European Commission

EXTENSION OF THE MDR TRANSITIONAL PERIOD AND REMOVAL OF THE 'SELL OFF' PERIODS

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

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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[1].

Disclaimer: This Q&A document is intended to facilitate the application of Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR) as regards the transitional provisions for certain medical devices and 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) 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 (OJ L 80, 20.3.2023, p. 24). Regulation (EU) 2023/607 has entered into force on 20 March 2023.

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Introduction – Objectives of the MDR/IVDR amendment

The amendment of the MDR and of the IVDR through Regulation (EU) 2023/607 aims to ensure a high level of public health protection, including patient safety and an avoidance of shortages of medical devices needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements. For that purpose, manufacturers and notified bodies are given sufficiently more time to carry out, in accordance with the MDR, the conformity assessment of devices covered by a certificate or a declaration of conformity issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC. Moreover, the deletion of the 'sell off' date in the MDR and the IVDR aims to prevent unnecessary disposal of safe devices.

The answers to the questions set out below 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 MDR transitional period.

PART A – SCOPE OF THE EXTENSION OF THE MDR TRANSITIONAL PERIOD

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

Only 'legacy devices' can benefit from the extended transitional period. In line with MDCG 2021-252[2] 'legacy devices' should be understood as devices, which, in accordance with the MDR's transitional provisions, are placed on the market after the MDR's date of application (i.e. 26 May 2021) 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.

The extension of the transitional period beyond 26 May 2024 only applies if the conditions laid down in Article 120(3c) MDR are fulfilled. In case of devices for which the relevant certificate has expired before 20 March 2023, also the conditions laid in the second subparagraph of Article 120(2), points (a) or (b), MDR need to be fulfilled (see below part C).

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

Yes, provided the MDD/AIMDD certificates have not been withdrawn by the notified body. 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 MDR certification of the device as such is not a reason for the notified body to withdraw a MDD/AIMDD certificate.

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

2 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 (October 2021). It is planned to revise MDCG 2021-25 to adapt it to Regulation (EU) 2023/607.

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

Manufacturers are not obliged to apply for their 'legacy devices' under the MDR. Nonetheless, if their device is covered by a certificate that expires after 20 March 2023 and before 26 May 2024, they benefit from the extension of the transitional period until 26 May 2024, provided the conditions set out in Article 120(3c), points (a) to (c), are fulfilled. If the manufacturer does not lodge an application for conformity assessment by 26 May 2024, the transition period will end on 26 May 2024.

4. Which classification rules apply to determine whether the extended transitional period ends on 31 December 2027 or on 31 December 2028?

For the purpose of Article 120(3a) MDR, which provides for the new transitional periods depending on the device's risk class, the classification rules laid down in Annex VIII to the MDR apply. In certain cases, where the classification rules of the MDR result in a different risk class, the device's risk class indicated on the certificate may differ from the risk class that determines the end date of the transitional period.

However, where during the transitional period the risk class of a device is needed to determine applicable MDR requirements (e.g. in relation to PSUR), the class of the device is the one established in accordance with the MDD classification rules (see MDCG 2021-25).

5. Does the extended transitional period also apply to custom-made devices?

The new Article 120(3f) MDR has introduced a specific transitional period for class III custom-made implantable devices. While all other custom-made devices can be placed on the market after their manufacturer has drawn up a statement in accordance with Annex XIII to the MDR, the conformity assessment of class III custom-made implantable devices requires the involvement of a notified body.

Pursuant to the new transitional provision, class III custom-made implantable devices can be placed on the market without the relevant certificate until 26 May 2026, provided the manufacturer has lodged an application with a notified body for conformity assessment no later than 26 May 2024 and signed a written agreement with that notified body no later than 26 September 2024.

6. If a certificate has expired before 20 March 2023 and a competent authority has granted a derogation in accordance with Article 59 MDR or has applied Article 97 MDR, how long is the transitional period?

Certificates that have expired before the entry into force of the amending Regulation 2023/607 (i.e. 20 March 2023) 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 59(1) MDR or has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure within a specified period of time (see the second subparagraph of Article 120(2) MDR).

