ADVENA.

AMENDING REGULATIONS (EU) 2017/745 AND (EU) 2017/746 REGARDING THE TRANSITIONAL PROVISIONS

A GUIDANCE DOCUMENT

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Table of Contents

1.0 Scope

This document is intended to provide guidance on the new proposal regarding the transitional provisions for certain medical devices and in vitro diagnostic devices.

This guidance also provides a timeline with all the important cut-off dates, FAQ's and flowcharts in the Annex's that one can follow to better understand and visualise the process more effectively.

- **Annex I** Timeline of Important Dates
- **Annex II** FAQ's
- **Annex III** - Flowchart for the Extension of CE certificates
- **Annex IV** - Flowchart for the Up-Classification of Devices
- **Annex V** – Flowchart for Device Class III Custom Made Implantable
- **Annex VI** – Important Links Concerning (EU) 2023/607

2.0 Introduction

On the 6th of January 2023, the EU Commission adopted a proposal amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices. This proposal was introduced to address the projected shortage of medical devices on the market in the coming years and to address the limited capacity of the notified bodies.

The proposal was voted upon in the EU Parliament on the 16th of February and the results showed that an overwhelming majority was in favour of this proposal, mirroring the sentiment of many medical device manufacturers. On the 20th of March 2023, the amendment was published in the Official Journal of the European Union and hence entered in to force on that same day. Prior to this amendment, the transition period for MDR was capped on the 27th May 2024. The provisions extend the certificates by another 3 to 4 years depending on the classification of the device which can help curb the projected shortage of medical devices in the European market. The extension in timelines provides the medical device industry time to make the transfer from the MDD/AIMDD to the MDR and would, at least on paper, provide manufacturers some relaxation. That being said, certain criteria need to be satisfied to make them eligible for these extended timelines, most notably the manufacturer needs to show that it has taken **active steps towards MDR transition.**

3.0Which devices would be benefitting in this amendment?

3.1 Devices with CE certificate

This new amendment will apply to your device if your medical device was certified by a notified body under the Medical Device Directive 93/42/EC (**MDD**) or the Directive on Active Implantable Medical Devices 90/385/EEC (**AIMD**) and valid at the date of application of the MDR (26 May 2021), and **not later withdrawn by the notified body.** Depending on whether the CE certificate in question expires prior or after 20th March 2023 (the date of entry of this new amendment), one of the following will apply;

3.1.1. CE Certificate Expires After 20th March 2023

If your certificate expires after 20th March 2023 (the date of entry of the new amendment), then the device can continue to be placed on the market till 2027 or 2028 depending on the class (refer to section 4 for the timeline) and if certain criteria are met (refer to Section 5 for criteria).

3.1.2 CE Certificate Expired Prior to 20th March 2023

Conversely, if your CE certificate expired prior to 20th March 2023 (the date of this new amendment), you can still place the devices on the market if one of the following conditions is met:

- Prior to the expiration of the CE certificate, a written agreement has been signed between the manufacturer and a notified body for the conformity assessment of the device.

OR

- The manufacturer has applied for an Article 59(1) or Article 97(1) derogation in respect of the device and the Competent Authority has granted the derogation.

If you have one of the above agreements in place, then the device can continue to be placed on the market till 2027 or 2028 depending on the class (refer to section 4 for the timeline) and if certain criteria are met (refer to Section 5 for criteria).

Additional Note: It is important to note here that according to a recently published addendum guidance document MDCG 2022-18 ADD.1, the MDCG recommends that that national CAs limit the application of Article 97 to very exceptional situations, e.g., where the national competent authority (CA) has received information justifying the application of Article 97 MDR prior to 20 March 2023.

3.2 Other Devices

3.2.1 Class I Devices under MDD that have been up classified under the MDR.

The extended provisions also apply if your medical device was a Class I device under the MDD, which did not require the involvement of a notified body, and is up classifying under the MDR, and requires the involvement of a notified body for CE certification and has a Declaration of Conformity that has been drawn up prior to 21 May 2021. These devices can continue to be placed on the market till 2028 if certain criteria are met (refer to section 5 for criteria).

3.2.2 Class III Custom Made Implantable Device

The new amendment also applies if your Device is a Class III Custom Made Implantable Device. These devices can continue to be placed on the market till 2026 if certain criteria are met (refer to section 5 for criteria).

