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COMPREHENSIVE REVIEW OF RECENT AMENDMENTS TO THE EUROPEAN UNION MEDICAL DEVICE REGULATION

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ABSTRACT

The Medical Device Regulation (MDR) 2017/745, effective since 2021 May, 93/42/EEC, the previous Medical Device Directive (MDD), has been replaced. to enhance device performance and patient safety in the EU. Recent 2023 amendments focus on notified body requirements, performance and safety standards, technical documentation & post-market surveillance, and specific provisions for single-use devices. These changes aim to address evolving industry challenges and ensure continued safety and efficacy of medical devices. It is anticipated that the modifications will improve quality, which will benefit the patients.

Keywords: Medical device, annex and articles, amendments and corrigendum

INTRODUCTION

The Medical Device Regulation (MDR), first enacted as Regulation (EU) 2017/745 in April 2017, governs the regulation of medical devices within the European Union (EU). The previous "Medical Device Directive (MDD) 93/42/EEC" was replaced by this MDR. The revised regulatory framework, which came into full effect in May 2021, aims to enhance medical device performance, quality, and safety in order to improve patient safety **[1]**. To strengthen MDR's adaptability and meet current difficulties, the European Commission introduced various modifications to the regulation in 2023.

Improving patient safety through improved medical device guidance and accountability is one of the MDR's main goals. Stringent regulations for clinical assessment, post-market surveillance, and the implementation of a Unique Device Identification (UDI) system to enhance traceability are used to achieve this. The regulation is extensive, consisting of 10 chapters with 123 articles and 17 annexes that together provide a comprehensive regulatory framework for medical device safety, performance, and oversight in the European Union **[2]**.

A number of significant modifications have been implemented to the MDR in 2023 in order to address new issues that the medical device industry was facing. These cover everything from requirements for notified bodies to assessment and monitoring of notified bodies, to repeal, date of application, entry into force, general performance and safety requirements & technical documentation on post-market surveillance, requirements for notified bodies, and provisions for single use devices and reprocessing, as well as provisions for post-market surveillance plans, trend reporting, clinical investigation involving devices that bear CE marking, and transitional provisions. These updates are intended to address the unique challenges posed by this innovation and ensure their safety and effectiveness **[3][4]**.

In this article, we will examine the recently amended and corrigendum regulation in detail, and provide overview and discussing their future implications. The ongoing evolution of the MDR need to adapt to technological advancements and emerging challenges, ensuring that medical device available in the EU continue to meet stringent safety and efficacy standards. By continually updating and refining the medical device regulation, the aim of the EU is to protect public health and ensure highest quality of medical care.

Definition

"Medical device means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means." **[2]**

Classification

Medical device classification is based on the level of risk as well as the device's intended use and the duration of time it keeps in contact with the body. It's classified into four types they are class I, class IIa, class IIb, class III and class IV **[2][5]**.

Tabel 1: Types of Medical device classification

Class	Risk level	examples
Class I	Low	Bandages and non-invasive device
Class IIa	Medium	Hearing aids, dental fillings
Class IIb	Medium to High	Infusion pump, anaesthesia machine
Class III	High	Pacemaker, heart valves

The European Union's regulatory framework for medical devices is structured through a series of detailed articles and annexures. This comprehensive image **(Figure 1 & Figure 2)** serves as a crucial reference for manufacturers, providing clarity on compliance expectations and ensuring the highest standards of patient safety and product quality within the EU market.

