European Commission

GRADUAL ROLL-OUT OF EUDAMED

Q&A on practical aspects related to the implementation of the gradual roll-out of Eudamed pursuant to the MDR and IVDR, as amended by Regulation (EU) 2024/1860 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

November 2024

Q&A on practical aspects related to the implementation of the gradual roll-out of Eudamed pursuant to the MDR and IVDR, as amended by Regulation (EU) 2024/1860 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 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) 2024/1860 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 amendment 3

ABBREVIATIONS 4

PART A – EUDAMED GRADUAL ROLL OUT (Article 34 MDR) 4

Q1. What are the implications of the amendment to Article 34 MDR, enabling the gradual roll-out of Eudamed? 4

PART B – EUDAMED'S TRANSITION PERIODS FOR MANDATORY USE (Articles 123 MDR and 113 IVDR) 5

Q2. What are the main changes introduced to Articles 123 MDR and 113 IVDR with respect to the transition period for the mandatory use of Eudamed? 5

PART C - TRANSITION PERIODS PER EUDAMED MODULE 5

ACTOR MODULE 5

Q3. When will the use of the ACTOR (ACT) module become mandatory? 5

Q4. Are there economic operators or other types of actors not in scope of Article 31 MDR and Article 28 IVDR who need to be registered in the ACT module? 6

Q5. Which economic operators do not have to register in Eudamed? 6

Q6. When can I register my organisation in the ACT module? 6

UDI/DEVICE MODULE 7

Q7. When will the use of the UDI/DEV module become mandatory? 7

Q8. Which devices do not need to be registered in the UDI/DEV module? 8

Q9. When can I start registering devices/SPPs in the UDI/DEV module? 8

NOTIFIED BODIES AND CERTIFICATES MODULE 9

Q10. When will the use of the notified bodies and certificates (NB/CRF) module become mandatory? 9

Q11. When can notified bodies start using the NB/CRF module? 10

POST-MARKET SURVEILLANCE AND VIGILANCE MODULE 10

Q12. When will the use of the Post-Market Surveillance and Vigilance (VGL) module become mandatory? 10

Q13. When can I start using the VGL module? 11

Q14: which devices need to be registered in UDI/DEV module only when a PMSV action occurs? 11

MARKET SURVEILLANCE MODULE 12

Q15. When will the Market surveillance (MSU) module become mandatory? 12

Q16. When can competent authorities start using the MSU module? 12

CLINICAL INVESTIGATIONS/PERFORMANCE STUDIES MODULE 12

Q17. When will the Clinical investigations/Performance studies (CI/PS) module become mandatory? 12

Q18. When will the coordinated assessment referred to in Articles 78(14) MDR and 74(14) IVDR become applicable? 12

Q19. Will the coordinated assessment procedure be possible in the absence of Eudamed? 12

Q20. When can I start using the CI/PS module? 12

Annex: Flowchart - device registration timelines 13

Introduction – Objectives of the MDR/IVDR amendment

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 this topic are set out in a separate document.

2. Regulation (EU) 2024/1860 also imposes a requirement on manufacturers to inform their 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 the gradual roll-out of Eudamed are set out in this document.

ABBREVIATIONS

- ACT module: Actor module
- Actor ID: Identifier similar to the SRN (same structure) for registered actors not under Article 31 MDR/Article 28 IVDR)
- CA: Competent authority
- CI/PS module: Clinical investigations and performance studies module
- CECP: Clinical evaluation and consultation procedure
- DA: Designating authority
- NB/CRF module: Notified bodies and certificates module
- IVD: *In vitro* diagnostic medical device
- IVDR: Regulation (EU) 2017/746 on in vitro diagnostic medical devices
- MD: Medical device
- MDCG: Medical Device Coordination Group
- MDR: Regulation (EU) 2017/745 on medical devices
- MfS: Mechanism for scrutiny
- MSU module: Market surveillance module
- NB: Notified Body
- NCAR: National competent authority report as referred to in Article 89 (7) and (9) MDR/Article 84 (7) and (9) IVDR
- OJEU: Official Journal of the European Union
- PMSV action[2]: Post-market surveillance (a PSUR for a Class III or implantable or Class D Regulation device) or Vigilance related action (a report of a serious incident, periodic summary report or FSCA/FSN for an Old, Legacy, Custom-Made or Regulation Device, or a trend report for a Legacy or Regulation Device to EUDAMED)
- QMS: Quality Management System
- SS(C)P: Summary of safety and (clinical) performance
- SPP: Systems and Procedure Packs
- SPPP: System and Procedure Pack Producers
- SRN: Single Registration Number (assigned to registered actors under Article 31 MDR/Article 28 IVDR)
- UDI/DEV module: UDI/Device module
- UDI-DI: UDI device identifier (pursuant to Article 27(1)(a)(i) MDR/Article 24(1)(a)(i) IVDR)
- VGL module: Post-market surveillance and Vigilance module