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[3], the device benefits from

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

the full transitional period until 31 December 2027 or 31 December 2028, as applicable, provided the conditions set out in Article 120(3c) MDR are fulfilled. The certificate is deemed to be valid until the end of the applicable transitional period, unless it is withdrawn.

PART B – EVIDENCE OF EXTENDED TRANSITIONAL PERIOD

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

The extension of the transitional period and the concomitant extension of the certificate's validity is done automatically by law, provided the conditions laid down in Article 120(3c) MDR are fulfilled. In case of devices for which the relevant certificate has expired before 20 March 2023, also the conditions laid in the second subparagraph of Article 120(2), points (a) or (b), MDR need to be fulfilled (see below part C).

In line with MDCG guidance 2020-34[4], during the transitional period, notified bodies cannot issue new MDD/AIMDD 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 validity of the certificate to third parties, 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 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. Such self-declaration should clearly identify the devices covered by the extension and certificates concerned. Additional 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 and be issued, in principle, without extra costs.

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, 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 MDR TRANSITION PERIOD

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

Pursuant to Article 120(3c), point (e), MDR 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 MDR no later than 26 May 2024. Manufacturer and notified body must sign a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII MDR no later than 26 September 2024 to benefit from the extended transitional period.

4 MDCG 2020-3 Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD (March 2020). A revision of MDCG 2020-3 is planned to be endorsed and published soon.

Article 120(3c), point (e), MDR does not refer to a review of applications in accordance with Section 4.3, third subparagraph, of Annex VII MDR. 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 MDR. 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 the time span between the deadline for the application (May 2024) and the actual conformity assessment activities to be performed by manufacturers and notified bodies can be very long (until 2028 at the latest). 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 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 by including the list of devices intended to be transferred to the MDR[5] and, where applicable, the device(s) intended to substitute a 'legacy device'. The information submitted with the application needs to allow the notified body to verify the qualification of the products as devices, their respective classification 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.

As the manufacturer needs to comply with the quality management system (QMS) requirements of the MDR by 26 May 2024 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.

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

Pursuant to Article 120(3c), point (e), MDR, a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII MDR must have been signed between the notified body and the manufacturer no later than 26 September 2024. Requirements laid down in Section 4.3, second subparagraph, of Annex VII MDR have not been amended.

The formal application lodged by the manufacturer or the authorised representative (see question no 8 of this document) should be the basis for signing the written agreement. The written agreement should include indication about 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.

5 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.

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 (e) of Article 120(3c) MDR.

10. 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 120(2), point (a), in Article 120(3c), point (e), and in the second subparagraph of Article 120(3e) MDR. 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 MDR conformity assessment before it can be placed on the market. The transitional period provided for in Article 120(3a) and (3b) MDR only applies to the 'legacy device' that is being replaced by the substitute device. Similar to what is stated in question no. 2, after MDR 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.

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

Pursuant to Article 120(3c), point (d), MDR the manufacturer must put in place a QMS in accordance with Article 10(9) MDR no later than 26 May 2024. Manufacturers must draw up the documentation on its QMS, which needs to be part of the application for conformity assessment. Compliance with QMS-related requirements concerning post-market surveillance, market surveillance, vigilance and registration are part of the appropriate surveillance pursuant to Article 120(3e) MDR, while the assessment of the compliance with the MDR of the entire QMS will be done by the notified body as part of its conformity assessment activities.

12. Do manufacturers, which have lodged an application for conformity assessment and have concluded a written agreement with a notified body before 20 March 2023, 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 2023/607 (i.e. 20 March 2023) remain valid and are sufficient for fulfilling the condition set out in Article 120(3c), point (e) MDR. No new written agreement needs to be signed either.

PART D – APPROPRIATE SURVEILLANCE TO BE PERFORMED BY NOTIFIED BODIES

13. What are the necessary elements of the arrangement for the transfer of the surveillance from the notified body that issued the MDD/AIMDD certificate to the MDR notified body?

