MDCG 2021-25

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

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This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

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Preface

At its meeting on 27/28 May 2021, the MDCG set up an *ad hoc* task-force regarding the application of transitional provisions laid down in Article 120(3) of Regulation (EU) 2017/745 (MDR) and the consequential 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.

The report of the MDCG *ad hoc* task-force on transitional provisions was endorsed by the MDCG by written procedure held from 23 August to 10 September 2021.

The report of the task-force has been forwarded to all MDCG working groups to orientate the development of specific guidance documents where the application of the transitional provisions laid down in Article 120(3) of Regulation (EU) 2017/745 is relevant.

At its meeting on 19 October 2021, the MDCG agreed to publish the task-force report as MDCG guidance.

Report of the MDCG *ad hoc* task-force on transitional provisions ('legacy devices' and 'old' devices)

I. Mandate of task-force and process

Having regard to the discussions under agenda item 2.2. of the MDCG meeting on 27/28 May 2021 on "*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*", the MDCG set up an *ad hoc* task-force to further discuss this topic in order to quickly find a solution that is legally defendable and pragmatic. The outcome should guide the ongoing work on guidance documents, such as on PSUR and notified bodies' appropriate surveillance.

MDCG members from BE, DE, DK, ES, FR, IE, IT, PL, RO and SE nominated participants to the task-force. The task-force met by video-conference on 16 and 30 June 2021.

Discussions were divided in three parts:

- Application of requirements set out in Chapter VII of Regulation (EU) 2017/745 on medical devices (MDR) to 'legacy devices'
- Application of other MDR requirements to 'legacy devices'
- Application of MDR requirements to 'old' devices

With this document, the task-force reports back to the MDCG about its position on the applicability of MDR requirements to 'legacy devices' and 'old' devices. The annex contains a non-exhaustive table illustrating MDR requirements that should apply to 'legacy devices'.

II. Legal provisions and terminology

Article 120(3) of Regulation 2017/745 (MDR)

By way of derogation from Article 5 of this Regulation, a device which is a class I device pursuant to Directive 93/42/EEC, 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, or which has 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 26 May 2024, provided that from 26 May 2021 it continues to comply with either of those Directives, and provided there are no significant changes in the design and intended purpose. However, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance,

registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives.

Without prejudice to Chapter IV and paragraph 1 of this Article, the notified body that issued the certificate referred to in the first subparagraph shall continue to be responsible for the appropriate surveillance in respect of all of the applicable requirements relating to the devices it has certified.

Terminology[1]

Legacy devices should be understood as devices, which, in accordance with Article 120(3) of the MDR, are placed on the market after the MDR's date of application (DoA) and until 26 May 2024 if certain conditions are fulfilled. 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 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 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 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[2].

III. Position of the task-force

1. Application of requirements set out in Chapter VII of the MDR on post-market surveillance, market surveillance and vigilance to 'legacy devices'

The task-force has come to the following position:

- in accordance with Article 120(3), 1st subparagraph, MDR all relevant requirements set out in Chapter VII of the MDR on post-market surveillance, market surveillance and vigilance apply to 'legacy devices';
- the appropriate surveillance regarding 'legacy devices' by notified bodies in accordance with Article 120(3), 2nd subparagraph, MDR, essentially is a continuation of the previous surveillance activities under the MDD/AIMDD, as notified bodies designated under the MDD/AIMDD are not designated to conduct assessments under the MDR;
- in the framework of their surveillance activities, notified bodies shall take into account that new requirements apply to manufacturers resulting from the transitional provisions;
- there needs to be flexibility as regards notified bodies' involvement when reviewing applicable requirements as part of their 'appropriate surveillance', as the notified bodies responsible for the appropriate surveillance in accordance

[1] The terminology of 'legacy devices' and 'old devices' is in line with existing MDCG guidance such as MDCG-2021-13 rev.1

[2] See Article 2(28) MDR and section 2.3. of the Commission Notice - The 'Blue Guide' on the implementation of EU products rules 2016, OJ C 272, 26.7.2016, p. 1.

with Article 120(3), 2nd subparagraph, MDR are not notified bodies involved in the conformity assessment procedure in accordance with Article 52 MDR;

- 'legacy devices' are subject to the requirements laid down in Article 85 or Article 86 based on their classification in accordance with the MDD. A possible change of their risk class under the MDR should not be taken into account during the transition period. Active implantable devices subject to the AIMDD should be considered as class III devices for the purpose of applying the relevant MDR requirements during the transition period.