PART A – EUDAMED GRADUAL ROLL OUT (Article 34 MDR)

Q1. What are the implications of the amendment to Article 34 MDR, enabling the gradual roll-out of Eudamed?

Article 34 MDR, as amended by Regulation 2024/1860, enables the gradual implementation of Eudamed by a roll-out of individual modules once each individual module is audited and a Commission notice confirming the functionality of the module is published in the OJEU. The amendment aims to speed up the mandatory use of individual modules of Eudamed that are confirmed functional.

The new wording of Article 34 MDR allows to conduct independent audit(s) on an individual or several modules when ready and consequently to have audit reports specific to those modules subject to the audit, considering the interdependencies between the modules.

[2] It includes the following: serious incident reports (MIR), Field safety corrective actions (FSCA), Field Safety Notice (FSN), Periodic safety update reports (PSUR), Periodic Summary Report (PSR), Trend report (MTR).

The steps to confirm the functionality of a module (or group of modules) have not been changed, as independent audit(s) will still have to verify that the module(s) meet(s) the functional specifications as drawn up by the MDCG and the Commission. Once the Commission has verified that the modules are functional following the independent audit(s), it will inform and consult the MDCG. Subsequently, the Commission will publish a notice(s) in the OJEU to confirm the functionality of the modules audited.

PART B – EUDAMED'S TRANSITION PERIODS FOR MANDATORY USE (Articles 123 MDR and 113 IVDR)

Q2. What are the main changes introduced to Articles 123 MDR and 113 IVDR with respect to the transition period for the mandatory use of Eudamed?

According to the new wording of Article 123(3)(d) MDR and Article 113(3)(e) IVDR, the obligations and requirements that relate to a certain module of Eudamed will become applicable 6 months after the publication in the OJEU of the notice confirming the functionality of the given module.

According to Article 123(3)(d) MDR and Article 113(3)(e) IVDR, until the date on which the obligations and requirements that relate to a certain Eudamed module become mandatory, the corresponding Directives[3] provisions and obligations relating to vigilance, clinical investigations/performance studies, registration of devices and economic operators, and certificate notifications apply. This provides for a clear cut-off date when the Directives' provisions (and the corresponding national transposition measures) cease to apply and the Eudamed-related provisions become mandatory, thus preventing double registrations issues.

Note: Regulation (EU) 2024/1860 deleted Article 120(8) MDR and Article 110(8) IVDR, which established that during the transition period from the publication of the notice confirming the functionality of Eudamed until its mandatory use for device and certificate registration, the registration of devices and certificates using Eudamed would have been considered to comply with the national registration requirements pursuant to the Directives.

PART C - TRANSITION PERIODS PER EUDAMED MODULE

Eudamed consists of six modules[4]:

- Actor module (ACT module)
- UDI/Device module (UDI/DEV module)
- Notified bodies and certificates module (NB/CRF module)
- Market surveillance module (MSU module)
- Post-market surveillance and Vigilance module (VGL module)
- Clinical investigations/performance studies module (CI/PS module)

ACTOR MODULE

Q3. When will the use of the ACTOR (ACT) module become mandatory?

Economic operators in scope of Article 31 MDR and Article 28 IVDR (manufacturers, importers and authorised representatives) must be registered as Actor and obtain a Single Registration Number (SRN), where applicable, before a device is placed on the market. Moreover, the registration in the ACT module is needed to enable, for example, a manufacturer to register devices and vigilance reports, or carry out any other activity in Eudamed. See Q4 for more details on other economic operators or types of actors who need to be registered as Actors in Eudamed.

