European Commission

EXTENSION OF THE IVDR TRANSITIONAL PERIODS

Q&A on practical aspects related to the implementation of the extended transitional period provided for in the IVDR, as amended by Regulation (EU) 2024/1860 of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices

JULY 2024

Health and Food Safety

Q&A on practical aspects related to the implementation of the extended transitional period provided for in the IVDR, as amended by Regulation (EU) 2024/1860 of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices[1].

Disclaimer: This Q&A document is intended to facilitate the application of Regulation (EU) 2024/1860 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro *diagnostic medical devices. This document has not been formally endorsed by the European Commission and is without prejudice to any interpretation of the relevant provisions by the Court of Justice of the European Union or national courts. The information in this Q&A document is of a general nature and not intended to address specific circumstances of any particular case; the document does not intend to provide professional or legal advice. The information is not necessarily comprehensive nor complete. If needed, this document will be updated in order to address additional questions that may arise.*

1 Regulation (EU) 2024/1850 of the European Parliament and of the Council of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain *in vitro* diagnostic medical devices (OJ L, 9.7.2024, p.1). Regulation (EU) 2024/1860 has entered into force on 9 July 2024.

TABLE OF CONTENTS

Introduction – Objectives of the MDR/IVDR amendments

The amendment of the MDR and of the IVDR through Regulation (EU) 2024/1860 addresses three topics:

1. Regulation (EU) 2024/1860 aims to ensure a high level of patient safety and public health protection, including mitigation of risk of shortages of *in vitro* diagnostic medical devices (IVDs) needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements. For that purpose, manufacturers and notified bodies are given extra time to carry out, in accordance with the IVDR, the conformity assessment of IVDs covered by a certificate or a declaration of conformity issued in accordance with Directive 98/79/EC. Questions and answers regarding the extension of the IVDR transitional periods are set out in this document.
2. Regulation (EU) 2024/1860 also imposes a requirement on manufacturers to inform the relevant competent authority and health institutions before the supply of certain medical devices or IVDs is interrupted or discontinued. If manufacturers do not supply directly to health institutions or healthcare professionals, they must inform the relevant economic operators in the supply chain, which then must inform the health institutions. This mechanism will enable the competent authority and health institutions to consider mitigating measures to ensure patient health and safety. Questions and answers regarding this topic will be set out in a separate document.
3. Regulation (EU) 2024/1860 also enables a gradual roll-out of the electronic systems integrated into the European database on medical devices ('Eudamed') that are finalised, instead of deferring the mandatory use of Eudamed until the last of the six modules is completed. The use of Eudamed – and especially its systems for the registration of economic operators, devices and certificates – will improve transparency and provide information on devices on the EU market, helping to monitor the availability of devices. Questions and answers regarding this topic will be set out in a separate document.

EXTENSION OF THE IVDR TRANSITIONAL PERIODS

The answers to the questions set out below follow the same approach as the Q&A on the extension of the MDR transitional period through Regulation (EU) 2023/607[2]. They have been developed taking into account the objectives pursued by the amendment with a view to making best use of the additional time provided by the extension of the IVDR transitional period.

PART A – SCOPE OF THE EXTENSION OF THE IVDR TRANSITIONAL PERIODS

1. Which devices can benefit from the extended transitional periods?

Only 'legacy devices' can benefit from the extended transitional period. In line with MDCG 2022-8[3], 'legacy devices' should be understood as IVDs, which, in accordance with the IVDR's transitional provisions, are placed on the market or put into service after the IVDR's date of application (i.e. 26 May 2022) if certain conditions are fulfilled. Those devices can be:

- 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;
- 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.

The extension of the transitional period beyond 26 May 2025 (for class D devices), beyond 26 May 2026 (for class C devices) and beyond 26 May 2027 (for class B and class A sterile devices) only applies if the conditions laid down in Article 110(3c) IVDR are fulfilled. In case of devices for which the relevant certificate has expired before 9 July 2024, also the conditions laid in the second subparagraph of Article 110(2), points (a) or (b), IVDR need to be fulfilled (see below part C).

A flowchart to assist manufacturers and other relevant actors in deciding whether or not a device is covered by the extended transitional period provided for in the amended Article 110 IVDR is provided in the appendix to this document.

Reminder: No transitional period applies to class A devices (except for class A sterile devices), because they do not require involvement of a notified body in the conformity assessment, nor to 'new' devices, i.e. devices that were not covered by a certificate or a declaration of conformity issued in accordance with the IVDD. The IVDR applies to those devices since 26 May 2022.

2. Can devices that have already been certified in accordance with the IVDR benefit from extended transitional periods?

Yes. As regards legacy devices covered by IVDD certificates, the device only benefits from the transitional period as long as the IVDD certificate(s) have not been withdrawn by the notified body[4]. A notified body may withdraw a certificate if the relevant legal requirements are no longer met by the manufacturer or where a certificate should not have been issued, taking account of the principle of proportionality. The IVDR certification of the device as such is not a reason for the notified body to withdraw a IVDD certificate.

2 Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices Rev. 2 (July 2024).

3 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 (May 2022). It is planned to revise MDCG 2022-8 to adapt it to Regulation (EU) 2024/1860.

