



ADVENA LTD.

**AMENDING REGULATIONS (EU) 2017/745 AND
(EU) 2017/746 AS REGARDS A GRADUAL ROLL-
OUT OF EUDAMED, INFORMATION OBLIGATION
IN CASE OF INTERRUPTION OF SUPPLY AND
THE TRANSITIONAL PROVISIONS FOR
CERTAIN IN VITRO DIAGNOSTIC MEDICAL
DEVICES**

**A GUIDANCE DOCUMENT
V2.0**

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Change History

Version	Date	Description
1.0	24/06/2024	Initial Issue
2.0	24/07/2024	Document updated with: <ul style="list-style-type: none"> • Date of entry of amendment, • Inclusion of EUDAMED Gradual Roll-out Roadmap • Addition of Important Reference Documents

1.0 Scope

This document is intended to provide guidance on the amendment to the regulation regarding the transitional provisions for certain in vitro diagnostic devices as well as the gradual roll-out of EUDAMED and the information obligation of manufacturers in case of interruption of supply, commonly referred to as [\(EU\) 2024/1860](#)

This guidance also provides a timeline with all the important cut-off dates, Q&A and flowcharts in the Annexes that one can follow to better understand and visualise the process more effectively.

- **Annex I** - Timeline of Important Cut-Off Dates
- **Annex II** - Q&A Section
- **Annex III** - Flowchart for the Extension of CE certificates
- **Annex IV** - Flowchart for the Up-Classification of Devices
- **Annex V** - Important Links Concerning This Proposal

2.0 Introduction

This guidance document discusses three main topics of the new legislation, which are the following:

- Extension in Transitional Periods of IVDR
- Gradual Roll-Out of EUDAMED
- Information obligation of manufacturers in case of interruption of supply.

2.1 Extension in Transitional Periods of IVDR

The introduction of the IVDR came with very substantial regulatory changes to the regulatory framework for IVDs. One of the most significant changes is the increased involvement of independent notified bodies for the conformity assessment that is proportionate to the classification of the device. Under the IVDD, only a small number of high-risk devices equating to around 8% of IVDs on the market required the involvement of a notified body. Under the IVDR, around 80% of IVDs on the market will require the involvement of a notified body.

There is also an issue that persists which concerns the limited capacity of notified bodies for IVDR. Currently, there are only 12 notified bodies that are designated for IVDR, with a further 8 applications that are in progress. This is quite a low number when compared to the 49 Notified Bodies designated under the MDR.

The combination of low notified body numbers designated under the IVDR and the fact that many manufacturers are not yet prepared for the requirements of the IVDR will hence result in delays in the certification of IVDs under the IVDR. Subsequently, this will result in shortages of vital IVDs on the EU market.

With concerns of IVD shortages on the market due to IVD manufacturers not having enough time to comply with the IVDR requirements, the EU commission proposed an extension of the transition periods of the IVDR. In their views, this will help to mitigate the risk of shortages of IVDs by giving manufacturers and notified bodies more time, provided certain conditions are met, to complete the necessary conformity assessment procedures, without lowering the requirements. The proposal faired quite well and was adopted and published in the official journal of the EU on the **9th of July**.

Under the old legislation ([EU 2022/112](#)), devices that had an IVDD certificate issued prior to 26th May 2022, would continue to be valid up until 26th May 2025. under the new legislation, this has been extended up until **31st December 2027**.

In addition, under the old legislation, devices that were considered general IVD's under the IVDD and need the involvement of a notified body for conformity assessment under the IVDR, would have an extension in transitional period depending on the classification under the IVDR. The extension in the transitional period was as follows: May 2025 for High-Risk Class D devices, May 2026 for Medium Risk Class C devices, and May 2027 for Low-Risk Class A in a sterile condition and Class B devices.

Under the new legislation, manufacturers would be given an extra 2 years and a half to fully comply with the IVDR requirements when compared to the old legislation. This means that the extension in the transitional period under this new legislation is as follows: **December 2027** for High-Risk Class D devices, **December 2028** for Medium Risk Class C devices, and **December 2029** for Low-Risk Class A in a sterile condition and Class B devices

The table below highlights the old deadlines and the newly proposed deadlines for the different classes of IVD devices.

