MDCG 2021-25 Rev. 1

Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC

October 2024

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Revision table

Date	Action
October 2021	Initial issue of MDCG 2021-25
October 2024	1st update (MDCG 2021-25 Rev. 1) Adjustments in the entire document to align with the general structure of MDCG guidance documents (e.g. removal of Preface, Mandate of task-force and process) and to take into account Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices. Substantial changes are in particular in sections 3.1, 3.2 and 4, namely: - clarification that Article 19 MDR does not apply to legacy devices; - clarification of the application of the transitional provisions to systems and procedure packs covered by a declaration drawn up pursuant to Article 12(2) MDD; - clarification regarding the requirement to put in place a QMS in accordance with Article 10(9) MDR.

1. Introduction

The transitional provisions of Regulation (EU) 2017/745 on medical devices (MDR) have been amended by Regulation (EU) 2023/607. In particular, the transitional period has been extended from 26 May 2024 until 31 December 2027 or 31 December 2028, depending on the risk class of the device and subject to certain conditions[1].

This document provides updated guidance as regards the applicability of MDR requirements to 'legacy devices' and 'old' devices, taking into consideration the amendments to the MDR transitional provisions[2]. The annex contains a non-exhaustive table illustrating MDR requirements applicable or not applicable to 'legacy devices'.

2. Legal provisions and terminology

2.1. Legal provisions

Article 120(3) to (3e) of the MDR as amended by Regulation (EU) 2023/607 states:

'3. By way of derogation from Article 5 and provided the conditions set out in paragraph 3c of this Article are met, devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates set out in those paragraphs.

3a. Devices which have a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and that is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until the following dates:

(a) 31 December 2027, for all class III devices, and for class IIb implantable devices except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors;

(b) 31 December 2028, for class IIb devices other than those covered by point (a) of this paragraph, for class IIa devices, and for class I devices placed on the market in sterile condition or having a measuring function.

3b. Devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, may be placed on the market or put into service until 31 December 2028.

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

(a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;

(b) there are no significant changes in the design and intended purpose;

[1] See Q&A document on practical aspects related to the implementation of Regulation (EU) 2023/607.
[2] This guidance concerns only legacy devices under the MDR; for guidance on IVD legacy devices, please consult MDCG 2022-8 IVD legacy devices (europa.eu).

(c) *the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;*

(d) *no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9);*

(e) *no later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII.*

3d. *By way of derogation from paragraph 3 of this Article, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply to devices referred to in paragraphs 3a and 3b of this Article in place of the corresponding requirements in Directives 90/385/EEC and 93/42/EEC.*

3e. *Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in paragraph 3a of this Article shall continue to be responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices it has certified, unless the manufacturer has agreed with a notified body designated in accordance with Article 42 that the latter shall carry out such surveillance.*

No later than 26 September 2024, the notified body that has signed the written agreement referred to in paragraph 3c, point (e), of this Article shall be responsible for the surveillance in respect of the devices covered by the written agreement. Where the written agreement covers a device intended to substitute a device which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC, the surveillance shall be conducted in respect of the device that is being substituted.

The arrangements for the transfer of the surveillance from the notified body that issued the certificate to the notified body designated in accordance with Article 42 shall be clearly defined in an agreement between the manufacturer and the notified body designated in accordance with Article 42 and, where practicable, the notified body that issued the certificate. The notified body designated in accordance with Article 42 shall not be responsible for conformity assessment activities carried out by the notified body that issued the certificate.

2.2. Terminology used in this guidance

Legacy devices should be understood as devices, which, in accordance with Article 120(3) of the MDR, are placed on the market or put into service after the MDR's date of application (DoA) and until either 31 December 2027 or 31 December 2028 if the conditions set in Article 120(3c) of the MDR are fulfilled[3]. Those devices can be:

- devices which are class I devices under Directive 93/42/EEC (MDD), for which an EC declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a notified body;
- devices covered by a valid[4] EC certificate issued in accordance with Directive 90/385/EEC (AIMDD) or the MDD prior to 26 May 2021.

'Old' devices are those devices that were placed on the market or put into service before 26 May 2021 in accordance with the AIMDD or the MDD or in accordance with the applicable rules before the Directives had entered into force.

MDR devices are those that are placed on the market or put into service as being in conformity with the MDR other than 'legacy devices'.

It should be recalled that the concept of 'placing on the market' refers to each individual product, not to a type of product[5].

