate category is set by MDR/2017/745 legislation by their characterization, scope and intended use as shown in below table 03.

Sr. No.	Group	Sub-Class	Class
1	Active Implantable devices	**I**	I- low risk (Blood pressure cuff, Hospital bed .etc.)
2	Active non-implantable devices for imaging, monitoring, and/or diagnosis	**Is**	
3	Active non-implantable therapeutic devices and general active non-implantable devices	**Im**	
4	Non-active implants and long-term surgically invasive devices	**Ir**	
5	Non-active, non-implantable devices	**IIa**	II- Medium-high Risk (Hearing aid, X-ray , Ventilator etc.)
6	Specifics of MDs	**IIb**	
7	Technologies for MD's- Auditing	**III**	III- High Risk (Pacemaker, brain spatulas etc.)
8	Custom-made devices	-	Special Class

Table. 03. Classification of medical devices EU-MDR 2017

According to Annex V, "'CE marking of conformity' or 'CE marking' refers to a marking by which a manufacturer indicates that a device is in compliance with the applicable requirements set out in this Regulation and other applicable Union harmonization legislation. " Medical devices other than custom-made or investigational devices that are considered to be in compliance with the requirements of MDR/745/2017/745 shall bear the CE marking of conformity. The identification number of the designated body in charge of the conformity assessment processes specified in Article 52 [10] must come well after CE marking.

6) India – Medical Device Regulation, 2017

Medical Device Regulations in India are the set of rules and guidelines that govern the manufacturing, import, sale, and distribution of medical devices in the country. These regulations are enforced by the Central Drugs Standard Control Organization (CDSCO), which is the national regulatory body for medical devices in India. The regulatory framework for medical devices in India is based on the Medical Device Rules, 2017, which were introduced to replace the earlier regulations that were in place since 2005. The new rules aim to streamline the regulatory process, improve patient safety, and ensure the quality of medical devices being sold in the country

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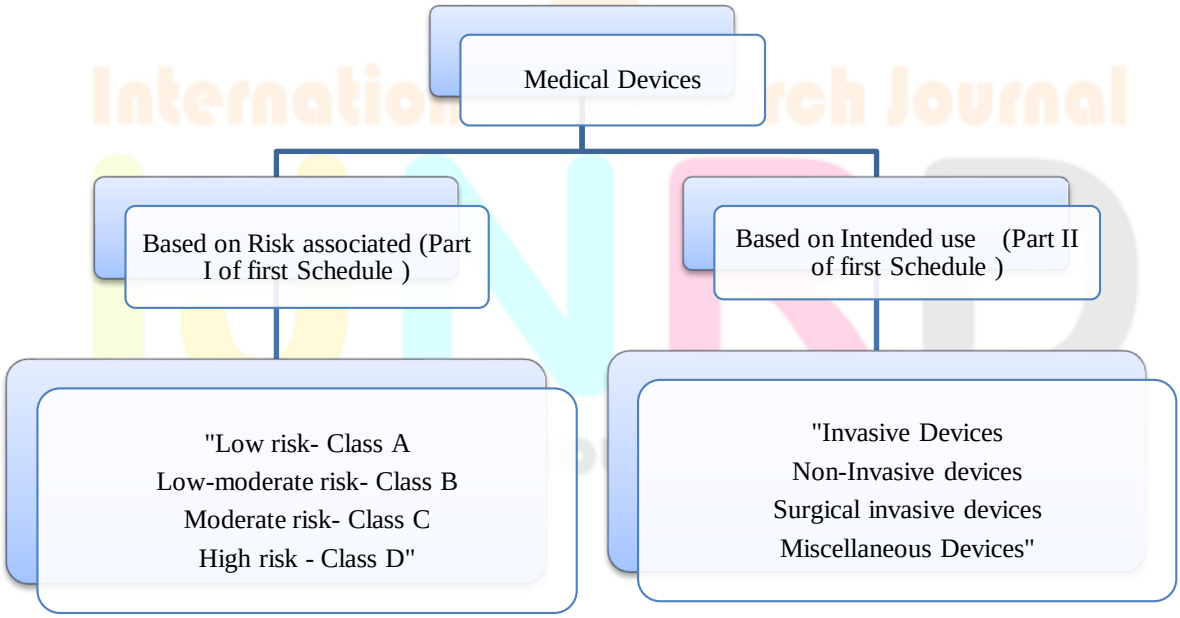

Figure 03. Brief classification of Medical Devices in India

Figure 03. illustrates how schedule M-III (Quality Management System) of the Medical Device Rules 2017 (G.S.R. 640 E) classifies medical devices. A limited number of devices, referred to as Notified Devices, are regulated by the CDSCO, Government of India, under the Central License Approval Authority (CLAA). The Indian government is considering steps to strengthen the regulatory framework [8].