Under Old Legislation (EU) 2022/112	Under New Legislation (EU) 2024/1860
26 th May 2025, for Devices that had a CE Certificate under IVDD	31 st December 2027, for IVD Devices that had a CE Certificate under IVDD*
26 th May 2025, for Class D devices	31 st December 2027 for Class D devices*
26 th May 2026, for Class C devices	31 st December 2028 Class C devices*
26 th May 2027, for Class B devices	31 st December 2029 Class B devices*
26 th May 2027, for Class A sterile devices	31 st December 2029 Class A sterile devices*

*The deadlines mentioned above are subject to manufacturers satisfying certain criteria.

2.2 Gradual Roll-Out of EUDAMED

EUDAMED is essential for the implementation of the MDR and IVDR. The Actor module has been available for voluntary use since December 2020 and the UDI/Devices and Notified bodies/Certificates have been available from October 2021. Two further modules, Market Surveillance; Post-Market Surveillance and Vigilance are expected to be completed in Q2 of 2024. The last module, Clinical investigations/Performance studies, will not be completed before Q3 of 2026. Pursuant to the current MDR rules, EUDAMED can only be used mandatorily from a certain date after the Commission has verified that EUDAMED is fully functional and has published a notice to that effect. Therefore, the delayed development of the last module holds back the mandatory use of the electronic systems that have been completed already. Under this legislation, the mandatory use of EUDAMED cannot be expected prior to Q4 of 2027, with additional transitional periods not ending prior Q2 of 2029.

Due to the above, the commission proposed the gradual roll-out of EUDAMED. This would mean that once a EUDAMED module has been audited and declared functional, it will be implemented and made mandatory, hence removing the reliance of other modules for the mandatory implementation. Under this new legislation, the mandatory use of several modules of EUDAMED will start from **Q1 of 2026**.

2.3 Information obligation of manufacturers in case of interruption of supply.

During the transitional period, many actors such as healthcare professionals and competent authorities have reported that the supply of many medical devices and IVDs has stopped, or likely to be stopped. If the medical device is a vital medical device, the interruption of supply can result in serious harm or a risk of serious harm to patients or public health. Due to these aforementioned concerns, the EU Commission is proposing to implement an obligation to the manufacturers making them inform the relevant actors if they intend to cease, temporarily or permanently, supply of a critical medical device.

3.0 Which Devices Would be Benefitting from the Extension in the Transition Period?

3.1 Devices with CE certificates

This new amendment will apply to your device if it was certified by a notified body under the In Vitro Diagnostic Directive 98/79/EC (IVDD) and the certificate was valid at the date of application of the IVDR (26 May 2022), and **not later withdrawn by the notified body**. Depending on whether the CE certificate in question expires prior or after the 9th of July 2024, the date of entry of this amendment, one of the following will apply;

3.1.1. CE Certificate Expires After 9th of July 2024

If your certificate expires after the date of entry of this amendment, then the device can continue to be placed on the market till **31st December 2027** if the criteria discussed in Section 5 are met.

3.1.2 CE Certificate Expired Prior to 9th of July 2024

Conversely, if your CE certificate expired prior to the date of entry of this amendment, you can still place the devices on the market till **31st December 2027** 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 54(1) or Article 92(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 **31st December 2027** if the criteria discussed in Section 5 are met.

3.2 Other Devices

3.2.1 General IVD's under IVDD that have been up classified under the IVDR.

The extended provisions also apply if your IVD was classified as a General IVD under the IVDD, which did not require the involvement of a notified body for the conformity assessment and are up classifying under the IVDR, hence requiring the involvement of a notified body and has a declaration of conformity was drawn up prior to **26th May 2022**. Depending on the classification of the device, these can continue to be placed on the market up until certain dates ranging from **31st December 2027** to **31st December 2029** if the criteria discussed on Section 5 are met.

4.0 Length of Extension

The length of the extension granted is dependent on whether the device was certified under the previous directive (IVDD) as well as on the classification of the device.

4.1 Devices that have been certified under the IVDD

For devices that have been certified under the IVDD, manufacturers can place their devices on the market up until **31st December 2027** if the criteria discussed in Section 5 are met.