4 A notified body letter informing about the expiry of the certificate, or a controlled phase-out of production agreed between notified body and manufacturer due to the expiry of a certificate prior to 9 July 2024, is not considered to be a withdrawal of a certificate.

Also legacy devices that require certification for the first time under the IVDR can benefit from the extended transitional period after issuance of the IVDR certificate, provided that they continue meeting the conditions set out in Article 110(3c) IVDR.

That means that a 'legacy device' and the corresponding IVDR compliant device can be placed on the market in parallel until the end of the relevant transitional period.

3. What about 'legacy devices' for which the manufacturer does not wish to apply for certification under the IVDR?

Manufacturers are not obliged to apply for certification of their 'legacy devices' under the IVDR.

If their legacy device is covered by an IVDD certificate that expires after 9 July 2024 and before 26 May 2025, they nonetheless benefit from the extension of the transitional period until 26 May 2025, provided the conditions set out in Article 110(3c), points (a) to (c), are fulfilled. If the manufacturer does not lodge an application for conformity assessment by 26 May 2025, the transition period will end on 26 May 2025.

As regards legacy devices that were not subject to notified body involvement in the conformity assessment under the IVDD ('self-declared' devices), and for which the deadline for lodging an application for conformity assessment is 26 May 2025 (for class D devices), 26 May 2026 (for class C devices) or 26 May 2027 (for class B and class A sterile devices), the manufacturer must put in place a quality management system (QMS) in accordance with Article 10(8) IVDR from 26 May 2025, if they want to benefit from the transitional period. If the manufacturer fails to put in place a QMS in accordance with the IVDR, the transition period will end on 26 May 2025. For further information on the condition to put in place an IVDR compliant QMS, see questions no. 9 to 9.2 of this document.

If, before the relevant deadline, the manufacturer applies for certification under the IVDR only for a part of the devices that are covered by an IVDD certificate or declaration of conformity drawn up prior to 26 May 2022, the condition set out in Article 110(3c), point (e), IVDR is not met for the devices not covered by the application. For those devices, the transition period will end with the lapse of the application deadline.

4. If a certificate has expired before 9 July 2024 and a competent authority has granted a derogation in accordance with Article 54 IVDR or has applied Article 92 IVDR, how long is the transitional period?

Certificates that have expired before the entry into force of the amending Regulation 2024/1860 (i.e. 9 July 2024) shall only be considered valid if

- either before the date of expiry of the certificate, the manufacturer and a notified body have signed a written agreement for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device,
- or a national competent authority has granted a derogation in accordance with Article 54(1) IVDR or has required the manufacturer, in accordance with Article 92(1) IVDR, to carry out the applicable conformity assessment procedure within a specified period of time (see the second subparagraph of Article 110(2) IVDR).

Even if the national derogation is limited in time or the manufacturer has been required to carry out the conformity assessment procedure within a given period of time[5], the device benefits from the full transitional period until 31 December 2027, provided the conditions set out in Article 110(3c) IVDR are fulfilled. The certificate is deemed to be valid until 31 December 2027, unless it is withdrawn.

5 Depending on national law, decisions of national authorities may need to be adapted.

4.1. Does a national derogation granted in accordance with Article 54 IVDR, or the application of Article 92 IVDR, after 9 July 2024 trigger the extension of the transitional period?

No. Where, after 9 July 2024, a competent authority has granted a derogation in accordance with Article 54 IVDR, or has required a manufacturer, in accordance with Article 92 IVDR, to carry out the applicable conformity assessment procedure, the condition set out in Article 110(2), second subparagraph, point (b), of the IVDR is not met. Therefore, an expired certificate will not be considered valid and the extended transitional period set out in Article 110(3a) IVDR does not apply.

4.2. Can a device for which a derogation was granted in accordance with Article 54 IVDR benefit from the transitional period even though it was required to not bear the CE marking?

Yes. As long as the removal of the CE marking was a condition for or a consequence of the derogation granted by the national competent authority in accordance with Article 54 IVDR, the device can be placed on the market with CE marking, provided that all other conditions are met.

PART B – EVIDENCE OF EXTENDED TRANSITIONAL PERIOD

5. How can the manufacturer demonstrate that its legacy device benefits from the extension of the transitional period?

The extension of the transitional period and, if applicable, the concomitant extension of the certificate's validity is done automatically by law, provided the conditions laid down in Article 110(3c) IVDR are fulfilled. In case of devices for which the relevant certificate has expired before 9 July 2024, also the conditions laid down in the second subparagraph of Article 110(2), points (a) or (b), IVDR need to be fulfilled (see below part C).

In line with MDCG guidance 2022-6[6], during the transitional period, notified bodies cannot issue new IVDD certificates. However, they can provide written confirmation correcting or complementing information on an existing certificate.

It is acknowledged that the manufacturer may need to demonstrate to third parties that the device can be lawfully placed on the EU market or put into service, for example to access the market in third countries or to submit tenders in procurement procedures. For that purpose, manufacturers should have access to different means of demonstrating that their device is covered by the extended transitional period and, if appicable, a valid certificate.

The manufacturer should be able to provide a self-declaration confirming that the conditions for the extension are fulfilled, stating the end date of the transition period. Such self-declaration could be based on a harmonised template[7]. Such self-declaration should clearly identify the devices covered by the extension and any certificates concerned.

