MDCG 2022-8

Regulation (EU) 2017/746 - application of IVDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC

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I. Introduction

Regulation (EU) 2022/112[1] extended the transitional provisions of Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR), in particular its Article 110(3), in terms of scope and timing. Following the approach set out in the report of the MDCG *ad hoc* task-force on transitional provisions of Regulation (EU) 2017/745 on medical devices (MDR) published as MDCG 2021-25[2], the present document provides guidance as regards the applicability of IVDR requirements to 'legacy devices' and 'old' devices. The annex contains a non-exhaustive table illustrating IVDR requirements applicable or not applicable to 'legacy devices'.

II. Legal provisions and terminology

Article 110(3) of Regulation 2017/746 (IVDR), as amended by Regulation (EU) 2022/112, states:

By way of derogation from Article 5 of this Regulation, the devices referred to in the second and third subparagraphs of this paragraph may be placed on the market or put into service until the dates set out in those subparagraphs, provided that, from the date of application of this Regulation, those devices continue to comply with Directive 98/79/EC, and provided that there are no significant changes in the design and intended purpose of those devices.

Devices with a certificate that was issued in accordance with Directive 98/79/EC and which is valid by virtue of paragraph 2 of this Article may be placed on the market or put into service until 26 May 2025.

Devices for which the conformity assessment procedure pursuant to Directive 98/79/EC did not require the involvement of a notified body, for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with that Directive, 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 the following dates:

(a) 26 May 2025, for class D devices;

(b) 26 May 2026, for class C devices;

(c) 26 May 2027, for class B devices;

(d) 26 May 2027, for class A devices placed on the market in sterile condition.

By way of derogation from the first subparagraph of this paragraph, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance,

[1] Regulation (EU) 2022/112 of the European Parliament and of the Council of 25 January 2022 amending Regulation (EU) 2017/746 as regards transitional provisions for certain *in vitro* diagnostic medical devices and the deferred application of conditions for in-house devices.

[2] MDCG 2021-25 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.

registration of economic operators and of devices shall apply to devices referred to in the second and third subparagraphs of this paragraph, instead of the corresponding requirements in Directive 98/79/EC.

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

Terminology used in this guidance

Legacy devices under the IVDR (hereafter '**legacy devices**') should be understood as devices referred to in the 2nd or 3rd subparagraph of Article 110(3) IVDR, which are placed on the market or put into service after 26 May 2022 (i.e. the IVDR's date of application) and until the end of the respective transition period set out in the 2nd or 3rd subparagraph of Article 110(3), if the conditions laid down in the 1st subparagraph of Article 110(3)[3] are fulfilled. Those devices can be:

a) devices covered by a valid EC certificate issued by a notified body in accordance with Directive 98/79/EC on *in vitro* diagnostic medical devices (IVDD) prior to 26 May 2022; or

b) devices for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with the IVDD and for which the conformity assessment procedure pursuant to the IVDR (contrary to the IVDD) requires the involvement of a notified body.

'Old' devices are those devices that were placed on the market or put into service before 26 May 2022 in accordance with the IVDD or the applicable national rules before the IVDD had become applicable and which are still on the market or in use after 26 May 2022.

IVDR devices are those devices that are placed on the market as being in conformity with the IVDR other than 'legacy devices'. In order to be placed on the market or put into service from 26 May 2022 all class A non-sterile devices and all devices not benefitting from the transitional provisions laid down in Article 110(3) IVDR, i.e. all 'new' devices, must be IVDR-compliant.

[3] According to the 1st subparagraph of Article 110(3) IVDR, in order to benefit from the transition period, devices (1) must continue to comply with Directive 98/79/EC and (2) must not be subject to significant changes in the design and intended purpose. With regard to the meaning of 'significant changes' see MDCG 2022-6 Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR.

Transition periods

For devices covered by a valid EC certificate issued in accordance with the IVDD prior to 26 May 2022 (i.e. **devices listed in Annex II IVDD and devices for self-testing**), the transition period ends on **26 May 2025** (see 2nd subparagraph of Article 110(3) IVDR). If placed on the market before 26 May 2025, those devices may continue to be made available until 26 May 2026 ('sell-off date', see 2nd subparagraph, point (a) of Article 110(4) IVDR).

For devices that fall in **class D** in accordance with the IVDR classification rules for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with the IVDD and for which the conformity assessment procedure pursuant to the IVDR (contrary to the IVDD) requires the involvement of a notified body, the transition period ends on **26 May 2025** (see 3nd subparagraph, point (a), of Article 110(3) IVDR). If placed on the market before 26 May 2025, those devices may continue to be made available until 26 May 2026 ('sell-off date', see 2nd subparagraph, point (a) of Article 110(4) IVDR).

For devices that fall in **class C** in accordance with the IVDR classification rules for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with the IVDD and for which the conformity assessment procedure pursuant to the IVDR (contrary to the IVDD) requires the involvement of a notified body, the transition period ends on **26 May 2026** (see 3nd subparagraph, point (b), of Article 110(3) IVDR). If placed on the market before 26 May 2026, those devices may continue to be made available until 26 May 2027 ('sell-off date', see 2nd subparagraph, point (b) of Article 110(4) IVDR).