4.2 Devices that will be Up-Classifying

Devices that did not require the involvement of a notified body for the conformity assessment and are up classifying under the IVDR, hence requiring the involvement of a notified body, will be extended to the following dates depending on the classification and if the criteria discussed in Section 5 are met:

- **31st December 2027** for Class D devices. These encompass high individual and public health risk devices such as HIV or hepatitis tests.
- **31st December 2028** for Class C devices. These encompass high individual and/or moderate public health risk devices such as cancer tests.
- **31st December 2029** for Class A in a Sterile Condition and Class B devices. These encompass lower risk devices such as pregnancy tests and blood collection tubes.

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 IVDR certification**. In order for manufacturers to avail from the extension, they must satisfy the following criteria:

- The devices continue to comply with Directive 98/79/EC (IVDD).
- 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.
- no later than **26th May 2025**, the manufacturer has put in place a quality management system in accordance with Article 10(8).
- The manufacturer or the authorised representative has lodged a formal application with a notified body no later than
 - **26th May 2025**: for devices having a risk classification of **Class D**
 - **26th May 2026**: for devices having a risk classification of **Class C**
 - **26th May 2027**: for devices having a risk classification of **Class B**
 - **26th May 2027**: for devices having a risk classification of **Class A in a Sterile Condition**
- The notified body and the manufacturer have signed a written agreement no later than
 - **26th September 2025**: for devices having a risk classification of **Class D**
 - **26th September 2026**: for devices having a risk classification of **Class C**
 - **26th September 2027**: for devices having a risk classification of **Class B**
 - **26th September 2027**: for devices having a risk classification of **Class A in a Sterile Condition**
- By way of derogation, the requirements of this Regulation relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of

devices shall apply to devices referred to in the above, instead of the corresponding requirements in Directive 98/79/EC.

- The notified body that issued the certificate shall continue to be responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices it has certified, unless the manufacturer has agreed with a notified body designated in accordance with Article 42 that the latter shall carry out such surveillance.
 - No later than **26th September 2025**, the notified body that has signed the written agreement shall become responsible for the surveillance in respect of the devices covered by the written agreement. Where the written agreement covers a device intended to substitute a device which has a certificate that was issued in accordance with Directive 98/79/EC, the surveillance shall be conducted in respect of the device that is being substituted. The arrangements for the transfer of the surveillance from the notified body that issued the certificate to the notified body designated in accordance with Article 38 shall be clearly defined in an agreement between the manufacturer and the notified body designated in accordance with Article 42 and, where practicable, the notified body that issued the certificate. The notified body designated in accordance with Article 42 shall not be responsible for conformity assessment activities carried out by the notified body that issued the certificate.

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6.0 Gradual Roll-Out of EUDAMED

As many manufacturers are aware, the Actor module on EUDAMED has been available for voluntary use since December 2020 and Devices and the Notified Body/Certificates module have been available since October 2021. Under the old legislation, the use of EUDAMED would have been mandatory once all six modules were audited and functional. Due to the delay in the clinical investigations module which was projected to be completed not before Q3 of 2026, the mandatory use of EUDAMED was delayed to Q2 of 2029. This was not seen as viable in the EU since EUDAMED is vital for the implementation of the MDR and IVDR. Due to this, the EU commission proposed the gradual rollout of EUDAMED where modules would be audited, tested and subsequently made available separately, hence removing the reliance of the other modules.

To further clarify their plan moving forward, the EU Commission published a [roadmap](#) to demonstrate how the gradual rollout of EUDAMED would work in practise. This roadmap is intended to give the relevant actors estimated timeframes of when each module will become mandatory for use.

According to the roadmap published, the notice for the Actor, UDI/Devices, NB & Certificates and Market Surveillance (MSU) Modules will be published in the OJEU in Q2 of 2025. This means that the mandatory use of these modules will be effective 6 months from this date in **Q1 of 2026**.

Furthermore, the notice for the vigilance module will be published in Q1 of 2026, hence meaning that this module will become mandatory as from **Q3 of 2026**.

It is interesting to note that although there is mention of the Clinical Investigation module, they have only stated the timeframe of when this module will be under development (Q4 2024 – Q3 2036) and there is no mention of when the notice will be published in the OJEU or when it will be made mandatory for use.

The table below summarizes the roadmap published by the EU commission.