Additional optional evidence could be provided by a 'confirmation letter' issued by the notified body stating the receipt of the manufacturer's application for conformity assessment and the conclusion of a written agreement. Such confirmation should clearly identify the devices covered by the extension and certificates concerned. Such confirmation letter could be based on a harmonised template[8] and be issued, in principle, without extra costs. Alternatively, the manufacturer could demonstrate that he has lodged an application for conformity assessment

6 MDCG 2022-6 Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR (May 2022). A revision of MDCG 2022-6 is planned to align it with the transitional provisions as amended by Regulation (EU) 2024/1860.

7 A template for a manufacturer's declaration will be developed by the EU level industry association MedTech Europe and made available on its website. The industry association and the European Commission do not take any responsibility for the use of the template by the manufacturer nor for the content or the terms of the declaration issued by the manufacturer.

8 A template for a notified body confirmation letter will be made available on the webpage for NBCG-Med documents after endorsement by NBCG-Med, which is the coordination group of notified bodies in the field of medical devices established in accordance with Article 49 of the MDR and Article 45 of the IVDR.

and/or concluded a written agreement with a notified body also by other means, such as a copy of the relevant documents.

Competent authorities should be able to issue certificates of free sale for the duration of the extended certificate validity.

The European Commission will update its factsheets for competent authorities in non-EU/EEA countries[9], for healthcare professionals and healthcare institutions and for the procurement ecosystem, explaining the functioning of the extended transition period.

PART C - CONDITIONS TO BE FULFILLED TO BENEFIT FROM THE EXTENDED IVDR TRANSITION PERIODS

6. What are the necessary elements of a formal application lodged by the manufacturer?

Pursuant to Article 110(3c), point (e), IVDR, the manufacturer or the authorised representative must lodge a formal application for conformity assessment in accordance with Section 4.3, first subparagraph, of Annex VII IVDR. The deadline for lodging the application depends on the device's risk class:

- no later than 26 May 2025 for devices covered by an IVDD certificate and for class D devices that were 'self-declared' under the IVDD,
- no later than 26 May 2026 for class C devices that were 'self-declared' under the IVDD and
- no later than 26 May 2027 for class B and class A sterile devices that were 'self-declared' under the IVDD.

Moreover, pursuant to Article 110(3c), point (f), IVDR, the manufacturer and notified body must sign a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII IVDR within four months after the deadline for applications to benefit from the extended transitional period, i.e.

- no later than 26 September 2025 for devices covered by an IVDD certificate and for class D devices that were 'self-declared' under the IVDD,
- no later than 26 September 2026 for class C devices that were 'self-declared' under the IVDD and
- no later than 26 September 2027 for class B and class A sterile devices that were 'self-declared' under the IVDD.

Article 110(3c), points (e) and (f), IVDR do not refer to a review of applications in accordance with Section 4.3, third subparagraph, of Annex VII IVDR. That means that a full review of the application by the notified body is not required before the signature of the written agreement.

The application should, in principle, include the elements listed in the relevant conformity assessment as referred to in Annexes IX to XI to the IVDR. However, it needs to be taken into account that a full review of the application prior to the conclusion of the written agreement is not required and that there may be a certain time span between the deadline for the application (May 2025, 2026 or 2027) and the actual conformity assessment activities to be performed by manufacturers and notified bodies. Therefore, the documentation that the notified body does not need for the conclusion of the written agreement with the manufacturer and that is likely to be updated by the manufacturer before the actual conformity assessment does not need to be submitted with the application.

That means that the application does not need to include, for example, the technical documentation for each device which is covered by the application and which is subject to technical documentation review. However, the application must clearly identify the manufacturer and the devices covered by the application, for example

9 See updated factsheet for competent authorities in non-EU/EEA countries

by including in this application the list of devices intended to be transferred to the IVDR[10] and, where applicable, the device(s) intended to substitute a 'legacy device'. The information submitted[11] with the application needs to allow the notified body to verify the qualification of the products as IVDs, their classification under the IVDR and the chosen conformity assessment procedure.

When lodging the application, the manufacturer should provide a timeline for possible submission of the individual technical documentation and any other relevant information. Notified body and manufacturer should agree on a plan for submission of the relevant technical documentation or other information needed for the conformity assessment activities in due time. The timing of the submission should provide sufficient time for completing the conformity assessment procedure by notified body and manufacturer before the end of the transitional period, taking into consideration the time needed by the manufacturer to finalise the technical documentation, the notified body's available capacity for the assessment of the relevant product and its indicative timelines for completion of conformity assessment activities. Agreed timelines should be respected by both parties; delays and 'waiting until the last minute' should be avoided to prevent further bottlenecks in the certification process towards the end of the respective transitional period.

As the manufacturer needs to comply with the quality management system (QMS) requirements of the IVDR by 26 May 2025 at the latest, the application for conformity assessment of the QMS should include the documentation on the manufacturer's QMS.

Where the manufacturer lodges an application for conformity assessment of a device that is intended to substitute a legacy device, the manufacturer does not only need to identify the substitute device but also the legacy device that is intended to be substituted. The technical documentation of the substitute device can be submitted at a later stage.

