Research Article

A Study on Global Scenario and Updation in Regulations for EU Medical Devices

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ABSTRACT

Regulations are foreordain requirements for the development, promotion and approval of medical devices that assures it should be of good quality, safety and efficacy, in order to protect, improve and monitor the public health. After the development and before the distribution of medical devices into the market, it is supposed to be licensed by respective regulatory authorities across the globe. There is a giant-strides in the worldwide regulation of medical devices, as the manufacturers are forced to accomplish the regulatory requirements, documented standards, norms, guidelines, specifications, testing methods for the design, and manufacturing of devices. As proposed, various changes have to be implemented in the new EU MDR such as classification rules of medical device, technical document, registration of medical device, clinical investigations, post marketing surveillance and vigilance, conformity assessment, EUDAMED and so on. This work is an attempt to present the comparative study of regulations related to medical devices. The study will also explain the possibility of new regulatory regime to protect the rights of patients in the background of medical devices and technology.

Keywords: Medical Device, Regulations, Directives, MDR, EU, Timeline.

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INTRODUCTION

Importance of Regulations for Medical Device

Regulation is primarily concerned with equipping patient access to high quality, safe and effective medical devices, and avoiding their approach to products that are unsafe[1]. When appropriately implemented, regulation ensures public health benefit and the safety of patients, health care workers and the community. Therefore, this implies that regulations set the ground rules for health planning process.[2]

Regulations are a set of documents that are designed to ensure that medical device companies and all parties involved such as manufacturers, conformity assessment bodies, authorities, and professional users meet the performance and safety requirements in order to protect patients and arbitrators from hazards and frauds. To meet the requirements, companies, need to understand their device and revise the specifications required by the authorities to ascertain which laws are practicable to the case.[3,4]

Over the past years, there has been augmented expectations concerning quality, security, and effectiveness of the Medical Device Regulation (MDR)[5]. With the emerging step of new technology and thereafter the scandals related to them threatens the health of thousands of patients, hence, authorities recognized the need to take more rigorous measures for the safety of patients and users of medical devices. The regulation of devices carries through the 'New Approach' policy of the EC Commission[6] and culminates in more self-monitoring and conformity assessment[7]. The three-stage framing [Figure 1] comprehends broad range activities of a medical device to enhance safety and outcomes; in particular "good management practices[8] for medical devices" by the user. This is in proportionate with the regulatory requirement of "good manufacturing practices in QMS" by the manufacturer.[9]

As far as the acquirement of medical device regulations, the main challenge lies in the niche of innovation. Most of the innovative research in industrial unit of medical devices is undertaken by small to medium enterprises (SMEs)[10], that are based on the alliance of healthcare professionals and small local companies or university laboratories. Amongst, 25,000 MedTech companies in Europe, as many as 95 percent certified as SMEs. It is SMEs, rather than large companies, that are most exposed to forced market exit because of the high administrative costs of development.[11]

The regulations ensure that the same requirements are implemented throughout the EU at the same time. This means that there is consistency in the regulations which is considered as a great benefit for the medical devices[12]. A directive contains general rules that EU member[13] states transpose into their national laws.

Figure 1: Systems management framework for medical device safety and optimal performance[9]

Each member state does this in a manner considered appropriate for its own country. That's why, under the Medical Device Directives (MDD)[14], some EU countries such as France, Italy, Poland, Spain, Portugal, and Germany have extra requirements beyond those stipulated in the directive.[15]

In Europe, before the commencement of a new medical device, companies are required to provide technical documentation in order to set out the conformation that they follow the "regulatory framework, which validate a high level of safety and health while supporting innovation" (Regulation (EU) 2017/745).[16]

The list of the current EU Medical Device Regulations (MDRs) and Directives is presented in **[Table 1]**.[17] They are intended to harmonize the laws affiliated with medical devices within the European Union (EU)[18] and the European Economic Area (EEA)[19], as well as to remove technical barriers to trade in Europe. They belong to the group of New Approach Directives, and they are written for the following groups of MDs: Active Implantable Medical Devices,[20] general Medical Devices[21], and *In-vitro* Diagnostic Medical Devices[22,23].