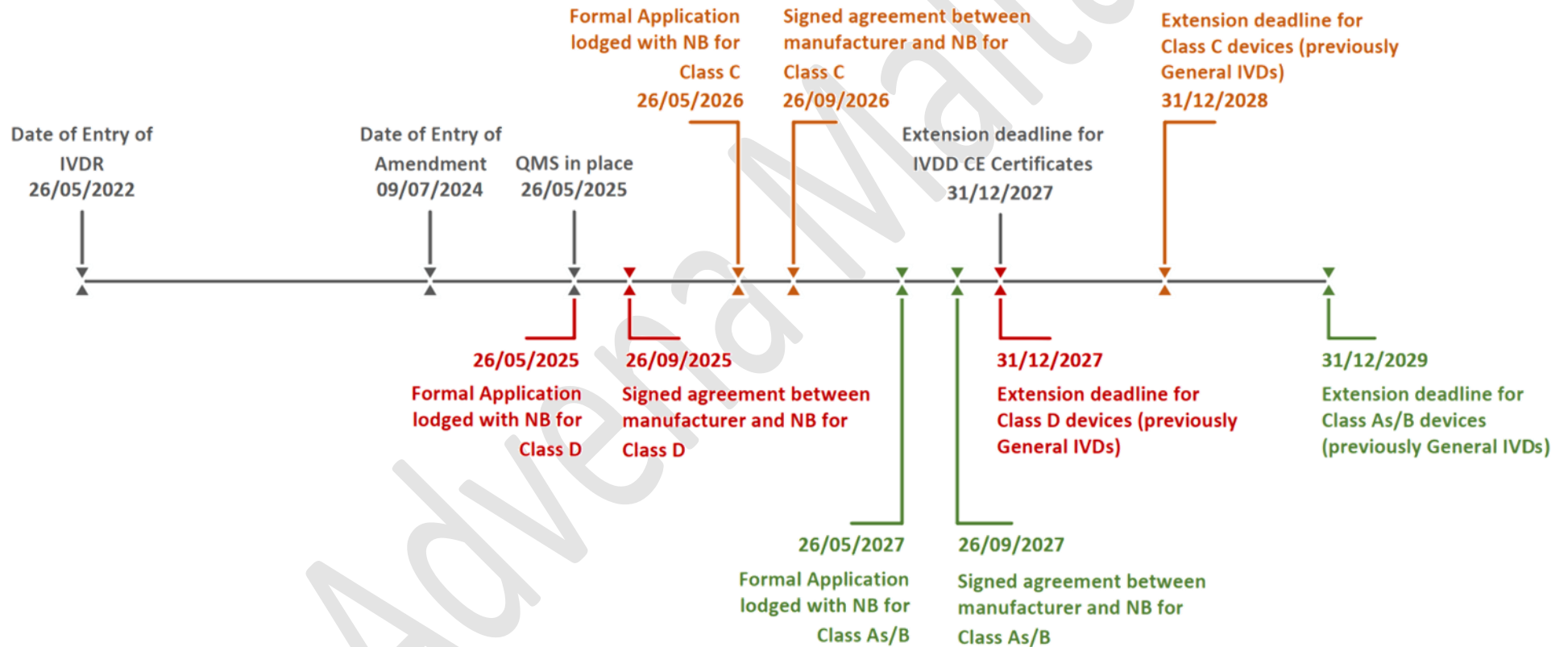
Module	Published in OJEU	Mandatory Use
Actor	Q2 of 2025	Q1 of 2026
UDI/Devices	Q2 of 2025	Q1 of 2026
NB & Certificates	Q2 of 2025	Q1 of 2026
Market Surveillance (MSU)	Q2 of 2025	Q1 of 2026
Vigilance Module	Q1 of 2026	Q3 of 2026

7.0 Information obligation of manufacturers in case of interruption of supply.

Lastly, the new regulation introduces an additional obligation for manufacturers to inform the relevant actors if they intend to cease supply of a critical medical device. To offer some background to this proposal, during the transitional period, many actors such as healthcare professionals and competent authorities have reported that the supply of many medical devices and IVDs has stopped, or likely to be stopped. If the medical device is a vital medical device, the interruption of supply can result in serious harm or a risk of serious harm to patients or public health. The proposal aims to impose an additional obligation to the manufacturers making them inform the relevant actors if they intend to cease, temporarily or permanently, supply of a critical medical device, hence enabling the authorities to carry out the necessary mitigating measures to ensure public health and safety. Under this new legislation, manufacturers will be required to inform the relevant actors **6 months** prior to anticipated interruption to the supply of a critical medical device on the EU market.