7. What are the necessary elements of a written agreement between the manufacturer and the notified body?

Pursuant to Article 110(3c), point (f), IVDR, a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII IVDR must have been signed between the notified body and the manufacturer:

- no later than 26 September 2025 for devices covered by an IVDD certificate and for class D devices that were 'self-declared' under the IVDD,
- no later than 26 September 2026 for class C devices that were 'self-declared' under the IVDD and
- no later than 26 September 2027 for class B and class A sterile devices that were 'self-declared' under the IVDD.

Requirements laid down in Section 4.3, second subparagraph, of Annex VII IVDR have not been amended.

The formal application lodged by the manufacturer or the authorised representative (see question no 6 of this document) should be the basis for signing the written agreement. The written agreement should include an indication of the possible schedule for submission of relevant documentation, such as full technical documentation for all devices covered by the formal application, not provided at the time the application is lodged.

With the purpose of promoting consistency among notified bodies, NBCG-Med, in agreement with the MDCG working group Notified Bodies Oversight (NBO), might provide additional clarification on standard elements to be included in the written agreement signed between the notified body and the manufacturer referred to in point (f) of Article 110(3c) IVDR.

10 E.g. using as basis the list of CE marked devices drawn up by the notified body that issued the certificate(s), see point 5 of the General comment in NBOG BPG 2010-3 – Certificates issued by Notified Bodies with reference to Council Directives 93/42/EEC, 98/79/EC, and 90/385/EEC.

11 Having regard to the obligations of notified bodies (e.g. Article 32(2) IVDR), submission of information requires the possibility for the notified body to add the relevant (digital) document(s) to its files. A 'read-only' access to the manufacturer's electronic data platform is not sufficient.

7.1. What happens if the application is withdrawn or the written agreement terminated?

If, after the relevant deadlines, the manufacturer withdraws its application for conformity assessment, or if the written agreement between notified body and manufacturer is terminated, the conditions set out in Article 110(3c), points (e) and (f), IVDR are not met any longer; therefore the transitional period ceases to apply. However, if the manufacturer or the notified body terminates the written agreement and the manufacturer simultaneously enters into a written agreement with another notified body, to which the application is transferred, the conditions set out in Article 110(3c), points (e) and (f), IVDR are considered to be still met and the transitional period continues to apply, provided that also the other conditions are met. The arrangements for the change of notified body should be defined in an agreement between the manufacturer, the incoming notified body and the outgoing notified body in analogy with the principles laid down in Article 53 IVDR. This kind of change of notified body may occur, for example, when the manufacturer intends to make use of available capacity of another notified body e.g. when the incoming notified body has been newly designated under the IVDR or when the outgoing notified body has capacity constraints. The manufacturer should make sure that the documentation demonstrating that its legacy device benefits from the extended transitional period is updated after the change of notified body (see question no. 5 of this document).

In contrast, the transitional period should not continue to apply where, after the relevant deadlines, the manufacturer changes notified body as a reaction to the notified body's reasoned decision to refuse the manufacturer's application or to refuse the issuance of a certificate due to non-compliance with relevant IVDR requirements.

7.2. What is the impact of changes related to the manufacturer during the transitional period?

Administrative changes concerning the manufacturer's organisation (e.g. changes of the manufacturer's name, address or legal form, including a merger or acquisition involving the manufacturer) should generally not be considered as changes in the design or intended purpose[12]. They are therefore possible without impact on the transitional period. Not covered are situations where the manufacturer indicated on the IVDD certificate or IVDD declaration of conformity transfers device(s) covered by those IVDD certificate(s)/declaration(s) of conformity to another manufacturer who intends to place those device(s) on the market under the IVDR, unless the manufacturer indicated on the IVDD certificate or declaration of conformity and the manufacturer seeking IVDR certification are part of the same larger organisation.

8. What is the meaning of “device intended to substitute that device”?

The term *“device intended to substitute that device”* is used in the second subparagraph of Article 110(2), point (a), in Article 110(3c), point (e), and in the second subparagraph of Article 110(3e) IVDR. A device intended to substitute the legacy device will usually (but not necessarily) differ from the legacy device because the manufacturer has made (significant) changes with regard to its design or intended purpose with a view to replacing the legacy device. It is the responsibility of the manufacturer to determine the device that is intended to substitute a legacy device and to explain the link to the substituted legacy device.

It should be noted that the substitute device will need to undergo the full IVDR conformity assessment before it can be placed on the market. The transitional period provided for in Article 110(3a) and (3b) IVDR only applies to the ‘legacy device’ that is being replaced by the substitute device. Similar to what is stated in question no. 2, after IVDR certification of the substitute device, the ‘legacy device’ and the substitute device can be placed on the market in parallel until the end of the relevant transitional period.

12 MDCG 2022-6 Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR (May 2022), section 4.2.

9. Which evidence does the manufacturer have to provide for having put in place a QMS in accordance with the IVDR?

Pursuant to Article 110(3c), point (d), IVDR, the manufacturer must put in place a QMS in accordance with Article 10(8) IVDR no later than 26 May 2025. The condition to put in place a QMS in accordance with the IVDR aims to ensure that manufacturers gradually move towards full compliance with the IVDR requirements. Manufacturers must draw up the documentation on its QMS by this date (regardless of the device risk class under the IVDR). The documentation on the QMS needs to be part of the application for conformity assessment for any devices which the manufacturer intends to transfer to the IVDR, and must be submitted by the relevant deadlines for applications to a notified body no later than 26 May 2025 for class D devices and for devices covered by an IVDD certificate, 26 May 2026 for class C devices and 26 May 2027 for class B and class A sterile devices. Compliance with QMS-related requirements concerning post-market surveillance, market surveillance, vigilance and registration is part of the appropriate surveillance pursuant to Article 110(3e) IVDR, where such surveillance is required. The assessment of the compliance of the entire QMS with the IVDR will be done by the notified body as part of the IVDR certification.