Table 1: List of Current European Union Medical Device Regulations and Directives.[17]

Directive	Date	About
Council Directive 90/385/ EEC	• July 20, 1990	EEC Active Implantable Medical Devices Directive (AIMDD) Revisions/modifications/amendments: - Council Directive 93/42/EEC - Directive 93/68/EEC - Directive 2007/47/EC
Council Directive 93/42/EEC	• June 14, 1993	Medical Devices Directive (MDD) Revisions/modifications/amendments: -Directive 93/68/EEC - Directive 98/79/EC - Directive 2000/70/EC - Directive 2001/104/EC - Directive 2007/47/EC
Directive 93/68/EEC	• July 22, 1993	CE marking
Directive 98/79/EC	• October 27, 1998	*In Vitro* Diagnostic Medical Devices Directive (IVDD)
Directive 2000/70/EC	• November 16, 2000	Amending Council Directive 93/42/EEC as regards to medical devices incorporating stable derivates of human blood or human plasma
Directive 2001/104/EC	• December 7, 2001	Amending Council Directive 93/42/EEC concerning medical devices
Directive 2007/47/EC	• December 5, 2007	Amending: - Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices - Council Directive 93/42/EEC concerning medical devices - Directive 98/8/EC concerning the placing of biocidal products on the market

Regulation (EU) 2017/745	• April 5, 2017	Medical Device Regulation (MDR) Repealing - Council Directive 90/385/EEC - Council Directive 93/42/EEC Amending - Directive 2001/83/EC (Community code relating to medicinal products) - Regulation (EC) No 178/2002 (General principles and requirements of food law) - Regulation (EC) No 1223/2009 (Cosmetic products)
Regulation (EU) 2017/746	• April 5, 2017	*In Vitro* Diagnostic Medical Device Regulation (IVDR) Repealing - Directive 98/79/EC - Commission Decision 2010/227/EU

The MDR merge the legislation for medical devices and active implantable medical devices into one document, replacing the Medical Device Directive (MDD)[14] and Active Implantable Medical Device Directive (AIMD)[20], **[Figure 2].**

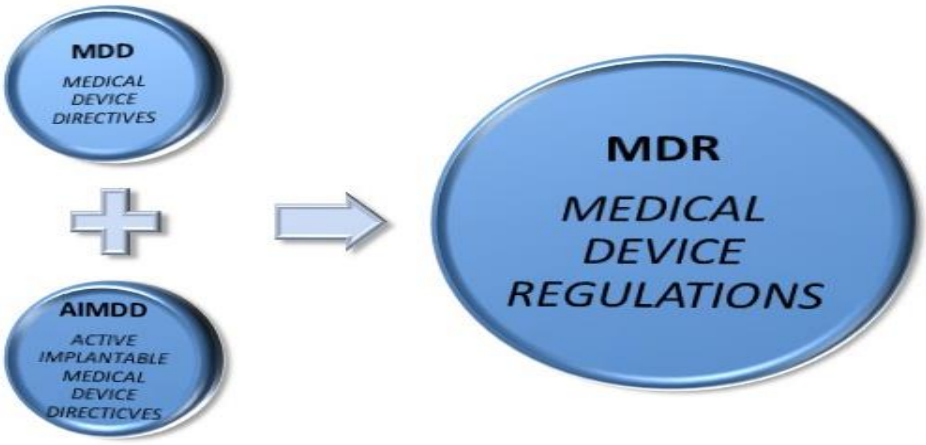

Figure 2: Structure for new regulation formation

The MDR is much longer and more comprehensive than the MDD – it has 101 Recitals and 123 article numbers across 10 chapters, 17 annexes and 175 pages[24]. This is a massive change and will greatly increase the rigor and robustness of the regulations governing bringing products to EU markets.[24,25]

The Medical Device Regulation (MDR) will compel the manufacturers to utilize clinical data that has already stored on multiple databases to a greater effect. It will also provide the basis for upgraded legalized clarity in post-market safety by improving governance standards[26].