State licensing authorities manage Class A and B Medical Device (MD) manufacturing (SLA). However, the CDSCO regulates the manufactured of Class C and Class D MDs, which may lead to pre-inspection of the manufacturing plant [16].

Chapters	Section
I	Preliminary
II	Regulation of medical device.
III	Authorities, officers and bodies
IV	Manufacture of medical devices for sale or for distribution
V	Import of medical devices
VI	Labelling of medical devices
VII	Clinical investigation of medical device and clinical performance evaluation of new *in vitro* Diagnostic medical device
VIII	Import or manufacture medical device which does not have a predicate device
IX	Duties of medical device officer, medical device testing officer and notified body
X	Registration of laboratory for carrying out tests or evaluation
XI	Sale of medical devices
XII	Miscellaneous

Table 04. Summary of Medical Device Regulation, 2017 chapters [8].

Medical devices are classified as Class -A, Class B, Class C, and Class D under the aforementioned rules' Schedule M-III, Part-I, on risk basis. Medical equipment are divided into two categories in Part II, those used for in-vitro diagnostics and those used for other purposes. The intended use of devices, combined with the following criteria, regulate this classification provision:

6.1 "Parameters of classification of In-vitro diagnostic medical devices :

i) *In vitro* diagnostic medical devices for detecting transmissible agents, etc (Class C / D)
ii) *In vitro* diagnostic medical devices for blood grouping or tissue typing (Class C / D)
iii) *In vitro* diagnostic medical devices for self-testing (Class B/C)
iv) *In vitro* diagnostic medical devices for near-patient testing (Class C)
v) *In vitro* diagnostic medical devices used in *in vitro* diagnostic procedures (Class A)
vi) Other *in vitro* diagnostic medical devices (Class B)" [8]

6.2 "Parameters of classification of other medical devices :

i) Non-invasive medical devices which come into contact with injured skin. .(Class A/B/C)
ii) Non-invasive medical devices for channelling or storing substances (Class A/B/C)
iii) Non-invasive medical devices for modifying compositions of substances (Class B/C)
iv) Other non-invasive medical devices (Class A)
v) Invasive (body orifice) medical devices for transient use (Class A/B)
vi) Invasive (body orifice) medical devices for short-term use (Class A/B)
vii) Invasive (body orifice) medical devices for long-term use (Class B/C)
viii) Invasive (body orifice) medical devices for connection to active medical devices.(Class B)
ix) Surgically invasive medical devices for transient use (Class B/C / D)
x) Surgically invasive medical devices for short-term use (Class B/C/D)
xi) Implantable medical devices and surgically invasive medical devices for long long-term (Class B/C / D)
xii) Active therapeutic medical devices for administering or exchanging energy (Class B/C)
xiii) Active diagnostic medical devices (Class A/B/C)
xiv) Other active medical devices (Class A)
xv) Medical devices incorporating medicinal products (Class B/C)
xvi) Medical devices incorporating animal or human cells, tissues or derivatives (Class A/D)
xvii) Medical devices for sterilization or disinfection (Class B/C)
xviii) Medical devices for contraceptive use (Class C/D)" [8].

7. Overview of Medical Device Regulation in the USA, EU and India

Overview of Medical Device Regulation in the USA, EU and India			
Factors	USA-FDA	EU-MDR	INDIA- MDR
Purpose/structure	The FDA is a federal organization tasked with maintaining the peoples welfare.	MDCG evaluates whether a product is within its purview on a case-by-case basis. Device approval is governed by notified bodies, which are private entities. Government organizations are competent authorities.	G.S.R.78(E) NABCB (QCI body) prepares norms, standards, and procedures for the accreditation of Notified Bodies and conducts audits.