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Annex I Timeline of Important Cut-Off Dates



Annex II- FAQ's (Frequently Asked Questions)

Questions Concerning the Extension in the Transitional Period

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

No, this amendment is not applicable to simple Class A devices under the IVDR.

2. I manufacture General IVD's devices under the IVDD that will require notified body assessment under the IVDR, will I be eligible for the extension?

Yes, you will be eligible for the extension. Depending on the classification of your device under the IVDR, you will be able to place your device on the market until certain dates, ranging from December 2027 to December 2029 if certain criteria have been met.

3. My CE Certificate expires after the date of entry of this new amendment (9th July 2024). 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 provided that certain criteria are met.

4. My CE Certificate expired prior to 21st May 2022, does this amendment apply to me?

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

5. My CE Certificate expired prior to the date of entry of this new amendment (9th July 2024) and after 21st May 2022, 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.

6. My CE Certificate expired prior the date of entry of this new amendment (9th July 2024). 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 provided that certain criteria are met.

7. My CE Certificate expired prior to the date of entry of this new amendment (9th July 2024). 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 54(1) or Article 92(1) (as applicable) with the Competent Authority. With the derogation granted, you can continue placing your devices on the market until 31st December 2027 provided that certain criteria are met.

8. My CE Certificate expired prior to the date of entry of this new amendment (9th July 2024), 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 49(1) or Article 92(1) (as applicable) with the Competent Authority. With the derogation granted, you can continue placing your devices on the market until 31st December 2027 provided that certain criteria are met.

9. My CE Certificate expired prior to the date of entry of this new amendment, and I don't have a signed agreement with the notified body and the Article 54(1)/Article 92(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 the Gradual Roll-Out of EUDAMED

10. When can I start to use EUDAMED?

The Actor module in EUDAMED has been available for voluntary use since December 2020. Additionally, the UDI/Devices and Notified bodies/Certificates have been available for voluntary use from October 2021. Technically speaking you were able to use EUDAMED from these dates.

11. When will EUDAMED become mandatory?

*Under the old legislation, the mandatory use of EUDAMED was scheduled for some time in 2029 once all modules would have been audited. They will then become mandatory for use 6 months after their publication in the OJEU. Under this new legislation, the first modules of EUDAMED are projected to become mandatory from **Q1 of 2026**.*

12. Under the previous legislation, why was EUDAMED going to be delayed for mandatory use till 2029?

As mentioned previously, under the old legislation, the use of EUDAMED would be mandatory when all 6 modules have been audited and tested. The last module, Clinical investigations/Performance studies, will not be completed before Q3/2026

13. Which EUDAMED modules will become mandatory first?

*The first modules that will be made mandatory first will be the Actor, UDI/Devices, NB & Certificates, Market Surveillance (MSU). These modules will become mandatory as from **Q1 of 2026**.*

Questions Concerning the Information obligation of manufacturers in case of interruption of supply.

14. Why is the EU Commission proposing a mechanism where manufacturers need to inform relevant actors if they intend to cease supply of a critical medical device?

To ensure availability of devices, Member State authorities and healthcare providers need to know in advance whether devices will be discontinued, and whether such discontinuation may pose a risk to patients or public health. Under this new proposal manufacturers are required to submit a notice 6 months in advance to give the relevant actors enough time to implement mitigating measures.