4.0 Length of Extension

The length of the extension granted is dependent on the classification of the device. Devices benefiting from the extension of their certificates may be placed on the market or put into service until;

- **31 December 2027** for High-Risk device incorporating **Class III and Class IIb implantable devices** except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors.

- **31 December 2028** for Low-Medium Risk Devices incorporating **Class IIb devices not mentioned above, Class IIa, Class Is, Class Im and Class Ir.**

- **31 December 2028** for devices that are **up-classifying under the MDR** (did not require the involvement of a notified body for conformity assessment under the MDD and that now require the involvement of a notified body under the MDR.

- **26 May 2026** for **Class III Custom Made Active Implantable Devices.**

5.0 Criteria for Qualification of this Extended Transition Period

In order to be eligible for these transitional provisions, you as the manufacturer need to show that **active steps have been taken towards MDR certification**.

5.1 Criteria A

This criterion is concerning all devices excluding Class III Custom Made Active Implantable.

- The manufacturer has a quality management system in accordance with Article 10(9) in place by no later than **26 May 2024.** The formal proposal states that no specific attestation, i.e. no self-declaration nor verification of the appropriateness of the QMS by a notified body, is required at this stage. However, by submitting an application for conformity assessment to a notified body the manufacturer **implicitly confirms that its QMS is in compliance with the MDR.**

- The manufacturer has lodged a formal application for conformity assessment in respect of a device by no later than **26th of May 2024**, and have signed a written agreement by no later than **26 September 2024**

- There are no significant changes in the design and intended purpose.

- The devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.

- The devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable.

- The MDR requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply to the above "extended" devices in place of the corresponding requirements of the MDD and AIMDD.

- A notified body is responsible for the surveillance of the device/devices.

According to the Q&A document that has been released by the EU Commission, the manufacturer can demonstrate that they meet the aforementioned criteria by means of a self-declaration. A harmonised template to the manufacturers self-declaration is available for download using the following Link. Additionally, the notified body of the manufacturer can issue a confirmation letter where they confirm the criteria that pertains specifically to them, including an application has been lodged and signed with them and that they are responsible for the surveillance of the 'extended devices'. We urge all manufacturers to obtain this confirmation letter from the notified body as it will add weight to the manufacturer declaration. A template to the notified bodies confirmation letter can be downloaded using the following Link.

Additional Note: When the manufacturer chooses a different notified body from the notified body that issued the MDD/AIMDD CE Certificate, then there is a question that arises on who would be responsible for the surveillance of these devices. The main consensus would be that the notified body that issued the CE Certificate would be responsible for surveillance of the devices, however, in some cases they might agree that 'new notified body' will take over this responsibility. In such cases there should be an agreement between the outgoing notified body, the incoming notified body and the manufacturer, commonly referred to as a tri-partite agreement, where the surveillance is agreed upon.

5.2 Criteria B

This criterion is concerning Class III Custom Made Active Implantable Devices only.

The manufacturer has lodged a formal application for the applicable conformity assessment by no later than **26 May 2024** and has signed a written agreement with the notified body by no later than **26 September 2024**.

6.0 MDR and IVDR Removal of the Sell-Off Date

6.1 MDR Sell-Off Date Removal

This provision deletes the current 'sell-off' date (27 May 2025) set out in ***Article 120(4)*** of the MDR. Consequently, devices placed on the market before the end of the transition period can be made further available on the market without a legal time restriction.

6.2 IVDR Sell-Off Date Removal

This provision deletes the current 'sell-off' dates (25 May 2025 - 26 May 2028) set out in ***Article 110(4)*** of the IVDR. Consequently, devices placed on the market before the end of the transition period laid down in Article 110(3) IVDR can be made further available on the market without a legal time restriction.

One thing to note is that the provision would not allow devices with a limited shelf-life to be offered past expiry.

Annex I- Timeline of Important Cut-Off Dates

Annex II- FAQ's (Frequently Asked Questions)

Questions Concerning Class I Devices

1. I manufacture simple Class I devices under the MDR, will I be eligible for this extension?

   No, this amendment is not applicable to simple Class I devices under the MDR.

2. I manufacture Class I devices under the MDD that will require notified body assessment under the MDR, will I be eligible for the extension?

   Yes, you will be eligible for the extension. You will be able to place your device on the market till the 31st of December 2028 if you meet the criteria A mentioned in Section 5.