3. Application of MDR requirements to 'legacy devices'

3.1. Requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices

In accordance with Article 120(3d) of the MDR, the requirements of the MDR relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices apply to 'legacy devices'. This provision is the same as in the initial version of the MDR and has not been changed by Regulation 2023/607.

That means that all relevant MDR requirements set out in Chapter VII of the MDR on post-market surveillance, market surveillance and vigilance apply to 'legacy devices'. To determine the applicability of requirements which depend on the risk class of a device (e.g. Article 85 or Article 86 of the MDR) the legacy device's risk classification in accordance with the MDD should be taken into account. A possible change of their risk class under the MDR is relevant only for determining the end of the transitional period. Active implantable devices and their accessories subject to the AIMDD should be

[3] To provide guidance for manufacturers and other actors in deciding whether or not a device is covered by the extended transitional period provided for in Article 120 of Regulation (EU) 2017/745 (MDR), as amended by Regulation (EU) 2023/607, see flowchart. Products falling outside the scope of the MDR (e.g. products referred to in Article 1(6), point (h), MDR) cannot be subject to an application or a written agreement for conformity assessment with a notified body in accordance with Section 4.3 of Annex VII MDR, so that they do not benefit from the extended transitional period.

[4] See Article 120(2) MDR regarding the extended validity of certificates.

[5] See Article 2(28) MDR and Section 2.3. of the Commission Notice - The 'Blue Guide' on the implementation of EU products rules 2022, OJ C 247, 29.6.2022, p. 1.

considered as class III devices for the purpose of applying the relevant MDR requirements during the transition period.

In addition to the requirements set out in Chapter VII MDR, also other MDR requirements related to post-market surveillance, market surveillance, vigilance, registration of economic operators and devices should apply to 'legacy devices'.

Such an approach respects the wording of Article 120(3d) of the MDR. At the same time, it extends the application of the MDR to those requirements that support a well-functioning vigilance and market surveillance system as well as proper registration of economic operators and devices.

Firstly, the general obligations of manufacturers and importers to place only devices on the market that are in conformity with the MDR (Articles 10(1) and 13(1) of the MDR) apply, whereas for 'legacy devices' conformity with the MDR means conformity with the MDD or AIMDD and the additional requirements in accordance with Article 120(3d) of the MDR. In addition, the obligations of economic operators set out in the following provisions should also apply to economic operators with respect to 'legacy devices':[6]

- for manufacturers: Article 10(10), (12)-(15);
- for authorised representatives[7]: Article 11(3)(c)-(g);
- for importers: Article 13(2), 2nd subparagraph, (4), (6)-(8), (10);
- for distributors: Article 14(2), last subparagraph, (4)-(6).

MDR requirements that are not related to post-market surveillance, market surveillance, vigilance, registration of economic operators and devices should in principle not apply to economic operators in respect to 'legacy devices'. Examples for provisions not applicable in respect to 'legacy devices' are Article 15, Article 16(3) and (4), Article 18[8], Article 19[9], Article 25[10], Article 27[11], Article 32. This is without prejudice to the possibility for economic operators to follow any MDR requirements also for 'legacy devices', especially if they deal with both 'legacy devices' and MDR devices and want to apply the same procedures for all devices.

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6 In all cases, 'conformity with the requirements of this Regulation' shall mean for 'legacy devices' conformity with the MDD or AIMDD and the additional requirements in accordance with Article 120(3d) MDR.

7 The requirement that manufacturers not established in the EU shall designate an authorised representative (Article 11(1) MDR) stems already from the AIMDD and MDD and therefore also applies to 'legacy devices'. For the purpose of clearly identifying the relevant competent authority, Article 11(7) should be applied also in respect of 'legacy devices' clarifying that any reference to the competent authority of the Member State in which the manufacturer has its registered place of business shall be understood as a reference to the competent authority of the Member State in which the authorised representative has its registered place of business.

8 Without prejudice to national rules on implant cards applicable to 'legacy devices'.

9 For legacy devices, the Declaration of Conformity (DoC) needs to refer to the MDD or AIMDD, as applicable. The manufacturer may additionally declare conformity with Article 120 MDR confirming that the conditions laid down therein are fulfilled. Where the manufacturer updates its DoC to reflect changes regarding information provided in the declaration (e.g. changes concerning the address, the authorised representative, or the validity date) the manufacturer should add a reference to the DoC which was drawn up for the legacy device before 26 May 2021. In addition, traceability of all versions of the DoC needs to be ensured.