The article will act as a guideline for manufacturers who aim to register their product as a medical device under new regulations. Based entirely on the new Medical Device Regulation (MDR), this study intends to facilitate the scrutiny of the Regulation, explaining the key points to consider before, during and after placing the medical device on the market or putting into service.[27] Delivery of safe & effective medical devices depends upon the development processes which often get struck by different risks and regulatory compliance. The work influences the changes which have been developed by the Medical Device Coordination Group (MDCG)[28] in collaboration with the European directives.

Therefore, to meet the requirements, companies, need to understand their device and amend the specifications required by the authorities to determine which laws will be best applied to the particular case.[29]

The theoretical base continually refers to the new Medical Device Regulation, invoke the annexes and recitals present on it. The paper describes essential requirements to obtain compliance with the Medical Device Regulation. The terms "new regulation," "MDR," "Regulation" is used as an alternative to address the Medical Devices Regulation (EU) 2017/745[16].

MATERIALS AND METHODS

The proposed study was done on the medical devices keeping in view the key change that will seek in the new EU Medical Device Regulations that has to be implemented from 26th May 2020, but due to COVID-19 pandemic[30] European Union has postponed the implementation of the new regulations until 26th May 2021.[31]

The critical study of medical devices regulations can be done based on:

a) Essential Principles for Approval of Medical Devices[32]

b) Medical Device Regulations[5]

Essential Principles for Approval of Medical Devices

The manufacturers of medical devices or *in-vitro* diagnostics (IVDs) are expected to design and manufacture products that are safe and perform as

intended throughout its life. The essential principles can be considered during the design and manufacturing process. Typically, they would be considered as design and development inputs within the manufacturer's quality management system. Verification and validation that the design and development outputs meet these inputs should demonstrate that these principles have been met.[33]

There are six general Essential Principles of Safety and Performance that apply to all medical devices. There are a further nine Essential Principles of Safety and Performance about design and construction that apply to devices on a case-by-case basis. [32,34]

General Principles [32,35,36]

- Use of medical devices not to compromise health and safety
- Design and construction of medical devices to conform to safety principles
- Medical devices to be suitable for intended purpose
- Long-term safety
- Medical devices not to be adversely affected by transport or storage
- Benefits of medical devices to outweigh any side effects

Principles about design and construction [36,37]

- Chemical, physical and biological properties
- Infection and microbial contamination
- Construction and environmental properties
- Medical devices with a measuring function
- Protection against radiation
- Medical devices connected to or equipped with an energy source
- Information to be provided with medical devices.
- Clinical evidence
- Principles applying to IVD medical devices only

Manufacturers of medical devices must ensure that their devices comply with all applicable rules and regulations that relate to the operation or supply of their device globally, regardless of whether the requirements directly relate to medical device regulatory aspects or not.

Medical Device Regulations[5]

The proposal of MDR would allow the manufacturers for prominent oversight and responsibility for medical device and IVDs[38]. When came across MDD and MDR, it was found that the greater emphasis is laid on clinical evaluation in MDR. The responsibility of the manufacturers raises in context with the documentation based on effectiveness, safety and quality of their own devices.[2] The requirements for CIs are significantly enhanced in the MDR with many peculiar provisions to ensure that patients involved in clinical studies are secured and protected. To improve transparency, CI reports, summarising study results, will be made available to the public via a centralised European database (Eudamed)[39] which will be easily accessed by those who manufacture and supply medical devices, as well as Notified Bodies, health institutions and Competent Authorities.[40,41]

EU Directives That Impact Medical Devices [20-22]

- **Medical Devices (MDD) 93/42/EEC [21]**
  - Covers the bulk of medical devices marketed in the EU
  - Examples: orthopaedic implants, heart valves, medical software
- **Active Implantable Medical Devices (AIMDD) 90/385/EEC [20]**
  - Covers devices that require external power sources in order to function properly
  - Examples: pacemakers, implantable defibrillators
- ***In-Vitro* Diagnostics (IVDD) 98/79/EC [22]**
  - Covers devices used for the examination of specimens taken from the human body
  - Examples: pregnancy self-testing strips, blood glucose self-testing strips