[3] Directive 98/79/EC of the European Parliament and of the Council on In Vitro Diagnostic Medical Devices (IVDMD), Council Directive 93/42/EEC on Medical Devices (MDD) and Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD).
[4] For further technical information on Eudamed, visit the Eudamed information center.

Registration in the ACT module in accordance with Articles 31 MDR and 28 IVDR will become mandatory 6 months after the publication in the OJEU of the notice confirming its functionality.

Q4. Are there economic operators or other types of actors not in scope of Article 31 MDR and Article 28 IVDR who need to be registered in the ACT module?

Yes, registration in the ACT module is needed for any actor who needs to perform an action in Eudamed. That means that also the following economic operators or other actors need to register in the ACT module:

- System or procedure pack producers (SPPPs) need to register in the ACT module and receive an Actor ID (similar to an SRN) before placing the system or procedure pack on the market.
- Manufacturers who exclusively place custom-made devices on the market need to register in the ACT module and receive an Actor ID before they can use other Eudamed modules, e.g. to report a serious incident regarding a custom-made device.
- Manufacturers who exclusively place class III custom-made implantable devices on the market need to register in the ACT module to enable NB to register the QMS certificates issued in accordance with Article 52(8) 2nd subparagraph MDR.
- Sponsors of clinical investigations/performance studies need to register as actor in the ACT module and receive an Actor ID to be able to use the CI/PS module, e.g. to submit an application for clinical investigation, performance study or report a serious adverse event.

For further information, see Commission Implementing Regulation (EU) 2021/2078 as regards the European Database on Medical Devices (Eudamed), MDCG 2021-13 Rev. 1 – 'Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR[5]' and the infographic on Actor roles and Actor ID/SRN.

Q5. Which economic operators do not have to register in Eudamed?

Distributors are not required to register in Eudamed. However, distributors may be obliged to register at national level in accordance with the requirements applicable in the Member State in which they have made devices available.

Manufacturers (and their authorised representatives), importers, and SPPPs that do not place devices or SPPs on the market anymore after the mandatory use of the UDI/DEV module, do not need to register as Actors. Manufacturers (and their authorised representatives) shall however register if a PMSV action is required.

Q6. When can I register my organisation in the ACT module?

Manufacturers, importers, authorised representatives and SPPPs can already register in the ACT module since December 2020. It is highly recommended that all relevant economic operators (excluding distributors) register in the Actors module without delay to make sure that their registration is submitted by the date of mandatory use of the Actors module.

Register now!

Note: registration of sponsors will be possible only when the CI/PS module will become mandatory to use.

[5] MDCG 2021-13 Rev. 1 is planned to be updated.

UDI/DEVICE MODULE

Clarification of the meaning of 'device/SPP' in the context of device/SPP registration in Eudamed:

In MDR and IVDR the term 'device' almost exclusively refers to each individual device, which means each (sales) unit or single product item that is produced and placed on the market at a certain point in time. However, in Eudamed, device/SPP registration in the UDI/DEV module means registering a device/SPP at the level of the device identifier (excluding production identifiers). The device/SPP identifier is UDI-DI for devices/SPPs that are placed on the market under the Regulations, and EUDAMED ID or UDI-DI for legacy devices[6]. This means that there will be only one registration in the UDI/DEV module covering all individual devices/SPPs per device identifier (UDI-DI or Eudamed ID) but having different production identifiers, UDI-PIs, representing lot number, serial number, manufacturing date etc.

Q7. When will the use of the UDI/DEV module become mandatory?

The obligations and requirements laid down in Article 29 MDR and Article 26 IVDR regarding the registration of devices and systems and procedure packs in the Eudamed UDI/DEV module will become applicable 6 months after the publication in the OJEU of the notice confirming its functionality.