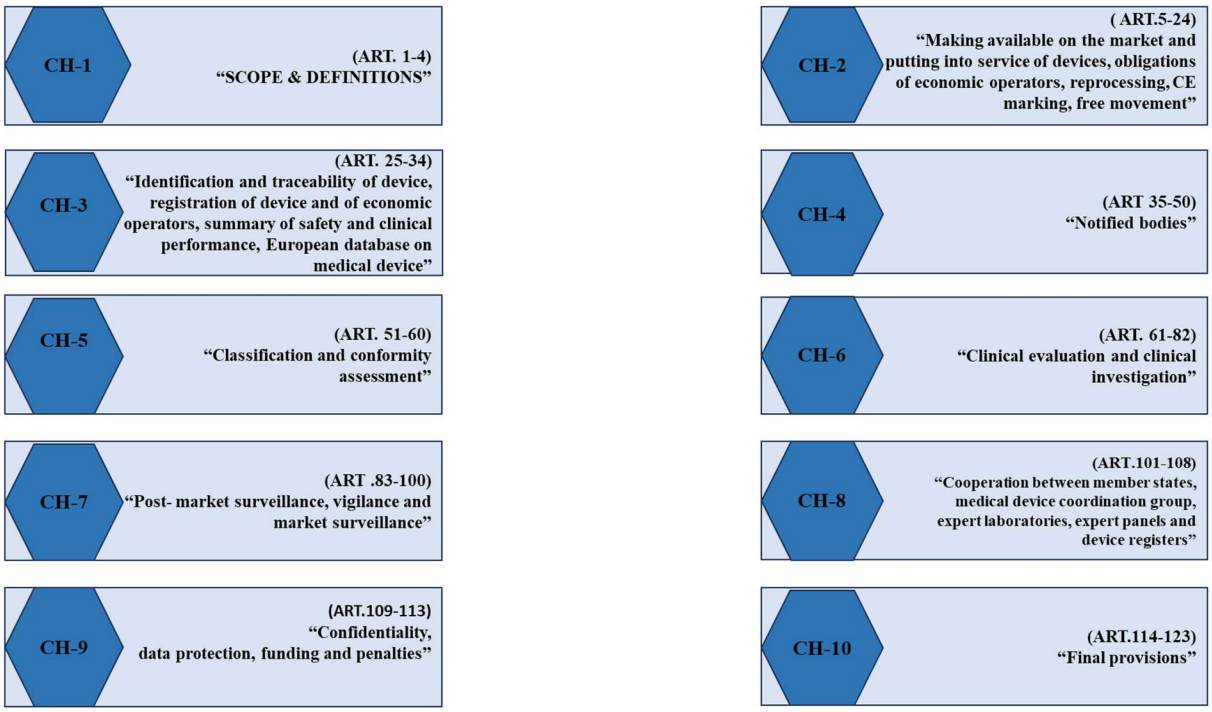

Figure 1: Total number of articles and list of chapters

Figure 2: Total number of annexures

RECENTLY UNDERGONE REVISIONS OF EU MEDICAL DEVICE-REGULATION (MDR 2017/745).

In order to resolve a number of concerns and improve its applicability, the "REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND THE COUNCIL" has lately undergone major revisions in amendments (M1, M2& M3) and corrigendum (C1 & C2). This is a concise summary of the updated amendments and corrigendum. The overall change in article and annexure is mentioned in **Tabel 2.1 & Tabel 2.2**. **[2][6-10]**

Article 1

The following amendment has been adopted in Article 1(2)'s second subparagraph, "26 May 2021" is changed to "26 May 2020" in the first sentence and for second line, the date "26 May 2020" is changed to "26 May 2021."

Article 2

The word "trademark" in Point 30 of Article 2 has been changed to "trade mark."

Article 7

The first sentence of Article 7 has been clarified; the meaning of the word "it shall be prohibited" remains unchanged.

Article 10

Point 15 of Article 10 has been corrected as follows, Information on the identity of persons designing or manufacturing devices must be submitted with Article 29(4) instead of Article 30(1).

Article 17

Article 17 paragraph 5 has been revised as follows, "26 May 2020" is changed to "26 May 2021"in the first sentence and In third sentence "26 May 2020" is changed to "26 May 2021."

Article 34

In the date "25 March 2020" has been changed to "25 March 2021" in paragraph 1 of Article 34.

Article 44

Paragraph 10 has been replaced with the following: Article 44 of Regulation (EU) 2017/745 has been changed to require notified bodies to perform a thorough reassessment every five years after the first notification and then every five years after that, in order to verify compliance with Annex VII criteria. According to Article 39, a joint assessment team and the Member State of the authority carry out this re-evaluation. Reassessments may also be started earlier by the authority at the notified body's request or in response to yearly assessments. Assessments that were started before to March 11, 2023, will continue unless suspended or terminated, with the authority required to consult the notified body before making such decisions.

Article 59

The first paragraph of Article 59 of Regulation has been amended to permit any competent authority to authorize the introduction of certain medical devices on the market or into service upon an approved request. This derogation applies to situations where the procedures specified in Article 52 of the Regulation, or in "Directives 90/385/EEC" or "93/42/EEC", have not yet been finished but are thought to be essential for patient safety, public health, or health interests within the borders of the Member State, between 24 April 2020 and 25 May 2021.

In second paragraph, the following sub-paragraph has been added as "The member state may inform the commission and other member states of any authorization granted in accordance with article 9(9) of directive 90/385/EEC or article 11(13) of directive 93/42/EEC before 24 April 2020".

In the third paragraph of the first sub-paragraph has been changed and has to allow the commission to extend, in uncommon cases related to publish patient safety or health, the validity of member state authorizations granted under paragraph 1. This extension also covers authorization granted before April 24, 2020, under "Directive 90/385/EEC" or "Directive 93/42/EEC", broadening their application to the entire union and specifying market placement or service conditions. Implementation of these measures follow the examination protocol detailed in article 114(3).

Article 74

The following revisions have been made to paragraph 1: Article 62(4), Article 76 & 77, Article 80(5) & (6), and the applicable sentences.