For devices that fall in **class B or class A sterile** in accordance with the IVDR classification rules for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with the IVDD and for which the conformity assessment procedure pursuant to the IVDR (contrary to the IVDD) requires the involvement of a notified body, the transition period ends on **26 May 2027** (see 3nd subparagraph, points (c) and (d), of Article 110(3) IVDR). If placed on the market before 26 May 2027, those devices may continue to be made available until 26 May 2028 ('sell-off date', see 2nd subparagraph, point (c) of Article 110(4) IVDR).

It should be recalled that the concept of 'placing on the market' refers to each individual product, not to a type of product[4].

III. Application of IVDR requirements to legacy devices

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

In accordance with the 4th subparagraph of Article 110(3) IVDR, the relevant requirements set out in Chapter VII of the IVDR on post-market surveillance, market surveillance and vigilance apply to 'legacy devices'.

That means that manufacturers of 'legacy devices' need to set up a **post-market surveillance (PMS) system** based on a **PMS plan** (Articles 78, 79 IVDR) with the exception of aspects related to pre-market requirements, which are not applicable to

[4] See Article 2(21) IVDR 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.

'legacy devices', such as to update the summary of safety and performance (Article 78(3), point (d), IVDR).[5]

As part of the manufacturer's post-market surveillance system, the post-market performance follow-up (**PMPF**) requirements (Annex XIII, Part B, IVDR) should apply to 'legacy devices'. PMPF further develops the requirement in Annex III, section 5, of the IVDD[6]. That means that, under the IVDR, manufacturers need to "*proactively collect and evaluate performance and relevant scientific data from the use of a device*". However, this does not mean that the manufacturer would have to draw up, retrospectively, a performance evaluation report in line with the IVDR as performance evaluation and its documentation according to the IVDR is a pre-market requirement not applicable to 'legacy devices'.

The requirements and procedures related to **serious incidents and field safety corrective actions** and **trend reporting** (Articles 82, 83 and 84 IVDR) as well as market surveillance provisions apply to 'legacy devices'.

As Directive 98/79/EC, contrary to the IVDR, does not provide for rules for the classification of devices in risk classes as specified in the IVDR, an appropriate distinction cannot be made between 'legacy devices' to which Article 80 IVDR (**PMS report**)[7] and 'legacy devices' to which Article 81 IVDR (periodic safety update report, **PSUR**)[8] apply. Therefore, Article 80 IVDR (PMS report) should, as a minimum requirement, apply to all legacy devices, unless a manufacturer of 'legacy devices' that will fall under class C or D voluntarily prepares a PSUR pursuant to Article 81.

Regarding 'legacy devices' covered by certificates issued under the IVDD (i.e. for devices listed in Annex II IVDD and devices for self-testing), the notified bodies that issued the respective certificates conduct the 'appropriate surveillance' in accordance with the 5th subparagraph of Article 110(3) IVDR, which essentially is a continuation of the previous surveillance activities under the IVDD. In the framework of their surveillance activities, notified bodies should take into account the new requirements that apply to manufacturers resulting from the transitional provisions. However, 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 with the 5th subparagraph Article 110(3) IVDR[9] are not notified bodies designated to conduct conformity assessments under the IVDR.

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

In addition to the requirements set out in Chapter VII IVDR, also other IVDR requirements should apply to 'legacy devices', provided that those requirements

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5 No full revision of the technical documentation in accordance with Annexes II and III IVDR required.

6 According to Annex III, section 5, and Annex IV, last indent of section 3.1, of the IVDD, "*the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions, taking account of the nature and risks in relation to the product*."

7 Article 80 IVDR applies to class A and B devices.

8 Article 81 IVDR applies to class C and D devices.

9 A MDCG guidance on appropriate surveillance referred to in Article 110(3) IVDR is under development.

relate to post-market surveillance, market surveillance, vigilance or registration of economic operators and devices.

Such an approach respects the wording of Article 110(3) IVDR. At the same time it extends the application of the IVDR 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 IVDR (Articles 10(1) and 13(1) IVDR) apply, whereas for 'legacy devices' conformity with the IVDR means conformity with the IVDD and the additional requirements in accordance with Article 110(3) IVDR. In addition, the obligations of economic operators set out in the following provisions should also apply to economic operators with respect to 'legacy devices'[10]:

- for manufacturers: Article 10(9), (11)-(14);
- for authorised representatives[11]: 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.

IVDR 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'[12]. Examples for provisions not applicable in respect to 'legacy devices' are Article 15, Article 16(3) and (4), Article 22[13], Article 24[14], Article 29 IVDR. This is without prejudice to the possibility for economic operators to follow any IVDR requirements also for 'legacy devices', especially if they deal with both 'legacy devices' and IVDR devices and want to apply the same procedures for all devices.