When the placing on the market is done on or after the date of mandatory use:

In case the first individual (sales) unit of a Regulation device (except for custom-made devices, investigational devices and devices for performance studies which should not be registered in the UDI/DEV module) or an SPP with a certain UDI-DI is placed on the EU market on or after the date of mandatory use of the UDI/DEV module, the corresponding device registration in the UDI/DEV module must be done before the first individual unit is placed on the EU market. This device registration covers all individual units being placed on the market with the same UDI-DI[7] subsequently.

When the placing on the market is done before the date of mandatory use:

In case the first (sales) unit of a legacy device[8] or Regulation device[9] (except for custom-made devices, investigational devices and devices for performance studies which should not be registered in the UDI/DEV module) or an SPP with a certain UDI-DI has been placed on the EU market before the date of mandatory use of the UDI/DEV module, and where additional (sales) units belonging to the same UDI-DI will be placed on the market on or after that date, the corresponding device registration in the UDI/DEV module must be done within 12 months from the publication in the OJEU of the notice confirming the functionality of the UDI/DEV module[10]. This device registration covers all individual units belonging to the same[11] UDI-DI.

Example: if the notice confirming the functionality of the UDI/DEV module is published in the OJEU on 1 July 2025, then the UDI/DEV module related requirements in Article 29 MDR and Article 26 IVDR will start applying on 1 January 2026. In case individual units/single products of a device were placed on the market before 1 January 2026 and other individual units/single products will also be placed on the market after that date, the device will have to be registered by 1 July 2026.

---

[6] See also Q8.
[7] For definition of 'same', see Q8.
[8] For the definition of the term 'legacy devices', refer to MDCG 2021-25 Rev. 1 and MDCG 2022-8 (MDCG 2022-8 planned to be updated).
[9] Devices compliant with the provisions of MDR/IVDR, other than legacy devices.
[10] For the rules on registration of legacy contact lenses in Eudamed, refer to the MDCG Guidance on the implementation of the Master UDI-DI solution for contact lenses and spectacle frames – (links to be provided once the Guidance is published).
[11] For definition of 'same', see Q8.

Finally, SPPs covered by Article 22 (1) to (3) MDR must be registered by the relevant SPPPs in the UDI/DEV module. In cases covered by Article 22(4), where the SPP is considered to be a device in its own right, it needs to be registered as 'device' in the UDI/DEV module[12].

Note: when submitting all required device information in the UDI/DEV module, the manufacturer has complied with its obligations regarding device registration as per Articles 29 MDR and 26 IVDR. For certain devices, the UDI and device data will become visible to the public only once the NB has entered the corresponding product certificate information in the NB/CRF module.

Q8. Which devices do not need to be registered in the UDI/DEV module?

Legacy and Regulation devices where individual (sales) unit are no longer placed on the market when the UDI/DEV module becomes mandatory, do not need to be registered, unless a PMSV action occurs.

Moreover, legacy devices do not need to be registered if 'the same device' is already registered as a Regulation device. In this context, 'the same device' means that Regulation device and legacy device have the same identification[13] such as UDI-DI[14], and/or catalogue/reference number and/or trade name which follows from shared characteristics. See exception from this general rule in Q14.

Note: devices where changes have been made for the Regulation device, which would lead to the assignment of a new UDI-DI, would not be considered as 'the same device'.

'Old' devices as described in MDCG 2021-25 Rev. 1 and MDCG 2022-8 cannot be registered in the UDI/DEV module. If the device is the subject of a serious incident report (MIR) or field safety corrective action (FSCA), the manufacturer will need to provide a limited device data set to submit the relevant report in the VGL module.

Custom-made devices cannot be registered in the UDI/DEV module either. If the custom-made device is the subject of a MIR or FSCA, the manufacturer will need to provide a limited device data set to submit the relevant report in the VGL module.

Q9. When can I start registering devices/SPPs in the UDI/DEV module?

The UDI/DEV module has been available for voluntary use since October 2021. Devices/SPPs can already be registered since that date. It is highly recommended to register devices and SPPs in the UDI/DEV module as soon as possible and to not wait until its mandatory use starts.

Note: until the mandatory use of the UDI/DEV module, national registration requirements may apply. Once the UDI/DEV module becomes mandatory, in case of registration in both the national system and Eudamed, the already existing registration of the device/SPP in the UDI/DEV module will become the legally required registration.