Specifically with regard to the application of **Article 86 MDR on the periodic safety update report (PSUR)**, the task-force suggests the following way forward:

- manufacturers of 'legacy devices' are subject to the requirement to draw up and update PSURs in accordance with Article 86 MDR. They need to make the PSURs available to competent authorities on request (outside EUDAMED);
- in the framework of the audit of the manufacturer's approved quality system, notified bodies need to check that the manufacturer has made the necessary adjustments in accordance with new MDR requirements on PMS and vigilance[3] (further guidance to be developed by NBO WG);
- manufacturers shall make available PSURs to their notified bodies in the framework of surveillance audits (outside EUDAMED) in order to allow the notified body to verify that the approved quality system and design remain compliant with the certificate issued under the MDD or AIMDD;
- existing contracts between the notified body and the manufacturer should cover surveillance activities to be performed by the notified body during the transition period. Addition of PSURs to the documentation to be provided to notified bodies in the framework of surveillance audits should therefore not justify the amendment of those existing contracts or extra fees;
- by the end of validity of the certificate issued in accordance with the MDD or AIMDD, or at the latest by the end of the transitional period, the responsibility of notified bodies to carry out the appropriate surveillance in accordance with Article 120(3), 2nd subparagraph, MDR, stops. Once 'legacy devices' are certified in accordance with the MDR, the PSURs drawn up during the transitional period should continue to be updated; the PSURs will then have to be communicated to the notified body involved in the conformity assessment procedure set out in Article 52 MDR and, if applicable, reviewed by them in accordance with Article 86 MDR.

2. Application of other MDR requirements to 'legacy devices'

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

[3] No full revision of the technical documentation in accordance with Annexes II and III MDR required.

Such an approach respects the wording of Article 120(3) 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) 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(3) 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'[4]:

- for manufacturers: Article 10 (10), (12)-(15);
- for authorised representatives[5]: 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).

Based on this approach, further requirements applicable to 'legacy devices' may be identified by the relevant working groups.

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[6], Article 25[7], Article 27[8], 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.

It appears logical to apply the transition period also to systems and procedure packs consisting only of 'legacy devices' and for which a declaration has been drawn up in accordance with the MDD prior to 26 May 2021. In such cases, Article 22 MDR does not apply. Legal or natural persons combining 'legacy devices' and MDR devices (e.g. class I devices that are not covered by Article 120(3)) are subject to Article 22

[4] 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(3) MDR.

[5] 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.

[6] Without prejudice to national rules on implant cards applicable to 'legacy devices'.

[7] 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.

[8] See in this respect also MDCG 2019-5 on registration of legacy devices in Eudamed.

MDR, whereas the 'legacy devices' as such included in a system or procedure pack fall under the transitional provisions of Article 120(3) MDR.

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

The task-force considers that MDR requirements are in principle not applicable to 'old' devices. However, Articles 93 to 100 MDR, which lay down rights and obligations of competent authorities with regard to market surveillance activities, apply also to 'old' devices. 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.

Practical aspects in relation to market surveillance activities concerning 'old' devices should be clarified in the framework of the Market Surveillance working group.

With regard to the desirability of allowing the reporting of incidents in relation to 'old' devices through EUDAMED in order to avoid different vigilance reporting tools (see in this respect recital 98 MDR), the task-force welcomed the clarification in point 5 of MDCG 2021-13[9].

IV. Next steps

The task-force invites the MDCG to take note of the proposed solution described above. Unless major objections are raised by the MDCG, the task-force suggests:

- forwarding this report to the relevant MDCG workings groups as orientation to be taken into account for the development of guidance documents and
- publishing this report on the Commission's website in order to inform interested stakeholders.

[9] MDCG 2021-13 rev.1 - Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR.

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

MDR requirement	Application to 'legacy devices'
Art. 10(10), (12)-(15)	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(3) MDR)
Art. 11(3)(c)-(g)	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(3) MDR)
Art. 11(7)	YES
Art. 13(2), 2nd subparagraph, (4), (6)-(8), (10)	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(3) MDR)
Art. 14(2), last subparagraph, (4)-(6)	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(3) MDR)
Art. 15	NO
Art. 16(3) and (4)	NO
Art. 18	NO (without prejudice to national rules on implant cards applicable to 'legacy devices')
Art. 22	YES for system or procedure packs combining 'legacy devices' and MDR devices
Art. 25	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	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 in the absence of EUDAMED's full functionality, specific transitional provisions apply in accordance with Art. 122, 123(3)(d)(e) MDR[10]
Art. 31 – registration of economic operators	In principle YES, but in the absence of EUDAMED's full functionality, specific transitional provisions apply in accordance with Art. 122, 123(3)(d)(e) MDR[11]
Art. 32	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 taken into consideration by notified body designated under AIMDD/MDD in the framework of surveillance audits, see further explanations above in the text)
Art. 87 – reporting of serious incidents	YES
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 – EUDAMED vigilance module	In principle YES, but in the absence of EUDAMED's full functionality, specific transitional provisions apply in accordance with Art. 122, 123(3)(d)(e) MDR[12]

[10] See MDCG 2021-1 Rev. 1 'Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional'.
[11] See MDCG 2021-1 Rev. 1 'Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional'.
[12] See MDCG 2021-1 Rev. 1 'Guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional'.

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(3) 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(3) MDR)
Art. 98 – preventive health protection measures	YES
Art. 99 – good administrative practice	YES
Art. 100	YES