Questions Concerning Advena

15. Can Advena help you?

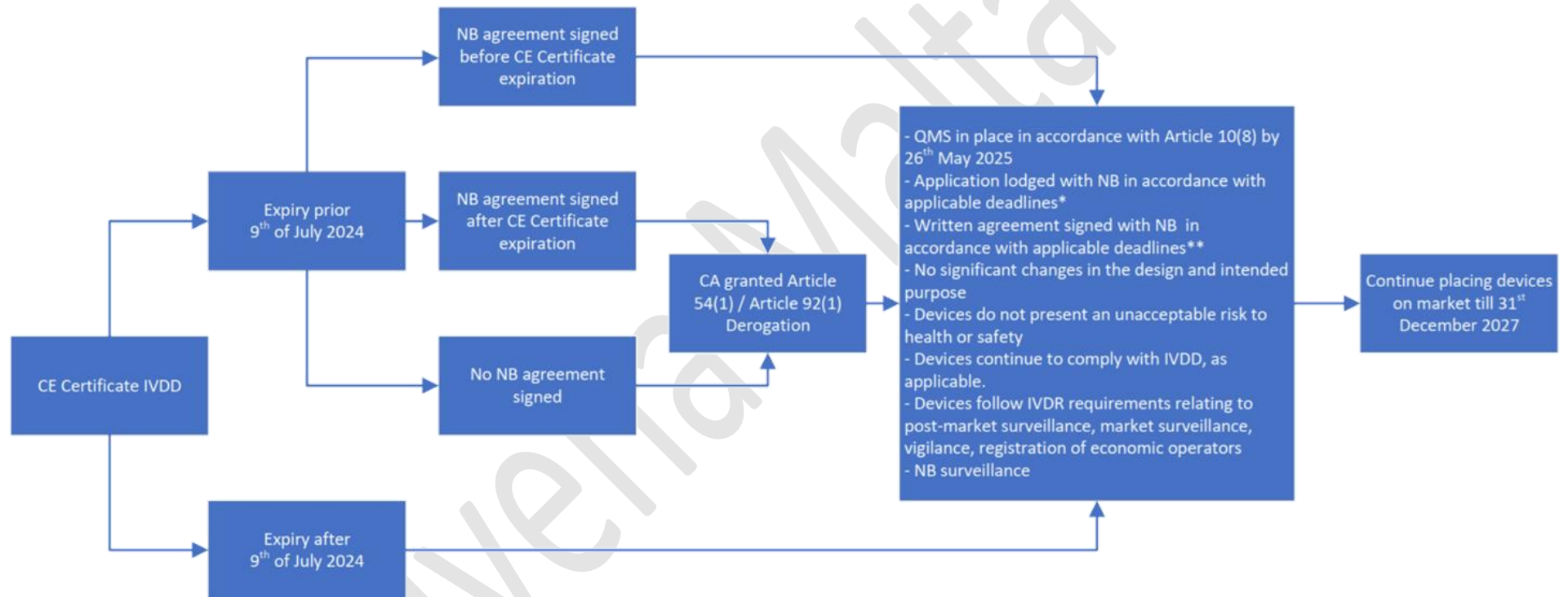
Yes, the team at Advena is always ready to help you navigate through the ever-changing environment of the MDR and IVDR. More specifically:

- *We can help manufacturers lodge an Article 92(1) application to the competent authority.*
- *We can also help manufacturers get ready for the changes in EUDAMED by specifically:*
 - *Helping with Actor Registration and hence obtaining the SRN*
 - *Helping with registering devices on the UDI-DI module.*

Should these be services that you are interested in, kindly let us know and we will provide you with further information.

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Annex III- Flowchart for the Extension of CE certificates