Register now!

[12] Pursuant to Article 22 (4) MDR, the natural or legal person shall assume the obligations incumbent on manufacturers and needs to register in the Eudamed Actor module as a manufacturer.
[13] Uniqueness of the UDI-DI refers to devices under MDR/IVDR only. Uniqueness checks are implemented in Eudamed when registering a device. For further information, please refer to the Eudamed documentation on the UDI/DEV module in the Eudamed information centre.
[14] Legacy devices are not subject to UDI requirements under MDR/IVDR. However, those devices are not prevented from being assigned UDI-DIs or may for example have been placed on other markets where UDI rules are in place. The assignment of UDI-DIs for compliance with other jurisdictions' rules is not relevant for EU compliance purposes.

NOTIFIED BODIES AND CERTIFICATES MODULE

Q10. When will the use of the notified bodies and certificates (NB/CRF) module become mandatory?

The obligation and requirements that relate to the Eudamed NB/CRF module will become applicable 6 months after the publication in the OJEU of the notice confirming its functionality.

This means that any certificate, issued after the NB/CRF module becomes mandatory, must be registered in the NB/CRF module.

Updates and decisions issued after the mandatory use of the NB/CRF module in relation to Regulation certificates issued before the mandatory use of the NB/CRF module, must be registered in the NB/CRF module.

The following provisions are concerned for NBs:

Provision	**Title /Content**
Art. 53(2) MDR and Art. 49(2) IVDR	Exchange between NBs on their decisions regarding the applications for conformity assessment in case of withdrawal and refusal of applications
Art. 54(3) MDR	Clinical evaluation consultation procedure for certain class III and class IIb devices (CECP)
Art. 55(1) MDR and Art. 50(1) IVDR	Mechanism for scrutiny
Art. 56(5) MDR and Art. 51(5) IVDR	NBs enter in Eudamed: information regarding certificates issued, including amendments and supplements thereto, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates

The following provisions are concerned for DAs:

Provision	**Title /Content**
2nd subpara of Art. 44(12) MDR and 2nd subpara of Art. 40 (12) IVDR	Monitoring and assessment of NBs
Art 46(7)(d) and (e) MDR and Art. 42(7) (d) and(e) IVDR	Changes to designations and notifications (exchange of information between DAs and competent authorities on requests for suspension or withdrawal of certificates)

For certificates issued in accordance with the MDR/IVDR before the mandatory use of the NB/CRF module the NBs have to register the related information in Eudamed within 18 months after the notice confirming the functionality of the NB/CRF module has been published in the OJEU. This only applies to Regulation devices that need to be or are registered in the UDI/DEV module. Moreover, only the latest certificate version and, if applicable, the latest NB decision taken in relation to that certificate version should be registered in Eudamed.

Note: pursuant to Articles 40(2), 42(10) and 43(2) MDR and Articles 36(2), 38(10) and 39(2) IVDR (publication of the national experts for joint assessment, list of NBs retrieved by NANDO and related notifications) the Commission will manage the relevant information in Eudamed.

Clarification on CECP (Article 54 MDR) and Mechanism for Scrutiny (Article 55(1) MDR/Article 50(1) IVDR)

After the NB/CRF module becomes mandatory, the obligation to provide the information under the mechanism for scrutiny (MfS) in Eudamed will apply when the certificate is registered in the NB/CRF module.

Until mandatory use of the NB/CRF module, certificates may be registered in Eudamed without the CECP and MfS functionalities. For such certificates, after the mandatory use, there will be a possibility to indicate that the CECP and possibly also the MfS were carried out outside Eudamed. If the NB had not notified pursuant to the MfS outside Eudamed before mandatory use of the NB/CRF module, it must be done in Eudamed when registering the certificate, even if the CECP registration was done outside Eudamed.

Clarification on SS(C)Ps

The obligation for NB to upload the SS(C)P in accordance with Articles 32(1) MDR and 29(1) IVDR apply from the moment when the related certificate is registered in Eudamed.

Q11. When can notified bodies start using the NB/CRF module?

The NB/CRF module has been available for voluntary use since October 2021. NB can already register certificates and SS(C)Ps in Eudamed.