Other EU Directives That May Apply To Medical Devices[42-49]

- Personal Protective Equipment 89/686/EEC
- Low Voltage 2006/95/EC
- Electromagnetic Compatibility 2004/108/EC
- Blood Product Directive 2002/98/EC
- Animal Tissue Use in Medical Devices 2003/32/EC
- Human Tissue Products Directives 2004 & 2005
- Breast Implants Re-Classification Directive 2003/12/EC
- Hip, Knee, Shoulder Joint Replacement Re-Classification Directive 2005/50/EC

State of play and next steps

- 26 September 2012: adoption of the two Commission proposals on medical devices and IVDs
- April 2017: Final adoption of the new Regulations
- May 2017: Publication of the new Regulations in the EU Official Journal
- To be progressively applied over the 3 years (Medical Devices) and 5 years (IVDs) thereafter, i.e May 2020 and 2022 respectively as shown in **[Figure 3].**

The new regulations are introduced to address infirmity in the current regimes, with the intention of increasing

protection for consumers who are deliberately using medical devices in any manner. [50]

The idea of implementing new regulations is to increase harmonisation across the EU with respect to medical devices and *in vitro* diagnostic devices. As the MDR and IVDR will not be fully effectual for another 12 to 36 months, respectively, therefore, the companies should ensure that they have appropriate systems in place to comply with accordingly. [51]

Figure 3: Timeline for MDR[52]

The MDR and IVDR will introduce wide-ranging changes **[Figure 4]** that will affect all aspects of the supply chain and life cycle for medical devices and *in-vitro* diagnostic devices.

In general, the MDR and the *in-vitro* diagnostic device regulation (IVDR) recruit all the requirements of the Directives[14,53], while adding some new requirements of their own. When compared with the current Directives, the new Regulations[54] emphasize a life-cycle approach to safety, backed up by clinical data. The Regulations add more uncompromising rules for the designation of Notified Bodies. For national competent authorities and the Commission, they add more controlled and monitoring requirements.[55]

The Regulations clarify the obligations of manufacturers, authorized representatives, importers, and distributors. The MDR re-classifies[56] certain devices and has an ample scope than the Directives. It provides an additional pre-market consultation procedure for certain high-risk medical devices.

For *In-vitro* Diagnostic Devices (IVDs)[22,57], the biggest change concerns the risk classification of *in-vitro* diagnostic devices and the role of Notified Bodies. As a result, around 85% of all IVDs will need oversight from Notified Bodies, compared to 20% under the Directive. The IVDR also reinforce the requirements for clinical evidence and conformity assessment.[58]