9.1. Do all QMS aspects listed in Article 10(8) IVDR have to be addressed?

In principle, yes. However, for some specific QMS aspects listed in Article 10(8) IVDR, 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) IVDR 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 as set out in Section 3 of Annex I IVDR, nor conducted a performance evaluation in line with Article 56 and Annex XIII IVDR. However, from 26 May 2025, the manufacturer's QMS should address how compliance with those requirements will be achieved.

9.2. Do legacy devices have to comply with UDI requirements during the extended transitional period?

No. Pursuant to MDCG 2019-5[13], 'legacy devices' are not subject to the IVDR UDI requirements. This approach is not changed through the condition that, from 26 May 2025, the manufacturer of the legacy device must put in place an IVDR compliant QMS. Article 10(8), point (h), IVDR, which states that verification of UDI assignments to all relevant devices is part of the QMS, only applies where UDI assignment is actually required for the relevant devices.

10. Do manufacturers, which have lodged an application for conformity assessment and have concluded a written agreement with a notified body before 9 July 2024, have to lodge a new application and/or conclude a new written agreement?

No. Provided the application has not been rejected, applications lodged prior to the entry into force of the amending Regulation 2024/1860 (i.e. 9 July 2024) remain valid and are sufficient for fulfilling the condition set out in Article 110(3c), point (e), IVDR. No new written agreement needs to be signed either.

11. What is meant by 'unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health' in Article 110(3c), point (c), IVDR?

The concept of "*unacceptable risk to health and safety*" is set out in Article 89 and 90 of the IVDR. Where, as part of their market surveillance activities, a competent authority finds that a device presents an unacceptable

13 MDCG 2019-5 Registration of legacy devices in EUDAMED (April 2019).

risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, the transition period ceases to apply for that device.

PART D – APPROPRIATE SURVEILLANCE TO BE PERFORMED BY NOTIFIED BODIES

12. Which devices are subject to appropriate surveillance by a notified body?

Appropriate surveillance in accordance with Article 110(3e) IVDR only applies to legacy devices that are covered by a certificate issued by a notified body in accordance with the IVDD. This also applies to devices covered by an IVDD certificate that had expired and that is considered valid because the conditions set out in the second subparagraph of Article 110(2) IVDR are met. In those cases, the appropriate surveillance has to be resumed.

Legacy devices for which the conformity assessment procedure pursuant to the IVDD did not require the involvement of a notified body ('self-declared' devices under the IVDD), but that require the involvement of a notified body under the IVDR, are not subject to surveillance by a notified body pursuant to Article 110(3e) IVDR.

Also regarding devices for self-testing covered by EC design-examination certificates issued pursuant to Annex III, section 6, IVDD the notified body does not need to perform surveillance pursuant to Article 110(3e) IVDR. However, changes to the approved design must be approved by the notified body that issued the IVDD certificate in accordance with arrangements agreed with the manufacturer for notification of changes. At the latest from 26 September 2025, the IVDR notified body, to which the application for conformity assessment under the IVDR has been lodged, should become responsible for change notifications pursuant to those agreed arrangements. Significant changes in the design or intended purpose of the legacy device may not be implemented during the transitional period (see Article 110(3c), point (b), IVDR)[14].

13. What are the necessary elements of the arrangement for the transfer of the surveillance from the notified body that issued the IVDD certificate to the IVDR notified body?

According to the third subparagraph of Article 110(3e) IVDR, an agreement between the manufacturer and the IVDR notified body, to which a formal application has been lodged, and, where practicable, the notified body that issued the IVDD certificates, must set arrangements for the transfer of the appropriate surveillance in respect to devices covered by the written agreement referred to in Article 110(3c), point (f) IVDR.

The written agreement referred to in Article 110(3c), point (f), IVDR and the agreement for the transfer of the surveillance address different subjects. However, they can be combined in one document depending on what is more convenient for the interested parties, e.g. when the notified body that issued the IVDD certificate is not involved.

The arrangement for the transfer of the surveillance should follow the principles outlined in Article 53(1) IVDR and should include the transfer of relevant documentation from the outgoing notified body to the incoming notified body. The agreement between the manufacturer, the outgoing notified body and the incoming notified body (‘tripartite agreement’) should also address the possibility of the IVDR notified body to suspend or withdraw a certificate issued by the IVDD notified body, where duly justified. Transfer of surveillance activities takes place also in case the IVDR notified body was not previously designated under the IVDD.