If the NB/CRF module is used to register certificate information, all subsequent updates and decisions related to the first registered certificate (e.g. withdrawal, suspensions, reinstatements) have to be registered in Eudamed (this is also applicable during the voluntary period).

It is highly recommended to register certificates in the NB/CRF module as soon as possible and to not wait until its mandatory use starts.

Register now!

POST-MARKET SURVEILLANCE AND VIGILANCE MODULE

Q12. When will the use of the Post-Market Surveillance and Vigilance (VGL) module become mandatory?

The obligation and requirements that relate to the Eudamed VGL module will become applicable 6 months after the publication in the OJEU of the notice confirming its functionality.

The following provisions are concerned for CAs, NBs, manufacturers and/or authorised representatives:

Provision	Title /Content
Art. 86(2) MDR and Art. 81(2) IVDR	Periodic safety update report
Art. 87 MDR and Art. 82 IVDR	Reporting of serious incidents (including periodic summary reports) and field safety corrective actions (with field safety notice (see below))
Art. 88 MDR and Art. 83 IVDR	Trend reporting
Art. 89(5), (7) and (9) and 3rd subpara of Art. 89(8) MDR and Art. 84(5), (7) and (9) and 3rd subpara of Art. 84(8) IVDR	Analysis of serious incidents and field safety corrective actions with the subsequent exchange of information between national competent authorities (with possible coordinated assessment and identification of a coordinating CA) and field safety notice publication by the manufacturer.

Note: Articles 90 MDR and 85 IVDR (analysis of vigilance data) will be implemented after the first mandatory version of the VGL module is made available.

Q13. When can I start using the VGL module?

The VGL module is not available for voluntary use. It will be released when it becomes mandatory and will have to be used from that moment. Therefore, economic operators need to continue using the national processes as explained in MDCG 2021-1 Rev. 1 and MDCG 2022-12 for compliance with MDR/IVDR vigilance provisions.

The submission of required PSURs (see Abbreviations section) and vigilance reports in Eudamed by manufacturers and authorised representatives and NCARs by CAs will start when the use of the VGL module becomes mandatory.

Note: for vigilance reports initiated in accordance with the national process in the absence of Eudamed and still open when the VGL module becomes mandatory to use, the subsequent actions should be done in Eudamed[15]. This does not imply retrospective registration of the vigilance report, only the actions occurred as from when the use of the VGL module will be mandatory are to be done in Eudamed.

Example: A serious incident related to a device is reported following national processes on 1 April 2026. If the VGL module becomes mandatory on 1 July 2026 and a follow up version of the serious incident report (MIR) is available on 1 August 2026, then this version of the MIR should be reported in Eudamed.

Q14: which devices need to be registered in UDI/DEV module only when a PMSV action occurs?

Regulation devices and legacy devices for which no individual (sales) units are placed on the market from the date when the UDI/DEV module becomes mandatory, only need to be registered in the UDI/DEV module when the manufacturer has to perform any PMSV action in the VGL module (see also Q8). In order to do so, the manufacturer and authorised representative where applicable, must first be registered as Actor in the ACT module.

Example: A Regulation device was placed on the market from May 2021 until November 2025. If the UDI/DEV module becomes mandatory on 1 January 2026, then the device does not need to be registered in Eudamed. If the VGL module becomes mandatory on 1 July 2026 and a serious incident related to the device occurs in September 2026, then the device must be registered in the UDI/DEV module to enable to report the serious incident in the VGL module.

In the case a vigilance action, which is to be reported in Eudamed (e.g. report of a serious incident, a FSCA/FSN or Trend report) concerns the legacy device[16] and not 'the same' Regulation device, the legacy device must exceptionally be registered in the UDI/DEV module and referenced for the PMSV action to be entered in the VGL module[17]. This is without prejudice to the principle that legacy devices do not need to be registered if 'the same device' is already registered as a Regulation device (see Q8 regarding what can be considered as 'the same device').

MARKET SURVEILLANCE MODULE

Q15. When will the Market surveillance (MSU) module become mandatory?