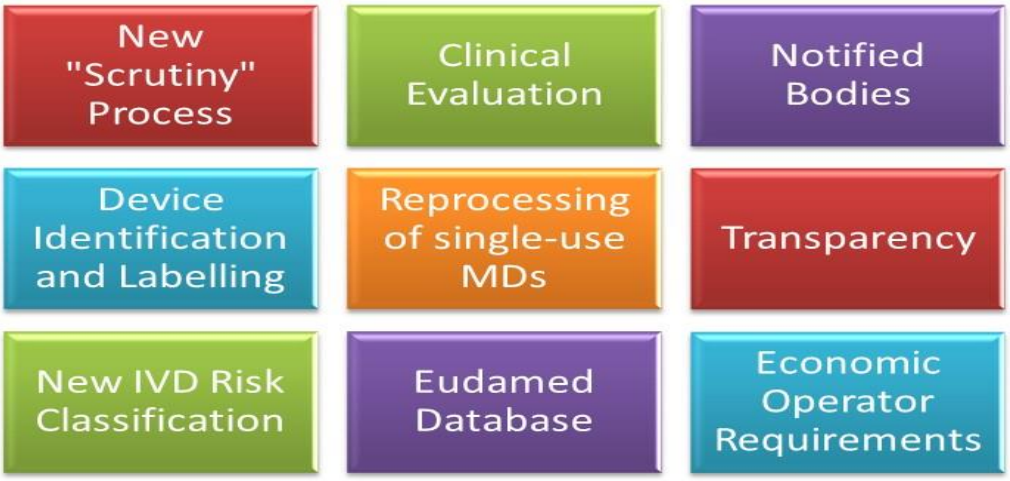

Figure 4: New Regulations- A Modernised, Strengthened System

The regulations increase transparency, requiring the publication of information on devices and on clinical and performance studies related to their conformity. The new European Database for Medical Devices and *in-vitro* Diagnostic Medical Devices (EUDAMED)[39] will play a central role in making data available and increasing both the quantity and quality of data (MDR Article 33 and IVDR Article 30).[59]

The new medical device regulation (MDR 2017/745) [60] was built with the aim to improve the existing Active Implantable Medical Devices Directive (AIMDD) 90/385/EEC [20] and the Medical Devices Directive (MDD) 93/42/EEC [21]. Some of the major changes are related to the following elements [61]:

- Expanded definition of the term 'medical device' that now will include products aimed to perform prediction and prognosis of diseases as well as those which don't have a direct medical intent (e.g. disinfection and sterilization products, fillers, condoms, software or implanted devices used for aesthetic and cosmetic purposes).
- Reclassification of some categories of devices to Class III (e.g. surgical meshes and spinal disc replacement implants) and increased assessment for IVD medical devices.[62,63]
- New (more-strict) designation requirements and roles for notified bodies to assure they have required capabilities and competences.
- New (more rigorous) procedures for the notified bodies for the assessment of high-risk (Class III) medical devices; equivalence to already existing devices will be possible only in some cases and only if the manufacturer has full access to technical documentation[64] of claimed equivalent device.
- Improved availability of clinical investigation data: Results of clinical investigations will be available on the European database for medical devices (Eudamed), which will be available to the public, within 1 year from the end of the investigation or within 3 months from its early termination or halt, whichever is the earliest.
- Improved traceability of medical devices by Unique Device Identification number and implant card for certain implantable devices. [65]

RESULTS AND DISCUSSION

Regulations are crucial requirement for the approval of medical devices globally. Regulations, justify the reasons for launching medical devices in the market and checking their quality, safety, efficacy and performance which are the fundamental factors to be considered for any product before reaching to serve the public healthcare.[65]

Medical devices are subjected to number of laws, regulatory schemes, strict standards and certification processes. As the time elapse, all these regulatory framework needs to refurbish or upgrade so as to fill the void generated by older versions to bring up the harmonization worldwide.[67]

Present research work had explained about the possibility of new regulatory regime – European Union Medical Device Regulations to protect the rights of patients in the background of medical device and technology. The work had explained all the possible key points which have to be implemented in MDR from May 26, 2020 but, now, has been delayed for a time period of one year because of COVID-19 Pandemic[30]. This has changed the planned structure of transition i.e. implementation of new Medical Device Regulations. The new implementation date is May 26, 2021. The work had also explained the journey of MDD to MDR transition.

All the concerned matter is compared with the existing Medical Device Directives (MDD) and is shown in [Table 2]. The changes may be considered as major or minor in the following parameters but some areas still remain similar and no change is determined in MDR for marketing of medical devices.

Table 2: Comparison of MDD and MDR parameters

Parameters	Old Medical Device Directives (MDD)	New Medical Device Regulations (MDR)
Classification Rules [68]	• The requirements for device classification are mentioned in Article 9 of the current MDD. • The rules to be followed in determining the classification are contained in Annex IX of the current MDD. • The MDD contain 18 rules for classification.	• The obligation to assign a classification to all devices is contained in Article 51 in the new EU MDR. This has replaced Article 9 of the MDD. • The rules to be followed in determining the classification are contained in Annex VIII in the new EU MDR. • The MDR will contain 22 rules for classification. Five new rules have been added to the new Annex VIII. The current MDD Rule 18 (blood bags) has been removed from the new EU MDR. • In the new regulations, IVDs will now be classified according to a set of rules instead of the list system. • Each of the seven rules divide IVDs into classes depending the risk that they pose to the patient and the public, based on GHTF.