Article 78

A revision has been made to the second subparagraph. Paragraph 4's point (d) has been updated with point (b).

Article 84

Section 1.1 has been corrected to section 1 of article 84 in first sentence

Article 88

Section 1 and 5 of annex I is replaced with section 1 and 8 of annex I in the first subparagraph of article 88

Article 113

Amended has been made in February 25th, 2020 has been replaced as 25 February 2021

Article 120

The first paragraph of Article 120 is changed as follows:

The date May 26, 2020 is replaced by the date 26 May 2021.

The second paragraph of Article 120 is replaced as Notified bodies. The certificates was issued according to "Directives 90/385/EEC" and "93/42/EEC", which came

into effect on May 26, 2021, are valid until the date specified in point 3a for the respective risk. category Certificates that expired before March 20, 2023 are valid until the dates specified in point 3a, if (a) a written agreement on conformity assessment is signed before the certificate expires or (b) a national authority has made an exception or required the manufacturer to carry out a conformity assessment procedure.

The third paragraph of the first sub- paragraph of Article 120 has been replaced by the following:

Exemption from Article 5 of this Regulation, Class-I device according to "Directive 93/42/EEC", for which the "Declaration of conformity" has been framed until 26th May, 2021, can be placed on the market for 26 days until May 2024 if it continues to adhere with both "Directive 90/385/EEC" or "Directive 93/42/EEC" without any remarkable change in design and intended use. Though, the requirements for the Regulation regarding post market surveillance, surveillance, market surveillance and enrolment shall apply.

The third paragraph has been replaced by Section 3a: Devices with valid certificates according to "Directives 90/385/EEC" or "93/42/EEC" can be marketed for Class III devices until December 31, 2027 and for certain class IIb implantable devices and until December 31, 2028 for other devices. Section 3b: Devices conforming to "Directive 93/42/EEC", which previously not required a "Notified body", may be placed on the market under certain conditions until December 31, 2028.

• Point 3c: Devices specified in points 3a and 3b may be marketed until these dates if they meet certain criteria, including compliance, absence of major changes and risk assessment.

• Section 3d: The post-market surveillance, monitoring and other requirements of regulation apply to devices 3a and 3b instead of "Directives 90/385/EEC" and "93/42/EEC".

• Section 3e: "Notified body" that issued the certificate is responsible for monitoring, unless another body is specified in the contract.

• Section 3f: "Class-III custom implantable devices" might be placed on the market under certain conditions until May 26, 2026 without certification by a Notified Body.

The fourth paragraph of Article 120 is replaced by the following, equipment legally marketed according to "Directives 90/385/EEC" and "93/42/EEC" before 26th May, 2021 and equipment marketed from 26 May 2021 onwards in accordance with 3rd paragraph of this article may available or used until 26th May, 2025. Paragraph five is

replaced by the following "26th May 2020 is replaced by May 26, 2021".

Eighth paragraph is replaced: "For the starting period from the later dates, specified in the Article 123(3)(d) and it will be ending 18 months later, in accordance with Article-29(4) and Article-31(1), and in accordance to Article-56(5) of this Regulation. The producers, authorized representatives, importers and notified bodies the relevant legislation of the Member States according to "Directives 90/385/EEC" and "93/42/EEC" as described in the decision 2010/227/EU".

In the tenth paragraph of Article 120 is replaced by the following: Equipment is covered in this Regulation, according to the Article1-(6)(g), which has been legally marketed or put into service according to the rules of the Regulation. Member States may continue marketing and use in the relevant Member States before 26 May 2021.

The eleventh paragraph of Article 120 is modified as 26th May, 2020 is replaced to "26 May,2021 in the first line" and 26th May, 2020 is replaced to 26 May 2021 in the second sentence.

Article 122

The introductory line of the first paragraph is replaced as: The monitoring of countries and manufacturers and the availability of documents according to "Directives 90/385/EEC" and "93/42/EEC", these directives, are repealed from May 26 2021.

26th May 2020 will be replaced by May 26, 2021, intended is added to Article 9, paragraph 9 of "Directive 90/385/EEC" and Article 11, paragraph 13 of "Directive 93/42 /EEC" will be revoked as of April 24 2020.

The second paragraph is replaced as for devices under article "120(3)-(3e) & (4) of the regulation, the directives mentioned in the paragraph one will still apply as needed for these provisions".

First paragraph second and fourth indent has added "article 10a and point(a) of article 10b(1), article 11(5) of "Directive 90/385/EEC" article 14(1) & (2), points (a) & (b) of article 14a(1) and the article 16(5) Directive of 93/42/EEC".