Questions Concerning CE Certificates Expired After the Date of Entry of the Amendment

3. My CE Certificate expires after the 20th March 2023 (the date of entry of this new amendment). Does this extension apply to me and what are my options?

   Yes, this extension does apply to you. You will be able to continue placing your devices on the market till the 31st of December 2027 or 31st December 2028 depending on the classification of the device and provided that the criteria mentioned in Section 5 are met.

4. My CE Certificate expires after the 20th March 2023 (the date of entry of this new amendment), however I do not wish to go forward with the MDR. Till when can I continue to place my devices on the market under the MDD?

   In this scenario, you will be able to benefit from an extension of the transitional period up until 26th May 2024, provided the conditions set out in Article 120(3c), points (a) to (c), are fulfilled.

Questions Concerning CE Certificates Expired Prior to Date of Entry of the Amendment

5. My CE Certificate expired prior to 21st May 2021, does this amendment apply to me?

   No, the amendment only applies to CE certificates that were valid on the date of entry of the MDR.

6. My CE Certificate expired prior to 20th March 2023 (the date of entry of this new amendment) and after 21st May 2021, does this extension apply to me?

Yes, this extension will apply to you, however there are certain conditions that need to be met. Please refer to the below questions for specific scenarios.

7. My CE Certificate expired prior to 20th March 2023 (the date of entry of this new amendment). I have signed the agreement with the notified body prior to the expiration of the CE certificate. What are the next steps?

   You can continue placing your devices on the market until 31st December 2027 or 31st December 2028, depending on the classification of the device (please refer to section 4) and provided that the criteria mentioned in section 5 are met.

8. My CE Certificate expired prior to 20th March 2023 (the date of entry of this new amendment). I have signed the agreement with the notified body after to the expiration of the CE certificate. What are the next steps?

   Since the agreement was signed after the expiration date, then the manufacturer has to apply for a derogation via Article 59(1) or Article 97(1) (as applicable) with the Competent Authority. With the derogation granted, you can continue placing your devices on the market until 31st December 2027 or 31st December 2028, depending on the classification of the device (please refer to section 4) and provided that the criteria mentioned in section 5 are met.

9. My CE Certificate expired prior to 20th March 2023 (the date of entry of this new amendment), additionally, I do not hold a signed the agreement with the notified body. What are the next steps?

   Since there is no agreement that was signed with the notified body, then the manufacturer has to apply for a derogation via Article 59(1) or Article 97(1) (as applicable) with the Competent Authority. With the derogation granted, you can continue placing your devices on the market until 31st December 2027 or 31st December 2028, depending on the classification of the device (please refer to section 4) and provided that the criteria mentioned in section 5 are met. Please refer to MDCG 2022-18 for more information regarding the Article 97(1) derogation.

10. My CE Certificate expired prior to 20th March 2023 (the date of entry of this new amendment), and I don't have a signed agreement with the notified body and the Article 59(1)/Article 97(1) derogation was not granted by the CA, does this extension apply to me?

    No, the extension will not apply to you in this case.

Questions Concerning Class III Custom Made Implantable Device

11. I manufacture Class III Custom Made Implantable Devices. how does this extension apply to me?

    The new amendment also applies if your Device is a Class III Custom Made Implantable Device. These devices can continue to be placed on the market till 2026 if certain criteria are met refer to section 5 for criteria.

General Questions

12. How can Manufacturers Demonstrate they meet the Criteria?

According to a Q&A document that has been published by the EU Commission, manufacturers can demonstrate that they meet the criteria set out in EU 2023/607 by means of a self-declaration.

13. Is there a template to this self-declaration document? And from where can I obtain it?

There is a harmonised template that manufacturers can use. It can be downloaded using the following Link .