		• The devices will be graded A, B, C or to D, with class A posing the lowest risk to the patient and class D being the highest risk to patient and public.
Essential Requirements [69]	• The 1985 Act "A new approach to technical harmonisation" introduced the concept of "Essential Requirements" for a product's safety and performance. • MDD specifies the essential requirements for medical devices in Annex I. • MDD's essential requirements covers thirteen areas and divided into two chapters.	• The new EU Medical Device Regulation (EU MDR) also specifies the essential requirements, also in the new Annex I. However, they have been renamed in the new EU MDR to "GENERAL SAFETY AND PERFORMANCE REQUIREMENT". • The new Annex I now contain requirements covering twenty-two areas and is now divided into three chapters. • The new third chapter on "Information" requirements contains the requirements for labelling and instructions which was previously under "DESIGN AND CONSTRUCTION" in MDD. • Example expanded requirements for devices incorporating materials of biological origin and the additional requirements for the contents of labels and instructions, the requirements for substances intended to be introduced into the human body were not present in the MDD.
Clinical Evaluation [70]	• The requirement to perform a pre-market clinical evaluation can be found in part I of Annex X of MDD	• In the new European Union Medical Device Regulation (EU MDR), the requirement for a pre-market Clinical Evaluation can be found in the new Article 61 and in the new Annex XIV, Parts A and B. • Part A of the new Annex XIV is focussed on the pre-market phase and updates and extends Part 1 of the current MDD Annex X. it does require; (a) a Clinical Evaluation Plan (content is specified), (b) an evaluation of clinical data, and (c) a Clinical Evaluation Report (CER). • Part B of the new Annex XIV is focussed on the post market phase and is a significantly expanded requirement compared to the current MDD (Annex X 1.1C). It does require; • (a) detailing the requirements for the PMCF Plan and • (b) introducing the requirement for a PMCF Evaluation Report.
Clinical Investigation [71]	• Clinical investigation in MDD is mentioned under Article 15. • The requirements in the current MDD are addressed to the "Manufacturer".	• Article 15 "Clinical investigation" is replaced by twenty articles in new EU MDR, Articles 62 through 82. This global alignment extends to both the requirements and the terminology. • The requirements in the new EU MDR are addressed to the "Sponsor". • These address the topics related to clinical investigations; the need for informed consent, considerations for vulnerable populations, the application process, requirements for the conduct of the investigation, Adverse Event reporting etc. • The new Annex XV updates and extends part 2. of the current MDD's Annex X "Clinical evaluation". This new and expanded Annex XV specifies the information to be considered in; (a) the Clinical Investigation Application form, (b) the Investigator's Brochure, (c) the Clinical Investigation Plan, (d) Sponsors obligations and (e) the Clinical Investigation Report.
Technical Documentation[64]	• The contents are described, but rather vaguely, in a few bullet points in the MDD's Annex VII.	• Annex II of the new EU MDR prescribes more than forty specific elements for the content of the (primary) "Technical Documentation".