10 Without prejudice to traceability requirements in the supply chain applicable to 'legacy devices' in accordance with other rules such as on market surveillance of goods or the General Product Safety Directive.

11 See in this respect also MDCG 2019-5 on registration of legacy devices in EUDAMED.

Systems and procedure packs

Following the logic of the transitional provisions laid down in Article 120(2) and (3) of the MDR, the transitional period also applies to systems and procedure packs:

- for which involvement of a notified body is required pursuant to the MDR,
- which consist only of 'legacy devices'[12] and
- for which a declaration has been drawn up in accordance with Article 12(2) of the MDD prior to 26 May 2021[13].

In such cases, Article 22 of the MDR does not apply. The transitional period for a 'legacy system or procedure pack' ends when the transitional period ends for the legacy device of the highest risk class according to the MDR that is included in the system or procedure pack. This also applies where a certificate was issued by a notified body prior to 26 May 2021 in accordance with Article 12(3) MDD, unless the certificate has been withdrawn.

A system or procedure pack that is to be treated as a device in its own right pursuant to the last subparagraph of Article 12(2) MDD needs to meet all the applicable requirements and conditions set out in Article 120(3) to (3d) MDR to benefit from the extended transitional period.

3.2. Other MDR requirements

Putting in place a MDR compliant quality management system

In accordance with Article 120(3c), point (d), of the MDR, manufacturers must put in place a **quality management system** (QMS) in accordance with Article 10(9) of the MDR no later than 26 May 2024 in order to be allowed to place their 'legacy devices' on the market after that date. That means that, since 26 May 2024, manufacturers must comply with Article 10(9) of the MDR, in addition to the requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices, which were applicable already from 26 May 2021. With regard to legacy devices, compliance of the QMS with the MDR does not need to be certified by a notified body by 26 May 2024, as the assessment of the QMS will be done by the notified body as part of the MDR certification.

For some specific QMS aspects listed in Article 10(9) of the MDR, e.g. points (b), (e) and (f), it needs to be taken into consideration that the QMS covers 'legacy devices', i.e. devices that are not yet (fully) MDR compliant. That means that for those devices it is not required that manufacturers have identified all relevant general safety and performance requirements and options to address those requirements, or have put in place a risk management system as set out in Section 3 of Annex I MDR, nor conducted the clinical evaluation in line with Article 61 and Annex XIV of the MDR.

[12] Including devices that used to be part of a system or procedure pack as 'legacy device' and that meanwhile have demonstrated compliance with the MDR without having undergone significant changes in design or intended purpose.

[13] Including any combinations of legacy devices covered by the Article 12(2) statement.

However, the manufacturer's QMS should address how compliance with those requirements will be achieved during the transitional period.

UDI assignment

As Article 10(9), point (h), of the MDR does not in itself establish a requirement for UDI assignment, the verification of UDI assignments only applies where UDI assignment is actually required for the relevant devices. As mentioned in MDCG 2019-5, 'legacy devices' are not subject to the MDR UDI requirements. This approach has not changed through Regulation 2023/607[14].

4. Application of MDR requirements to devices placed on the market prior to 26 May 2021 ('old' devices)

Serious incidents involving an 'old' device and field safety corrective actions (FSCA) in respect of 'old' devices must be reported in accordance with Article 87 MDR.

Furthermore, Articles 93 to 100 of the MDR, which lay down rights and obligations of competent authorities with regards to market surveillance activities is also applicable to 'old' devices as this allows competent authorities to check that those devices are in conformity with the rules applicable at the moment when they were placed on the market and to take appropriate measures against non-compliant or unsafe devices.

[14] See Q&A document on practical aspects related to the implementation of Regulation (EU) 2023/607, point 11.2.