Article 123

The following amended has been made in article 123, second paragraph, "26 may 2020" is replaced with "26 may 2021"

Third paragraph amendments have been made as follows:

a) "26 May 2020" is replaced by "26 May 2021."

d) "26 May" is replaced by "26 May 2021," and the 24th indent is changed by the following: "Article 120(3d)."

g) Third paragraph is changed as, regarding reusable devices requiring the "UNIQUE

DEVICE IDENTIFIER" carrier on the device of itself, Article 27(4) applies as follows:

"(a) For implantable devices and class-III devices from 26th May 2023;

(b) For class-IIa and class-IIb devices from 26th May 2025;

(c) For class-I devices from 26th May 2027;

(d) Additionally, Article 59 may apply from 24th April 2020".

Annex 1

Annex 1 of chapter 3, section 23.2 point (h) has been changed has:

Article 27(4) and part C of annex VII is changed as article 27(4) & part c of annex VI.

Annex III

Annex III, section 1.1 has been corrected has, 1.1. the post- market has been changed has 1. The post-market.

Annex VII

Section 4.4.2, point(a), fourth indent has been replaced has, "the plan shall ensure the entire range of devices covered by certificate, which is sampled over".

Annex VIII

Section 3.2 of chapter II has been corrected has, Addition of instruments for the medical devices shall be classified on their own rights.

Annex IX

Section 2.3 of chapter 1 third paragraph has been corrected has, sections 4.4 to 4.8 in Section 4. Section 3 has been changed has surveillance assessment. In section 3.5 first paragraph section 4.4 to 4.8 changed to section 4. In section 4.3 sentence has been replaced has the "Notified body" may assess the technical evidence using staff with accepted knowledge. In section 5.1, date has been replaced has 26 may 2020 to 26 may 2021.

Annex XV

Section 2.5 of chapter II has been changed has, undesirable effects to undesirable side-effects.

Tabel 2.1: An overview checklist of changed/amended articles

ARTICLES CHANGED	M1	M2	M3	C1	C2
[ARTICLE- 1]	✓				
[ARTICLE-2]				✓	
[ARTICLE-7]				✓	
[ARTICLE-10]				✓	
[ARTICLE-17]	✓				
[ARTICLE-34]	✓				
[ARTICLE-44]		✓			
[ARTICLE-59]	✓				
[ARTICLE-74]				✓	
[ARTICLE-78]				✓	✓
[ARTICLE-84]					✓
[ARTICLE-88]					✓
[ARTICLE-113]	✓				
[ARTICLE-120]	✓		✓		✓
[ARTICLE-122]	✓		✓		✓
[ARTICLE-123]	✓		✓		

Tabel 2.2: An overview checklist of changed/amended annexures

ANNEX CHANGED	M1	M2	M3	C1	C2
[ANNEX- I]					✓
[ANNEX-III]					✓
[ANNEX-VII]				✓	
[ANNEX-VIII]				✓	
[ANNEX-IX]	✓			✓	
[ANNEX-XV]				✓	

"M1- REGULATION (EU) 2020/561 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 23 April 2020, M2- COMMISSION DELEGATED REGULATION (EU) 2020/502 OF 1 December 2022, M3- REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 March 2023, C1- Corrigendum, OJ L 117, 3.5.2019, P.9 (2017/745), C2- Corrigendum, OJ L 334, 27.12.2019, P.165 (2017/745)"

CONCLUSION AND DISCCUSSION

"The European Union Medical Device Regulation (EU MDR) 2017/745" has undergone changes that have significant effects on patients, healthcare professionals, and manufacturers in the medical device companies. Positively, patient safety and product quality are prioritized in the amended regulation, which also includes stronger criteria for clinical assessment and post-market surveillance. By performing this, it is ensured that medical devices fulfil stricter requirements before being released into the market, which may improve patient outcomes and reduce adverse events. In addition, the implementation of the latest medical equipment is made easier by the streamlining of the clearance procedure brought about by the harmonization of regulatory standards throughout EU member states.

On the other hand, the increased regulatory requirements pose difficulties, especially for smaller businesses. Market entry can be delayed by higher compliance costs and the requirement for substantial clinical data, which may delay innovation and lower competitiveness. A source of controversy has also been the transition time for adjusting to the new standards, with worries about interruptions to the supply chain and the ongoing availability of medical equipment.

The medical device sector is experiencing significant growth, driven by increasing healthcare needs globally, rising prevalence of chronic illnesses, and aging populations. Given the critical role of medical devices in healthcare, ensuring their effectiveness and safety is paramount through rigorous regulations that account for varying levels of risk. However, the diversity and innovation in medical devices pose challenges to existing regulatory frameworks, prompting ongoing global reforms in regulatory systems. As the sector adjusts to the changing regulatory landscape, striking a balance between these good and negative characteristics is essential if it hopes to improve patient safety while

maintaining an energetic and innovative market.

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