	• There is also mention of a "Design Dossier" in MDD Annex II but this is not further defined in the MDD.	• Annex III of the EU MDR requires more than fifteen additional elements in the "Technical Documentation on Post Market Surveillance". • The MDD's "Design Dossier" has been dropped from the EU MDR. • Technical Documentation of Annex II of new EU MDR is clearly based on the Summary Technical Documentation or STED, developed by the former Global Harmonisation Task Force (GHTF). • There are a number of additional sections in the new EU MDR Annex II which reflect the specific focus of the European authorities on certain topics; information on medicinal substances, on tissues or cells of human or animal origin, on substances intended to be introduced into the human body.
UDI [72]	• Unique Device Identification or UDI is the bar-coding of all medical devices on the European market using a standard format. It will be supported by a database which provides users and regulators quick access to information about the coded device. • Current Medical Device Directive (MDD) doesn't mention UDI.	• According to Article 10 of the new EU MDR, UDI ranks among the basic obligations for all medical device manufacturers. • The UDI will be required for the new Technical Documentation (Annex II), for the new EU Declaration of Conformity (Annex IV) and for the new registration data (Annex VI, Part A). • According to Article 123 (f) and (g): The UDI labelling will be required for Class III devices from 26th May 2021. UDI labelling will be required for Class IIa and IIb devices from 26th May 2023. UDI labelling will be required for Class I devices from 26th May 2025. In the case of reusable device, the UDI is additionally required on the device itself, but only two years after the date of application on the labelling for the respective Class of device.
Conformity Assessment [73]	• The MDD's conformity assessment is the part of Article 11. • The MDD's conformity assessment comes under the Annexes II to VIII. • For Class III devices, the current MDD's Annex II is based on "full quality assurance" route. • In the current MDD, requirements for customer made devices are part of the Annex VIII.	• Conformity assessment in the new European Union Medical Device Regulation (EU MDR) has been renumbered as Article 11 of the current MDD will be replaced by Article 52 of the new EU MDR. • These will be replaced by Annexes IX to XI and XIII of the new EU MDR. • This will be replaced the new EU MDR's Annex IX "conformity assessment based on quality management system assurance and assessment of the technical documentation". • The new EU MDR's Annex XI "conformity assessment based on product conformity verification" includes both the MDD's current options; • Part A being the new "Production Quality Assurance" route, replacing the current MDD's Annex V "production quality assurance". • Part B being the new "Product Verification" route, replacing the current MDD's Annex IV "EC verification". • The new EU MDR has a dedicated Annex, Annex XIII "procedure for custom made devices".
Notified Bodies[74]	• European Competent Authorities are mentioned in Article 16 of Annex XI of the MDD.	• European Competent Authorities replacing Article 16 of the Medical Device Directive MDD with the new Articles 35-50 of Chapter VI and the new Annex VII. • The Notified Bodies under the new EU MDR will be largely unchanged compared to how they have been operating under the MDD since 2013. • The new Article 54 introduces a new "consultation procedure" for Notified Bodies, under which they must submit the Clinical Evaluations of certain high-risk devices to an expert panel for review.

		• The new Article 55 introduces a new "mechanism for scrutiny of conformity assessments" for certain high-risk devices. • These new obligations on Notified Bodies are likely to impact the approval times of the affected Class III and Class IIb devices.
Registration[75]	• The current MDD's single Article on registration is Article 14. • The economic operators who are required to register according to the EU IVDR are Manufacturers and their Authorised Representatives.	• Article 14 is replaced by several Articles in the EU IVDR such as, • the new Article 29 "Registration of devices", • the new Article 30 "Electronic system for registration of economic operators", and • the new Article 31 "Registration of manufacturers, authorised representatives and importers". • Manufacturers and their Authorised Representatives, the same as under the current MDD, now joined by Importers of medical devices for the registration. • According to the new Article 30, within two weeks of placing a device on the market, Importers must perform a compliance check on their suppliers. Importers must verify the information in the registration database is correct and inform the Manufacturer or Authorised Representative if any information is incorrect.
EUDAMED [39]	• Eudamed was established by the MDD (Article 14a). But the amount of data currently available to the European Authorities is minimal.	• According to the new EU MDR Article 33, the databases established under the new EU MDR will contain; comprehensive data on the devices themselves, including the Unique Device Identification (UDI) data, as well as data on all the economic operators associated with those devices, data on the Notified Bodies and the certificates they issue, data on clinical investigations conducted in Europe, as well as vigilance and post-market surveillance data. • Data uploading and maintenance is likely to characterise new era of the EU MDR. • The new EU MDR Article 34 obliges the EU Commission to make Eudamed available by 25th March 2021, although this deadline can be extended according to the new Article 123(d). Article 123(d) also allows Manufacturers, Authorised Representatives and Importers six months from the going live of Eudamed to comply with the various obligations to upload data.
Risk Management[76]	• The current MDD Annex I Chapter I (2) does require that the risks associated with an individual device be eliminated or reduced, that adequate protection measures are taken in relation to risks that cannot be eliminated, and that users are informed about any residual risks. • But, the current MDD does not contain an explicit requirement to employ risk management, other than for software devices. • There is no Article of the current MDD that requires manufacturers to have a risk management system.	• The new EU Medical Device Regulation (MDR) contains an explicit obligation in the new Article 10 (2), that Manufacturers establish, document, implement and maintain a system for risk management. The detailed requirements of which are listed in the new Annex I Chapter I (3). • Under the new EU MDR, **for each device**, Manufacturers must have a documented risk management plan, identify and analyse the known and foreseeable hazards, estimate and evaluate the associated risks and eliminate or control those risks. Additionally, in the "production phase", evaluate the impact of new information and if necessary, amend control measures accordingly.
Vigilance [77]	• In the existing Medical Device Directive (MDD), the concepts of Vigilance and PMS were barely distinguishable. • The limited vigilance requirements of the MDD (Annex VII (4) etc.), to notify the	• In the new European Union Medical Device Regulation (EU MDR) there is a very clear distinction made between; "Vigilance", the identification, reporting and trending of serious incidents and the conduct of safety related corrective actions. And "Post Market