Centralization	The FDA oversees both the approval of devices and their regular surveillance	More than 70 NBs compliance approval via their regulatory pathway. Device safety and surveillance are the responsibility of a competent authority in each of the member states of the European Union.	CDSCO delegates all or any of the regulations' power within the Central Licensing Authority and State Licensing Authority
Funding	80% of the funding comes from federal appropriations. Approximate fees contribute 20% of funds	Contracts with device manufacturers provide NB with all of their funding. Each country has different funding for competent authorities.	NAB act for purpose of entitling Notified Bodies. Registration holder deposits retention fee as per Schedule-II for every 5yrs.
Data requirement for registration	By premarket authorisation approval or 510(k) clearance, a device must demonstrate its safety and effectiveness as well as its substantial equivalent status to a predicate product.	The ability of the equipment to carry out its intended function must be demonstrated, and conformity assessment is needed. UDI-DI (Annex VI) and other core data elements (Annex VI)	The manufacturing site is inspected, application of rule 122DD of DCR,1945, pilot clinical investigation report, plant master file and device master file, Data Pertaining to Part- IV
Premarket transparency	Information exchange is subject to exclusive restrictions, however the FDA facilitates the sharing of safety and approval data.	The notified bodies' approval decisions are not made public. In Europe, there is no obligation to show the premarket clinical efficacy of high-risk devices.	Party shall maintain such data , records and other documents for period of 7years and disclosure of such data is made available with CLA .
Device Surveillance	Reporting by manufacturers and healthcare institutions to the FDA is mandatory. Reporting by healthcare professionals and consumers is voluntary. suspensions or withdrawals.	Manufacturers are required to report adverse incidents to competent authorities. After 2011, all adverse occurrences must be reported to the European Databank on Medical Devices.	ISO-1993, Biological Evaluation of Medical Devices should be followed. Demonstrate conformity of devices. Real-time aging data shall be submitted to support shelf-life
Post-market Surveillance	Public health advisories, safety alerts, and product announcements may be made by the FDA. To share information, CDRH created the Post-Approval Studies Database. mechanisms for tracking, reporting device failures, severe accidents, or fatalities, and registering the businesses that manufacture or distribute devices.	Competent authorities share post-market data but not with the general public. Adverse-event reports, field safety notifications, and equipment recalls can all be issued by competent authorities. The European Database on Medical Devices (EUDAMED), to which PSUR is referred in Article 85, was created and is administered by MDCG.	The dossier should contain vigilance reporting procedure and data collected, encompassing details of complaints received and CAPA taken within the validity period. The applicant should furnish Periodic Safety Update Reports (PSUR)
Technical Documentation (Sections)	*510(k) Submission* ✓ Design History File (DHF) ✓ Device Master Record (DMR) ✓ Device History Record (DHR)	✓ Summary Technical Documentation (STED) 1. Device description and specification, including variants and accessories 2. Information to be supplied by the manufacturer 3. Design and manufacturing information 4. General safety and performance requirements 5. Benefit-risk analysis and risk management	✓ Plant Master File ✓ Device Master File 1. Executive summary 2. Description and specification, including variants and accessories of the in vitro diagnostic medical device. 3. Essential principles checklist 4.Risk analysis and control summary 5.Design and manufacturing information 6. Product validation and verification

	Group 1 – Cover Sheet Forms Group 2 – Public Information About Your Device Group 3 – Templated Sections Group 4 – Comparing Your Device vs. Predicate(s) Group 5 – Ensuring Patient Safety Group 6 – Software and Electrically Powered Components Group 7 – Performance Testing	6. Product verification and validation 7. Post-market surveillance plan addressing the collection and utilization of available information	7. Analytical Studies 8. Specimen type 9.Analytical performance characteristics 10. Analytical sensitivity 11. Analytical specificity 12. Metrological traceability of calibrator and control material values 13. Measuring range of the assay 14. Definition of Assay Cut-off 15. Stability (excluding specimen stability) 16. Claimed Shelf life 17. In use stability 18. Shipping stability 19. Clinical Evidence 20. Labelling 21. Post marketing surveillance data (vigilance reporting) 22. Information required to be submitted for the in vitro diagnostic medical device
RECALLS, CORRECTIONS AND REMOVALS (DEVICES)	Under 21 CFR 7, manufacturers typically voluntarily recall medical devices. Under 21 CFR 810, Medical Device Recall Authority, FDA may order the manufacturer to recall a product. FDA's Manufacturer and User Facility Device Experience (MAUDE) database	The EU MDR categorizes recalls and field notifications as "field safety corrective actions" (FSCA). The national authority must receive a corrective and preventive action plan from the applicant conformity assessment body in a specified amount of time in order to handle the non-compliances.	In cases if doing so may prevent, minimize, or eliminate a hazard associated with the use of such a medical device, in accordance with the provisions of the Act and these regulations, with the authorised authorities. Corrective measures must be in accord with how the nonconformities were experienced. shall take action to eliminate the cause of nonconformities in attempt to prevent recurrence.
Conformity	Premarket Notification 510(k) is not required for the majority of Class I devices, but is required for the majority of Class II devices, the majority of Class III devices, and the majority of Class IV devices. FDA Approved/Clearance is conformity	EU declaration of conformity states that regulation requirements is covered by device (Annex IV). The CE mark of compliance must be clearly visible, legible, and permanent on the product or packaging.	A license or loan license is issued by licensing authority under rule 31. QMS certificate issued.