Annex - table illustrating MDR requirements applicable or not applicable to 'legacy devices' (non-exhaustive)

MDR requirement	Application to 'legacy devices'
Art. 10(9) – Manufacturer's quality management system	YES from 26 May 2024 in accordance with Article 120(3c), point (d), MDR as amended by Regulation (EU) 2023/607
Art. 10(10), (12)-(15) – Manufacturer's obligations	YES (*nota bene*: 'conformity with the requirements of this Regulation' shall mean for 'legacy devices' conformity with the MDD or AIMDD and the additional requirements in accordance with Article 120(3d) MDR)
Art. 11(3)(c)-(g) – Authorised representative	YES (*nota bene*: 'conformity with the requirements of this Regulation' shall mean for 'legacy devices' conformity with the MDD or AIMDD and the additional requirements in accordance with Article 120(3d) MDR)
Art. 11(7)	YES
Art. 13(2), 2nd subparagraph, (4), (6)-(8), (10) – Importers' obligations	YES (*nota bene*: 'conformity with the requirements of this Regulation' shall mean for 'legacy devices' conformity with the MDD or AIMDD and the additional requirements in accordance with Article 120(3d) MDR)
Art. 14(2), last subparagraph, (4)-(6) – Distributors' obligations	YES (*nota bene*: 'conformity with the requirements of this Regulation' shall mean for 'legacy devices' conformity with the MDD or AIMDD and the additional requirements in accordance with Article 120(3d) MDR)
Art. 15 – Person responsible for regulatory compliance (PRRC)	NO
Art. 16(3) and (4)	NO
Art. 18 – Implant card	NO (without prejudice to national rules on implant cards applicable to 'legacy devices')
Art. 19 – Declaration of Conformity	NO (for legacy devices, the Declaration of Conformity needs to refer to the MDD or AIMDD, see also footnote 9)
Art. 22 – Systems and procedure packs	NO for system or procedure packs containing 'legacy devices', see also footnotes 12 and 13
Art. 25 – Identification within the supply chain	NO (without prejudice to traceability requirements in the supply chain applicable to 'legacy devices' in accordance with other rules such as on

	market surveillance of goods or the General Product Safety Directive)
Art. 27 – UDI	NO (See in this respect also MDCG 2019-5 on registration of legacy devices in Eudamed)
Art. 29 – Registration of devices	In principle YES, but specific transitional provisions apply in accordance with Art. 122, 123(3) MDR as regards the application of Eudamed related provisions[15]
Art. 31 – Registration of economic operators	In principle YES, but specific transitional provisions apply in accordance with Art. 122, 123(3) MDR as regards the application of Eudamed related provisions[15]
Art. 32 – Summary of safety and clinical performance (SSCP)	NO
Art. 83, 84 – PMS system and PMS plan	YES (with exception of requirements that relate to non-applicable obligations, e.g. Art. 83(3)(d) – SSCP; no requirement for a full revision of the technical documentation in accordance with Annexes II and III)
Art. 85 – PMS report (class I devices)	YES (classification of devices in class I follows classification rules of the MDD, i.e. Art. 85 applies to class I 'legacy devices' despite the fact that those devices might be in a higher class under the MDR)
Art. 86 – PSUR (class IIa, IIb and III devices)	YES (manufacturers shall draw up and update PSURs; to be made available outside Eudamed to competent authorities upon request; to be made available outside Eudamed to notified bodies and to be taken into consideration by them in the framework of surveillance audits; see also MDCG 2022-4 Rev.2 and 2022-21)
Art. 87 – Reporting of serious incidents and FSCA	YES

[15] See MDCG 2021-1 Rev. 1 'Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional'. Please note that Regulation (EU) 2024/1860 of 13 June 2024 has amended Articles 122 and 123(3) MDR regarding transitional provisions in relation to EUDAMED.

Art. 88 – Trend reporting	YES (trend reporting was already part of the vigilance system established under the MDD/AIMDD)
Art. 89 – Analysis of serious incidents and FSCA	YES
Art. 90 – Analysis of vigilance data	YES
Art. 91 – Implementing acts	YES
Art. 92 – Electronic system on vigilance and on post-market surveillance	In principle YES, but specific transitional provisions apply in accordance with Art. 122, 123(3) MDR as regards the application of Eudamed related provisions[15]
Art. 93 – Market surveillance activities	YES
Art. 94 – Evaluation of non-compliances	YES (*nota bene*: 'conformity with the requirements of this Regulation' shall mean for 'legacy devices' conformity with the MDD or AIMDD and the additional requirements in accordance with Article 120(3d) MDR)
Art. 95, 96, 97 – Devices presenting an unacceptable risk; evaluation of national measures; other non-compliance	YES (*nota bene*: 'conformity with the requirements of this Regulation' shall mean for 'legacy devices' conformity with the MDD or AIMDD and the additional requirements in accordance with Article 120(3d) MDR)
Art. 98 – Preventive health protection measures	YES
Art. 99 – Good administrative practice	YES
Art. 100 – Electronic system on market surveillance	YES