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10 In all cases, 'conformity with the requirements of this Regulation' shall mean for 'IVD legacy devices' conformity with the IVDD and the additional requirements in accordance with Article 110(3) IVDR.

11 The requirement that manufacturers not established in the EU shall designate an authorised representative (Article 11(1) IVDR) stems already from the IVDD 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.

12 However, provisions on performance studies apply to studies started after 26 May 2022 regardless of the device's status.

13 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.

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

IV. Application of IVDR requirements to devices placed on the market prior to 26 May 2022 ('old' devices)[15]

IVDR requirements are in principle not applicable to 'old' devices. However, IVDR provisions should generally apply if they do not directly impact the device, its documentation or the conditions for the placing or making available of devices on the market. That means that Articles 88 to 95 IVDR, which lay down rights and obligations of competent authorities with regard to market surveillance activities, apply also to 'old' devices after 26 May 2022. 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.

Moreover, the reporting and analysis of serious incidents and field safety corrective actions occurring after 26 May 2022 in respect of 'old' devices should be done in accordance with Article 82 and 84 IVDR.

[15] The application of market surveillance and vigilance provisions to 'old' devices has in the past been interpreted differently at national level.

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

IVDR requirement	Application to 'IVD legacy devices'
Art. 10(9), (11)-(14) – manufacturers' obligations	YES (*nota bene*: 'conformity with the requirements of this Regulation' for 'IVD legacy devices' means conformity with the IVDD and the additional requirements in accordance with Article 110(3) IVDR)
Art. 11(3)(c)-(g), (7) – authorised representatives	YES (*nota bene*: 'conformity with the requirements of this Regulation' for 'legacy devices' means conformity with the IVDD and the additional requirements in accordance with Article 110(3) IVDR)
Art. 13(2), 2nd subparagraph, (4), (6)-(8), (10) – importers obligations	YES (*nota bene*: 'conformity with the requirements of this Regulation' for 'IVD legacy devices' means conformity with the IVDD and the additional requirements in accordance with Article 110(3) IVDR)
Art. 14(2), last subparagraph, (4)-(6) – distributors' obligations	YES (*nota bene*: 'conformity with the requirements of this Regulation' for 'IVD legacy devices' means conformity with the IVDD and the additional requirements in accordance with Article 110(3) IVDR)
Art. 15 – person responsible for regulatory compliance	NO
Art. 16(3) and (4) – repackaging and relabelling	NO
Art. 22 – identification in the supply chain	NO (without prejudice to traceability requirements in the supply chain applicable to 'IVD legacy devices' in accordance with other rules such as on market surveillance of goods or the General Product Safety Directive)
Art. 24 – UDI	NO (See in this respect also MDCG 2019-5 on registration of legacy devices in Eudamed)
Art. 26 – registration of devices	In principle YES, but in the absence of EUDAMED's full functionality, specific transitional provisions apply in

	accordance with Art. 112, 113(3)(f) IVDR[16]
Art. 28 – registration of economic operators	In principle YES, but in the absence of EUDAMED's full functionality, specific transitional provisions apply in accordance with Art. 112, 113(3)(f) IVDR[15]
Art. 29 – summary of safety and performance	NO
Art. 78, 79 – PMS system and PMS plan	YES (including PMPF according to Annex XIII Part B; however with exception of requirements that relate to non-applicable obligations, e.g. Art. 78(3)(d) – Summary of safety and performance; no requirement for a full revision of the technical documentation in accordance with Annexes II and III)
Art. 80 – PMS report	YES, applicable to all 'legacy devices', unless manufacturer voluntarily prepares a PSUR pursuant to Article 81
Art. 81 – PSUR	NO
Art. 82 – reporting of serious incidents	YES
Art. 83 – trend reporting	YES (trend reporting was already part of the vigilance system established under the IVDD)
Art. 84 – analysis of serious incidents and FSCA	YES
Art. 85 – analysis of vigilance data	YES
Art. 86 – implementing acts	YES
Art. 87 – EUDAMED vigilance module	In principle YES, but in the absence of EUDAMED's full functionality, specific transitional provisions apply in accordance with Art. 112, 113(3)(f) IVDR[15]
Art. 88 – market surveillance activities	YES
Art. 89 – evaluation of non-compliances	YES (*nota bene*: 'conformity with the requirements of this Regulation' for 'legacy devices' means conformity with the IVDD and the additional requirements in accordance with Article 110(3) IVDR)
Art. 90, 91, 92 – devices presenting an unacceptable risk; evaluation of national measures; other non-compliance	YES (*nota bene*: 'conformity with the requirements of this Regulation' for 'legacy devices' means conformity with

[16] A MDCG guidance on harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional (for Regulation (EU) 2017/746 on in vitro diagnostic medical devices) is under development.

	the IVDD and the additional requirements in accordance with Article 110(3) IVDR)
Art. 93 – preventive health protection measures	YES
Art. 94 – good administrative practice	YES
Art. 95 – EUDAMED market surveillance module	YES