According to the third subparagraph of Article 120(3e) MDR, an agreement between the manufacturer and the MDR notified body, to which a formal application has been lodged, and, where practicable, the notified body that issued the MDD/AIMDD certificates, must set arrangements for the transfer of the appropriate surveillance in respect to devices covered by the written agreement referred to in Article 120(3c), point (e) MDR.

The written agreement referred to in Article 120(3c), point (e), MDR 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 MDD/AIMDD certificate is not involved.

The arrangement for the transfer of the surveillance should follow the same principles outlined in Article 58(1) MDR 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 MDR notified body to suspend or withdraw a certificate issued by the MDD/AIMDD notified body, where duly justified. Transfer of surveillance activities takes place also in case the MDR notified body was not previously designated under the MDD/AIMDD.

As established by the third subparagraph of Article 120(3e) MDR, the incoming notified body does not take responsibility for conformity assessment activities performed by the notified body that issued the certificate. Involvement of the MDR notified body in respect to devices that were certified under the Directives and for which it has signed a written agreement with the manufacturer for MDR certification is limited to carry out the appropriate surveillance referred to in Article 120(3e) MDR and further clarified in MDCG 2022-46[6].

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 MDR notified body and the notified body that issued the Directive certificates.

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

In the third subparagraph of Article 120(3e) MDR, the limitation that requires the notified body that issued the relevant certificate under the MDD/AIMDD 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 MDR notified body to specify the arrangements concerning the appropriate surveillance to be performed by the latter even if the notified body that issued the MDD/AIMDD certificates cannot be involved.

15. Which notified body is responsible for carrying out the appropriate surveillance when a written agreement in accordance with Article 120(3c), point e, MDR is signed between the manufacturer and a notified body designated under the MDR?

6 MDCG 2022-4 Guidance on appropriate surveillance regarding the transitional provisions under Article 120 of the MDR with regard to devices covered by certificates according to the MDD or the AIMDD. It is planned to revise MDCG 2022-4 to adapt it to Regulation (EU) 2023/607.

Pursuant to Article 120(3e) MDR, the notified body that issued the relevant certificate under the MDD/AIMDD continues to be responsible for the appropriate surveillance in respect to the applicable requirements relating to devices it has certified.

Alternatively, before 26 September 2024, the manufacturer can agree with a notified body designated under the MDR that the latter becomes responsible for the surveillance.

At the latest by 26 September 2024, i.e. deadline by when the written agreement referred to in Article 120(3c), point (e), MDR needs to be signed, the notified body that signed that agreement will become responsible for the appropriate surveillance.

16. In case there is an arrangement for the transfer of the surveillance to a different notified body designated under MDR, 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 MDR, 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 Directive and 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 MDR has been lodged.

17. Is the notified body, which issued the certificate in accordance with Article 120(3b) of Regulation (EU) 2017/745, 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 42? May this notified body deny the manufacturer the use of its NB number?

Article 120(3e) MDR provides for the continuation of the surveillance (obligation) by the previous notified body until 26 September 2024 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.

PART E – DELETION OF THE 'SELL-OFF' DATE

18. Which devices will benefit from the removal of the 'sell-off' date?

In Article 120(4) MDR and in Article 110(4) IVDR, the deadline for the further making available on the market of devices placed on the market in accordance with the previously applicable Directives has been deleted. That means that medical devices that have been placed on the market prior to 26 May 2021 in accordance with the MDD/AIMDD or after 26 May 2021 during the transitional period provided for in Article 120 MDR (i.e. until 31 December 2027 or 31 December 2028, as applicable) may continue to be made available on the market or put into service without any limitation in time without prejudice to the device's possible shelf-life or expiry date.

The same applies to in vitro diagnostic medical devices that have been placed on the market prior to 26 May 2022 in accordance with the IVDD or after 26 May 2022 during the transitional period provided for in Article 110 IVDR (i.e. until 26 May 2025, 26 May 2026 or 26 May 2027, as applicable). Those IVD may continue to be made available on the market or put into service without any limitation in time without prejudice to the device's possible shelf-life or expiry date.