As established by the third subparagraph of Article 110(3e) IVDR, the incoming notified body does not take responsibility for conformity assessment activities performed by the notified body that issued the certificate. Involvement of the IVDR notified body in respect to devices that were certified under the IVDD and for which it

14 MDCG 2022-6 Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR (May 2022), section 4.2.

has signed a written agreement with the manufacturer for IVDR certification is limited to carrying out the appropriate surveillance referred to in Article 110(3e) IVDR and further clarified in MDCG 2022-15[15].

With the purpose of promoting consistency among notified bodies, NBCG-Med, in agreement with NBO, might provide additional clarification on a standard template for the tripartite agreement between the manufacturer, the IVDR notified body and the notified body that issued the IVDD certificates.

14. What does the limitation 'where practicable' imply?

In the third subparagraph of Article 110(3e) IVDR, the limitation that requires the notified body that issued the relevant certificate under the IVDD to sign the arrangement for the transfer of the appropriate surveillance „where practicable" takes into account that there might be cases when this notified body could be unable to sign the contract, e.g. termination of business.

In any case, it is required to have in place a written agreement between the manufacturer and the IVDR notified body to specify the arrangements concerning the appropriate surveillance to be performed by the latter even if the notified body that issued the IVDD certificates cannot be involved.

15. Which notified body is responsible for carrying out the appropriate surveillance when a written agreement in accordance with Article 110(3c), point (f), IVDR is signed between the manufacturer and a notified body designated under the IVDR?

Pursuant to Article 110(3e) IVDR, until 25 September 2025 the notified body that issued the relevant certificate under the IVDD continues to be responsible for the appropriate surveillance in respect to the applicable requirements relating to devices it has certified.

Alternatively, before 26 September 2025, the manufacturer can agree with a notified body designated under the IVDR that the latter becomes responsible for the surveillance.

At the latest by 26 September 2025, i.e. the deadline by when the written agreement referred to in Article 110(3c), point (f), IVDR needs to be signed in respect of devices covered by an IVDD certificate, the notified body that signed that agreement will become responsible for the appropriate surveillance. After that date, the notified body that issued the certificate under the IVDD can no longer perform appropriate surveillance. However, either in line with the tripartite agreement (see question no. 13) or in the absence of such agreement, it should cooperate with the IVDR notified body to enable a smooth transfer of the surveillance activities, including the transfer of relevant documentation to the incoming notified body.

16. In case there is an arrangement for the transfer of the surveillance to a different notified body designated under IVDR, what are the implication on the labelling concerning the notified body's identification number?

Even when the appropriate surveillance is transferred to a different notified body designated under the IVDR, legacy devices can continue to be placed on the market and made available without changes to the labelling, including CE marking, and thus indicate the number of the notified body that issued the certificate under the IVDD that is kept valid.

However, if practically feasible and depending on details included in the tripartite agreement (see question no. 13 of this document) the manufacturer may decide to modify the labelling of legacy devices indicating the number of the notified body to which a formal application under the IVDR has been lodged.

15 MDCG 2022-15 Guidance on appropriate surveillance regarding the transitional provisions under Article 110 of the IVDR with regard to devices covered by certificates according to the IVDD (September 2022). It is planned to revise MDCG 2022-15 to adapt it to Regulation (EU) 2024/1860.

17. Is the notified body which issued the certificate referred to in Article 110(3a) of Regulation (EU) 2017/746 legally obliged to continue to carry out the surveillance of the products concerned until the end of the new transitional period or until the manufacturer has transferred this surveillance obligation to a notified body whose designation has been made in accordance with Article 38? May this notified body deny the manufacturer the use of its NB number?

Article 110(3e) IVDR provides for the continuation of the surveillance (obligation) by the previous notified body until 25 September 2025 at the latest. Unless otherwise specified in the tripartite agreement (see question no. 16), the use of the number of the notified body that issued the certificate must not be denied until the end of the transition period.

To enable the notified body to carry out the surveillance and make the necessary arrangements with the manufacturer, the latter needs to inform the notified body about the device(s) subject to appropriate surveillance, in particular where surveillance activities have not been continued, e.g. due to the expiry of the certificate before 9 July 2024.

PART E – IN-HOUSE DEVICES: JUSTIFICATION REGARDING NON-AVAILABILITY OF AN EQUIVALENT CE MARKED DEVICE

18. From when will a health institution which manufactures and uses in-house IVDs have to justify that the target patient group's specific needs cannot be met, or cannot be met at the appropriate level of performance, by an equivalent device available on the market?

The condition set out in Article 5(5), point (d), of the IVDR will apply from 31 December 2030. As the health institution needs a complete overview of CE-marked IVDs available on the market, the condition obliging the health institution to justify that the target patient group’s specific needs cannot be met, or cannot be met at the appropriate level of performance, by an equivalent device available on the market will only become applicable one year after the last transitional period laid down in the IVDR has ended.[16]

16 Further guidance on in-house devices is provided in MDCG 2023-1 Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 (January 2023).

Appendix: Flowchart

Conditions and deadlines for placing 'legacy devices' on the market or putting them into service in accordance with Article 110 IVDR, as amended by Regulation 2024/1860

Introduction

The flowchart is intended to assist manufacturers and other relevant actors in deciding whether or not a device is covered by the extended transitional period provided for in Article 110 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), as amended by Regulation 2024/1860. The flowchart should help to deter mine the eligibility, conditions and deadlines for the placing on the market or putting into service of certain devices in accordance with Article 110 IVDR. The user of the flowchart is advised to consult the text of the IVDR, which takes precedence over the flowchart, and the questions & answers on practical aspects related to the implementation of Regulation (EU) 2024/1860.