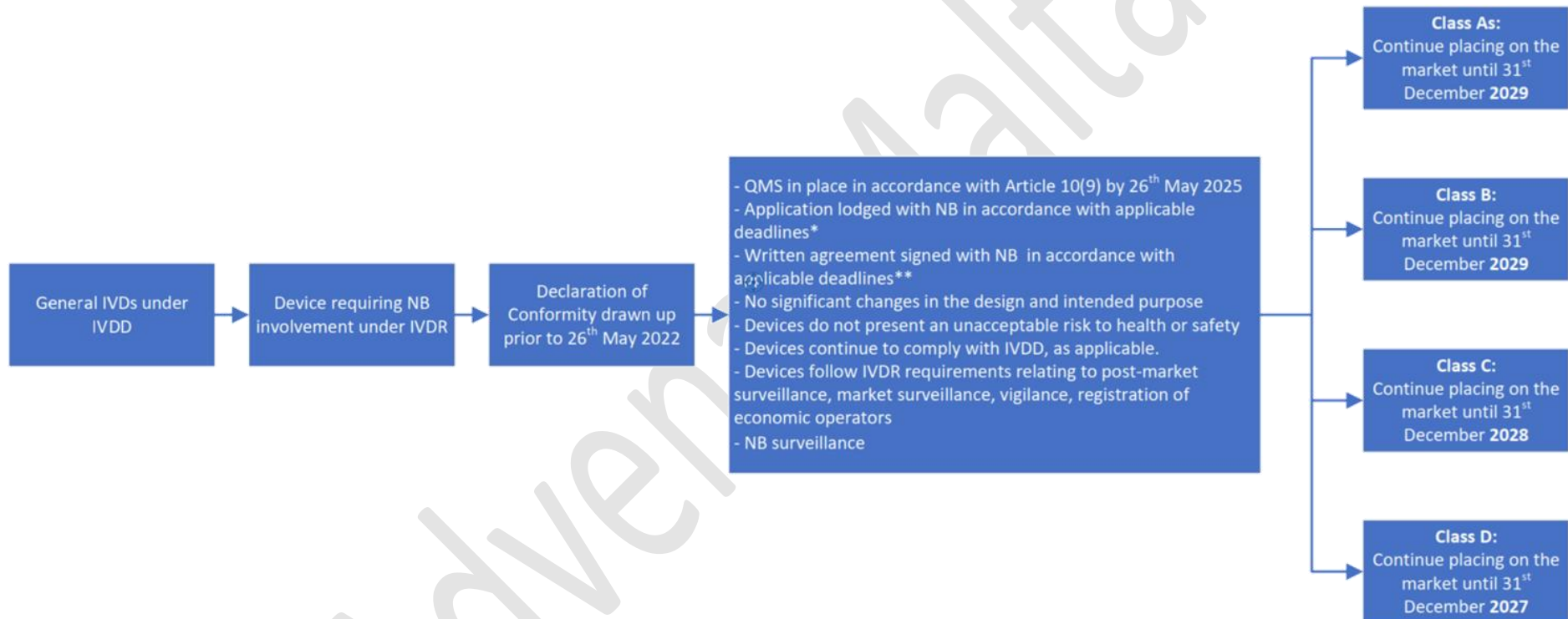
***Application Lodged by**

- 26th May 2025 for Class D devices
- 26th May 2026 for Class C devices
- 26th May 2027 for Class As/B devices

****Application Signed by**

- 26th September 2025 for Class D devices
- 26th September 2026 for Class C devices
- 26th September 2027 for Class As/B

Annex IV - Flowchart for the Upclassification of Devices



***Application Lodged by**

- 26th May 2025 for Class D devices
- 26th May 2026 for Class C devices
- 26th May 2027 for Class As/B devices

****Application Signed by**

- 26th September 2025 for Class D devices
- 26th September 2026 for Class C devices
- 26th September 2027 for Class As/B

Annex VI – Important Reference Links Concerning This Proposal

Description	Reference
<i>IVDR</i>	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32017R0746
<i>Press Release</i>	https://ec.europa.eu/commission/presscorner/detail/en/ip_24_346
<i>Q&A Document</i>	https://ec.europa.eu/commission/presscorner/detail/en/QANDA_24_347
<i>EU Commission Proposal</i>	https://health.ec.europa.eu/document/download/bcde7f36-b2fe-4d5f-989a-6daa80538b79_en?filename=mdr_in-vitro-proposal.pdf
<i>Factsheet</i>	https://health.ec.europa.eu/document/download/1b817e65-89c8-4235-ab74-c147aeff34db_en?filename=mdr_in-vitro-factsheet.pdf
<i>Published Legislation (EU) 2024/1860</i>	https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202401860
<i>Self-Declaration Template</i>	https://www.medtecheurope.org/resource-library/manufacturers-declaration-in-relation-to-regulation-eu-2024-1860/
<i>Notified Body Confirmation Letter Template</i>	https://www.team-nb.org/wp-content/uploads/2024/07/Team-NB-IVDConfirmationLetterTemplate-V2-20240710.pdf
<i>Q&A document released by EU Commission</i>	https://health.ec.europa.eu/document/download/dfd7a1c6-f319-4682-9bac-77bef1165818_en?filename=mdr_qna-ext-ivdr.pdf
<i>Gradual Roll-Out of EUDAMED Infographic</i>	https://health.ec.europa.eu/document/download/04ce2012-97df-4dd0-8a39-d4f6993b9e16_en?filename=md_eudamed_roadmap_en.pdf

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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