Table 05. Differences in MD Market Penetration in the United States, European Union and India

8. RESULTS AND CONCLUSION

The following table is outlined a comparative review on medical device regulation based on geography:

Sr. No.	Comparatives	India	U.S.	Europe
1	Regulatory authority	DCGI under CDSCO	Federal Food Drug and Cosmetic Act (FD&C Act)	EMA & RA of Member State
2	Regulation	Medical Device Rules, 2017	FDA QSR (21CFR820)	Regulation (EU) 2017/745
3	Classes of Medical devices	Four 1. Class A 2. Class B 3. Class C 4. Class D	Three 1. Class I 2. Class II 3. Class III	Three 1. Class I 2. Class II i) Class II a ii) Class II b 3. Class III
4	Regulatory Pathway	Market Authorization application to competent authority	510K application Premarket Approval (PMA)	Multiple Pathways for different classes.
5	QMS Requirement	ISO13485:2016	QSR 21CFR Part 820 (Similar to ISO13485:2016 but not same)	ISO 13485 or as needed under 94/42/EEC
6	Assessment of technical data	Notified bodies (NB) Under CDSCO	USFDA	Notified Bodies (NB) Under National Regulatory Authority
7	Establishment Registration Requirements	Premises Registration	Establishment Registration	Responsible person registration
8	Data Presentation (Electronic/Paper)	Paper / Electronic	Electronic/ Paper submission	Electronic/Paper submission
9	Language	English	English	English
10	Clinical test reports	Mandatory for class C and D devices	Class II and Class III devices that are inventive may also need	For Class IIb and III medical devices
11	In-country Clinical test	Not strictly required	Required and approved by IRB (institutional review board)	Must be approved by European Competent Authority
12	Fees for Pathway	Import Licenses: Registration fee-$1000 Premises Inspection fee- $ 5000 Manufacturing License: License fee - ₹ 6000 Registration fee-₹ 1500	510 (k) : $ 4690 PMA: $ 234,495	Fees for available pathways
13	Registration expiry	5 years from date of approval	Indefinite Unless revoked or recalled and no change in medical device	CE mark validity is 3 years for Class IIa, IIb, and III, and unlimited for Class I. (Shelf-life must not exceed 60 months further than expiration date.)
14	Time required for approval (in Months)	For the notified device, 6–12 months	Class I- (1 month) Class II- (6-9 months) Class III-PMA (18-30 months)	Class I (1 month) Class II (3-6 months) Class III (9-15 months)
15	Final Outcome	Import/Manufacturing License Number	Marketing Clearance 510k	CE Mark with NB number
16	On-site audits	Applicable (Notified Bodies)	Random unannounced audits	Applicable (Notified Bodies)

Table 06. Comparative review of Medical device regulations in US, EU, and India

The comprehensiveness of regulatory processes are an effort to control and elevate healthcare end users. A multistakeholder group aspiring to bring new, innovative, and effective medical devices to market is the metaphorical ‘a valley of death’ in which most

products get failed before being commercially marketed. Regulatory process envy from developing ideas to clinical uses and most of the country's regulatory amendments are designed for patient safety. The intended use of the device is a key factor determining the further review process. In the emerging era, telehealth has critically uplifted patient care during COVID-19 but there is a need of appropriate internal discussion between government bodies, industry, researcher's innovators for reboot risk assessment to improve medical products transition to patient care.

9. Challenges in Indian MDR

1. Limited Confirmatory Assessment facilities and notified bodies for Medical Devices in India
2. There is no specific regulations for most adult medical devices leading to ambiguity and delayed market conversion due to heterogeneity within adult population.
3. Indian government is establishing 'National Digital Health Ecosystem' (NDHE) and recently released Health Data Management Policy ("HDM Policy") in Dec-20 but its part of telecom regulations and not included in MDs regulation authority unlike US.
4. The International Medical Device Regulators Forum (IMDRF) produced guidelines for the regulatory framework for software as a medical device (SaMD), which may not be relevant for India's expanding incubating ecosystem..
5. The regulatory environment for medical devices in India is complex and fragmented, with multiple regulatory bodies involved in the process. This can create confusion and uncertainty for companies seeking to navigate the regulatory landscape and can lead to delays in the approval process.
6. The CDSCO has limited capacity for post-market surveillance of medical devices, which can pose a risk to patient safety and create challenges for companies seeking to comply with regulatory requirements.

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11. CONFLICT OF INTEREST

There are no conflict of interest.