Scope of the flowchart includes:

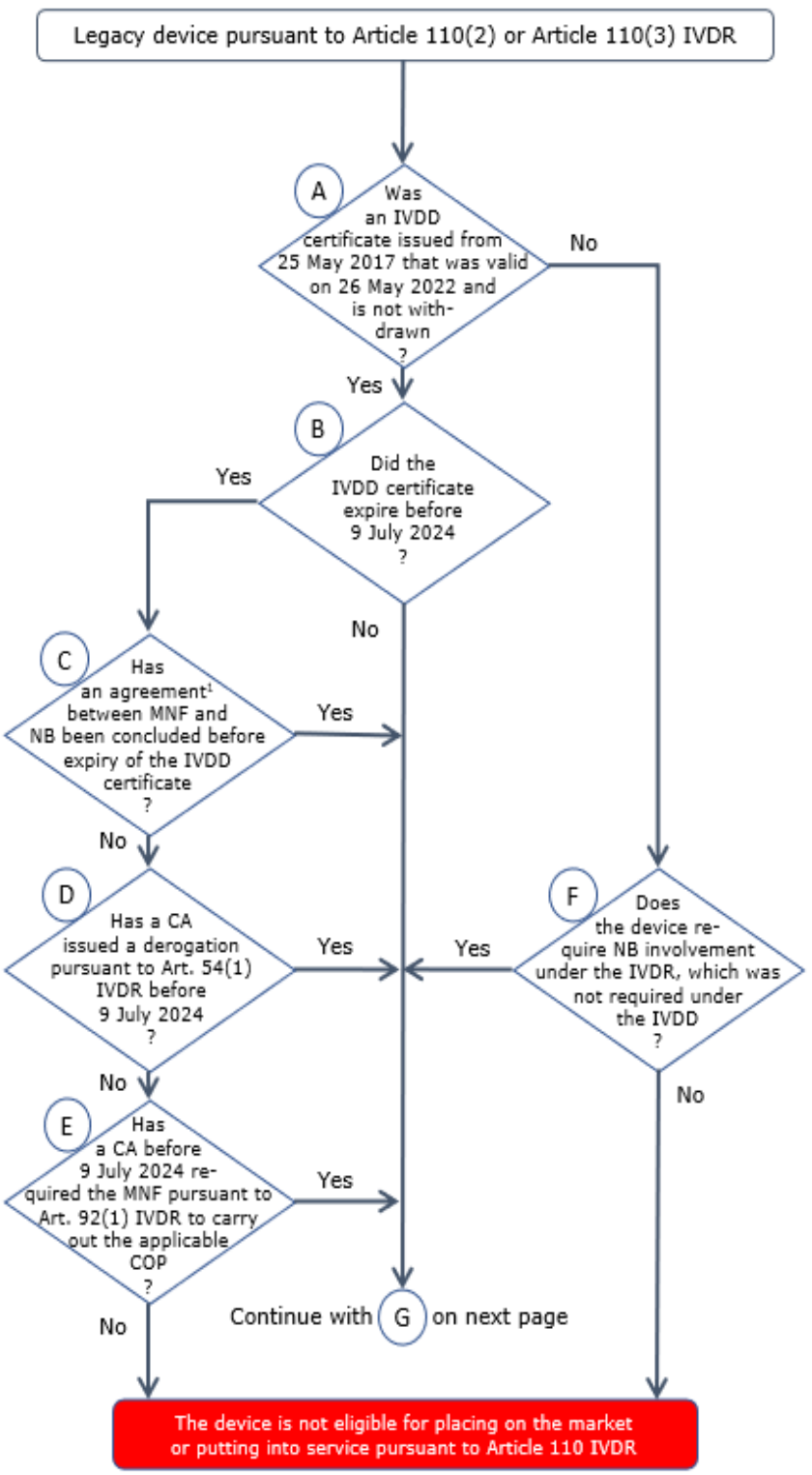
- 'Legacy devices' referred to in Article 110(3a) IVDR, i.e. devices covered by a certificate issued by a notified body in accordance with Directive 98/79/EC prior to 26 May 2022. Those 'legacy devices' may be placed on the market until 31 December 2027 if the conditions set out in Article 110(3c) IVDR are met; and

- 'Legacy devices' referred to in Article 110(3b) IVDR, i.e. devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to the IVDR requires the involvement of a notified body. Those 'legacy devices' may be placed on the market, if the conditions set out in Article 110(3c) IVDR are met, until the following dates:
  - 31 December 2027, for class D devices;
  - 31 December 2028, for class C devices;
  - 31 December 2029, for class B devices and for class A sterile devices.