14. What is the confirmation letter from the notified body and is it needed?

The notified body can issue a confirmation letter where they confirm the criteria that pertains specifically to them, including an application has been lodged and signed with them and that they are responsible for the surveillance of the 'extended devices'. Again, we urge all manufacturers to obtain this confirmation letter as it will add weight to their declaration. A template to the confirmation letter can be downloaded using the following Link

15. Where can I find more useful information about the extension?

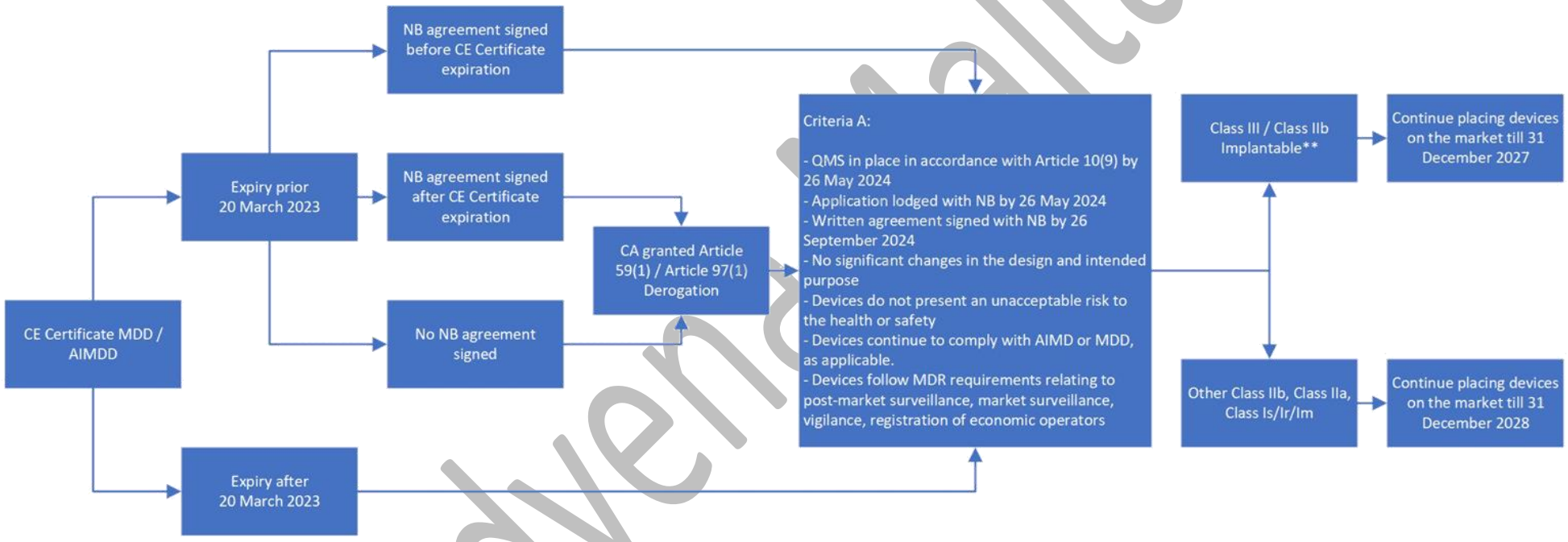
The EU Commission has published a question-and-answer document that contains a lot of useful information that can help you navigate the extension. The initial document was released on the 20th March 2023, however, they have recently updated this document to reflect the updates that have been published since then. The updated Q&A can be accessed using the following Link.

Questions Concerning Advena

16. Can Advena help you?

Yes, the team at Advena is always ready to help you navigate through the ever-changing environment of the MDR and IVDR. Should you need any assistance, please don't hesitate to contact us.

Annex III- Flowchart for the Extension of CE certificates



***Refer to main text for full conditions of Criteria A**

**** Except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors**

Annex IV - Flowchart for the Upclassifcation of Devices

***Refer to main text for full conditions of Criteria A**

Annex V – Flowchart for Device Class III Custom Made Implantable

***Refer to main text for full conditions of Criteria B**

Annex VI – IMPORTANT LINKS CONCERNING EU 2023/607

The table below makes reference to important documents that are relevant to the EU 2023/607. This includes guidance document, Q&A's and templates.

Description	Reference
MDR	Link
IVDR	Link
EU 2023/607	Link
Q&A Published by the Commission	Link
Manufacturers Self-Declaration Template	Link
Notified Body Conformation Letter	Link
MDCG 2020-3 Rev 1 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	Link
MDCG 2022-18 ADD.1 MDCG Position Paper on the application of Article 97 MDR to legacy devices for which the MDD or AIMDD certificate expires before the issuance of a MDR certificate	Link
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	Link

We hope this guidance document has helped you navigate through the everchanging landscape of the MDR and IVDR.

Should you have any queries, please don't hesitate to contact us!

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