	authorities of incidents, have long been considered insufficient. • The requirement under the MDD related to vigilance will be submitted to the individual national Competent Authorities.	Surveillance" (PMS), the monitoring of information from various sources used to periodically reconfirm that the benefits of the device continue to outweigh its risks. • The vigilance requirements of the new EUMDR can be found in Chapter VII Section 2 (Articles 87 to 92). • The new requirement in the EU MDR related to vigilance will be the requirement to submit vigilance reports to a centralised pan-European database (Article 92).
Post- marketing Surveillance [78]	• Post Market Surveillance (PMS) is mentioned in Annex X of the existing Medical Device Directive (MDD) it was not defined in the MDD. • This lack of definition was not addressed by the Competent Authorities, but by the Notified Bodies in their recommendation document NB-MED/2.12/Rec1.	• That lack of clarity is completely removed with the publication of the new EU MDR. Not only is PMS defined in Article 2 (60), it is listed as one of the general obligations of all manufacturers (new Article 10), it is also one of the topics specifically called out for monitoring by the person responsible for regulatory compliance (new Article 15). • The new Article 84 requires that a PMS plan be developed for each device. The content of the PMS plan being specified in Section 1.1 of the new Annex III. The PMS plan also has to be included in the Technical Documentation for the device. • In the case of Class I devices (new Article 85), the report must be be kept available for any Competent Authority who wishes to examine it. • In contrast for Class IIa, Class IIb and Class III devices (new Article 86), the main outputs of the new Periodic Safety Update Report (PSUR) are prescribed. • Additionally, in the case of Class III devices and implantable devices, the PSUR must be submitted annually to the Notified Body, and the Notified Body's evaluation report has to be made available to the Competent Authorities through the EUDAMED system.

The article supports and explained about the key points such as:

- Product scope expansion
- Implementation of UDI
- Rigorous post-market oversight
- Identification of person responsible for regulatory compliance
- Common specifications
- Reclassification of devices
- More rigorous clinical evidence for class III and implantable medical devices
- No "grandfathering" provisions
- Systematic clinical evaluation of Class IIa and IIb medical device.

CONCLUSION

The multifarious changes are occurring in the device development and approval process. The medical device life cycle is not a simple, linear progression from basic to applied research, to development, to marketing. Rather, it is an intricate stream of five parallel tracks involving regulation, research and development, marketing, manufacturing, and legal issues. There is room for continual improvement in the science and in the guidance given to those trying to get new devices through the regulatory process to market.

This work concludes that medical device regulatory regime faces criticism over the complexity of its legal framework, inadequacy in its ability to address turning-up technologies, and the lack of uniformity across member states.

Hence, in order to compensate such weaknesses, the EU commission released a roadmap for a proposed "recast" of the medical device directives. The medical device industry is simply evolving from the outdated practices of the past.

The work has explained the journey of Medical Device Directives (MDD) to Medical Device Regulations (MDR). The work has explained all the possible key points which have to be implemented in MDR from May 26, 2020 but, now, has been delayed for a time period of one year because of COVID-19 Pandemic.

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