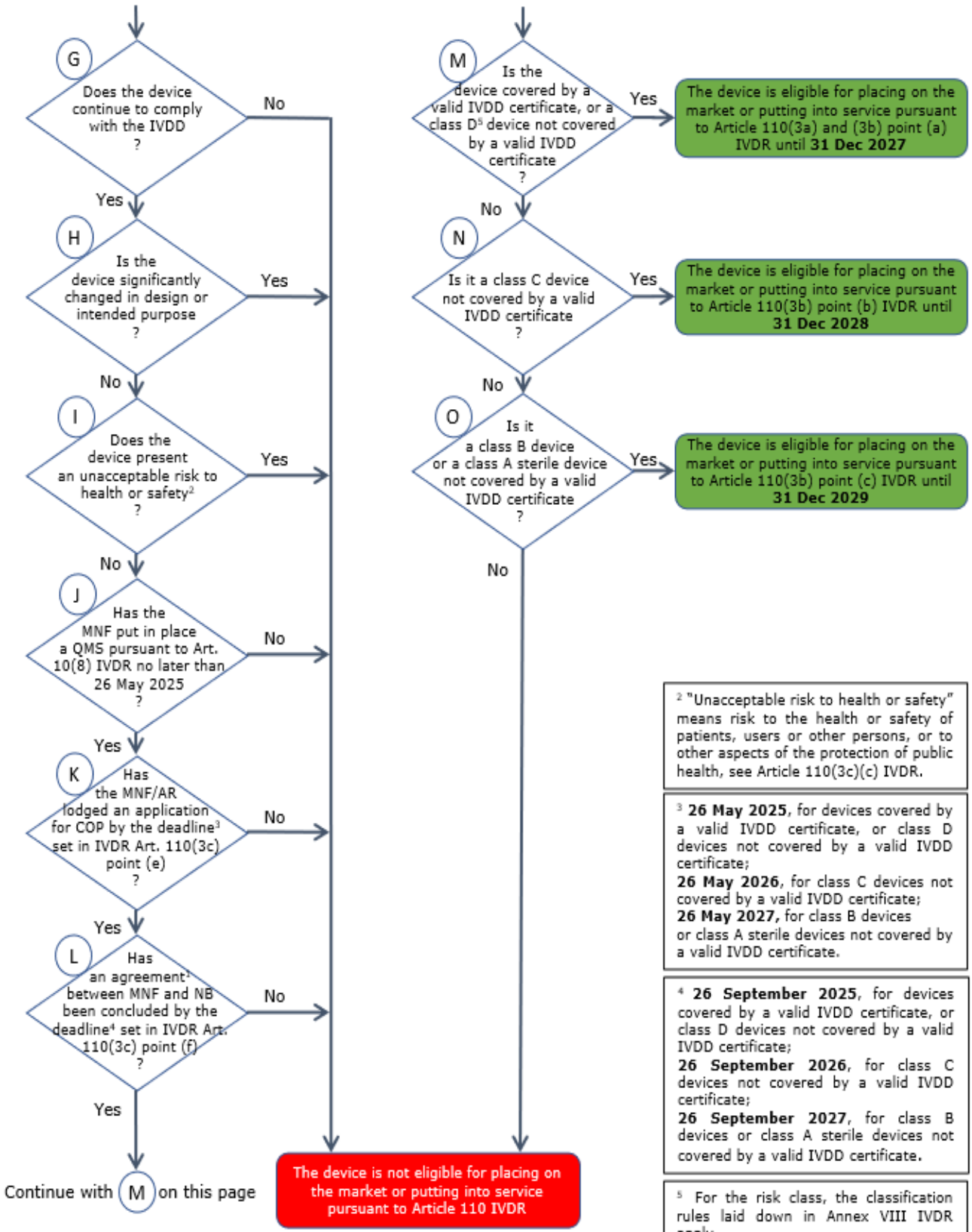
Used Abbreviations:

IVDD:	Council Directive 98/79/EEC concerning in vitro diagnostic medical devices
IVDR:	Regulation (EU) 2017/746 on in vitro diagnostic medical devices
AR:	Authorised representative, see Article 2(25) IVDR
CA:	Competent authority of an EU Member State
MNF:	Manufacturer, see Article 2(23) IVDR
NB:	Notified body, see Article 2(34) IVDR
QMS:	Quality management system in accordance with Article 10(8) IVDR
COP:	Conformity assessment procedure in accordance with Article 48 IVDR

Disclaimer: This document has not been formally endorsed by the European Commission and is without prejudice to any interpretation of the relevant provisions by the Court of Justice of the European Union or national courts. The information in the flowchart is of a general nature and not intended to address specific circumstances of any particular case; the document does not intend to provide professional or legal advice. The information is not necessarily comprehensive nor complete.



[1] "Agreement" refers to a written agreement for conformity assessment in accordance with Annex VII, Section 4.3, 2nd subparagraph, IVDR in respect of the legacy device or a substitute device.



[2] "Unacceptable risk to health or safety" means risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, see Article 110(3c)(c) IVDR.

[3] **26 May 2025**, for devices covered by a valid IVDD certificate, or class D devices not covered by a valid IVDD certificate;
26 May 2026, for class C devices not covered by a valid IVDD certificate;
26 May 2027, for class B devices or class A sterile devices not covered by a valid IVDD certificate.

[4] **26 September 2025**, for devices covered by a valid IVDD certificate, or class D devices not covered by a valid IVDD certificate;
26 September 2026, for class C devices not covered by a valid IVDD certificate;
26 September 2027, for class B devices or class A sterile devices not covered by a valid IVDD certificate.

[5] For the risk class, the classification rules laid down in Annex VIII IVDR apply.