[15] To be noted that in this context, Eudamed will allow the registration of the first version of vigilance reports in the VGL module that is not an 'Initial' one (e.g. follow up, final). This possibility will be temporary (until a time to be determined depending on the type of vigilance report – MIR, FSCA etc allowing to have all ongoing reports initiated before mandatory use registered in Eudamed).
[16] Legacy devices, custom-made devices and old devices do not require a PSUR in Eudamed, as per MDCG 2021-25 and MDCG 2022-21.
[17] In case of PMSV action where the Regulation device is referenced, but the action concerns also the legacy, Eudamed will provide the possibility to flag that the legacy is concerned without it being registered in the UDI/Dev module.

The obligation and requirements that relate to the Eudamed MSU module will become applicable 6 months after the publication in the OJEU of the notice confirming its functionality.

Note: Access to the MSU module is restricted to competent authorities and NB for viewing where applicable, and data for this module are managed only by competent authorities.

Q16. When can competent authorities start using the MSU module?

The MSU module is not available for voluntary use. It will be released when it becomes mandatory and will have to be used by competent authorities from that moment.

CLINICAL INVESTIGATIONS/PERFORMANCE STUDIES MODULE

Q17. When will the Clinical investigations/Performance studies (CI/PS) module become mandatory?

The obligations and requirements that relate to the Eudamed CI/PS module and sponsors registration in the ACT module will become applicable 6 months after the publication in the OJEU of the notice confirming the functionality of the CI/PS module.

Q18. When will the coordinated assessment referred to in Articles 78(14) MDR and 74(14) IVDR become applicable?

The coordinated assessment procedure will become applicable 6 months after the publication in the OJEU of the notice confirming functionality of the CI/PS module for those Member States which have agreed to apply it ('voluntary' phase).

After 5 years from the publication in the OJEU of the notice confirming functionality of the CI/PS module, the coordinated assessment will become mandatory for all Member States when a sponsor submits a single application.

Q19. Will the coordinated assessment procedure be possible in the absence of Eudamed?

The coordinated assessment procedure for clinical investigations and performance studies referenced in Article 78 MDR and Article 74 IVDR is based on the use of the CI/PS module of Eudamed. However, before the CI/PS module is available, Member States and sponsors may agree to make arrangements for a coordinated assessment with alternative means, according to the guidance that will be provided by the MDCG.

Q20. When can I start using the CI/PS module?

The CI/PS module is not available for voluntary use, it will be released when it becomes mandatory and will have to be used from that moment.

Annex: Flowchart

Gradual rollout of EUDAMED – device registration timelines

Disclaimer: this flowchart needs to be read in conjunction with the text in
'*Q&A on practical aspects related to the implementation of the gradual roll-out of Eudamed pursuant to the MDR and IVDR*'

Used abbreviations and terms / footnotes:

T1: date corresponding to 6 months after publication in OJEU of Commission notice on the functionality of the UDI/DEV module

T2: date corresponding to 12 months after publication in OJEU of Commission notice on the functionality of the UDI/DEV module

T3: date corresponding to 6 months after publication in OJEU of Commission notice on the functionality of the VGL module.

For use of this flowchart, it is assumed that the Vigilance module becomes mandatory after the use of the UDI/DEV module becomes mandatory and all transitional periods for device registration are expired: T3 ≥ T2

Vigilance action shall be the submission of

- a report of a serious incident, periodic summary report or FSCA/FSN for an Old, Legacy, Custom-Made or Regulation Device, or
- a trend report for a Legacy or Regulation Device

to EUDAMED.

PMSV action shall be the submission of

- a PSUR for a Class III or implantable (except custom-made) or Class D Regulation device, or
- a Vigilance Action

to EUDAMED.

For the meaning of "**same device**", refer to the text in Q8 of the Q&A.

Reference is made to MDCG 2021-25 Rev.1 and 2022-8 for the defined terms:

- Old devices (in context of MDR or IVDR respectively)
- Legacy devices (under MDR)
- MDR devices
- IVDR devices

Reference is made to the description contained in amended Article 110(3) IVDR:

- Legacy devices (under IVDR)

Used in this flowchart:

Old devices: are Old devices in context of MDR or IVDR,

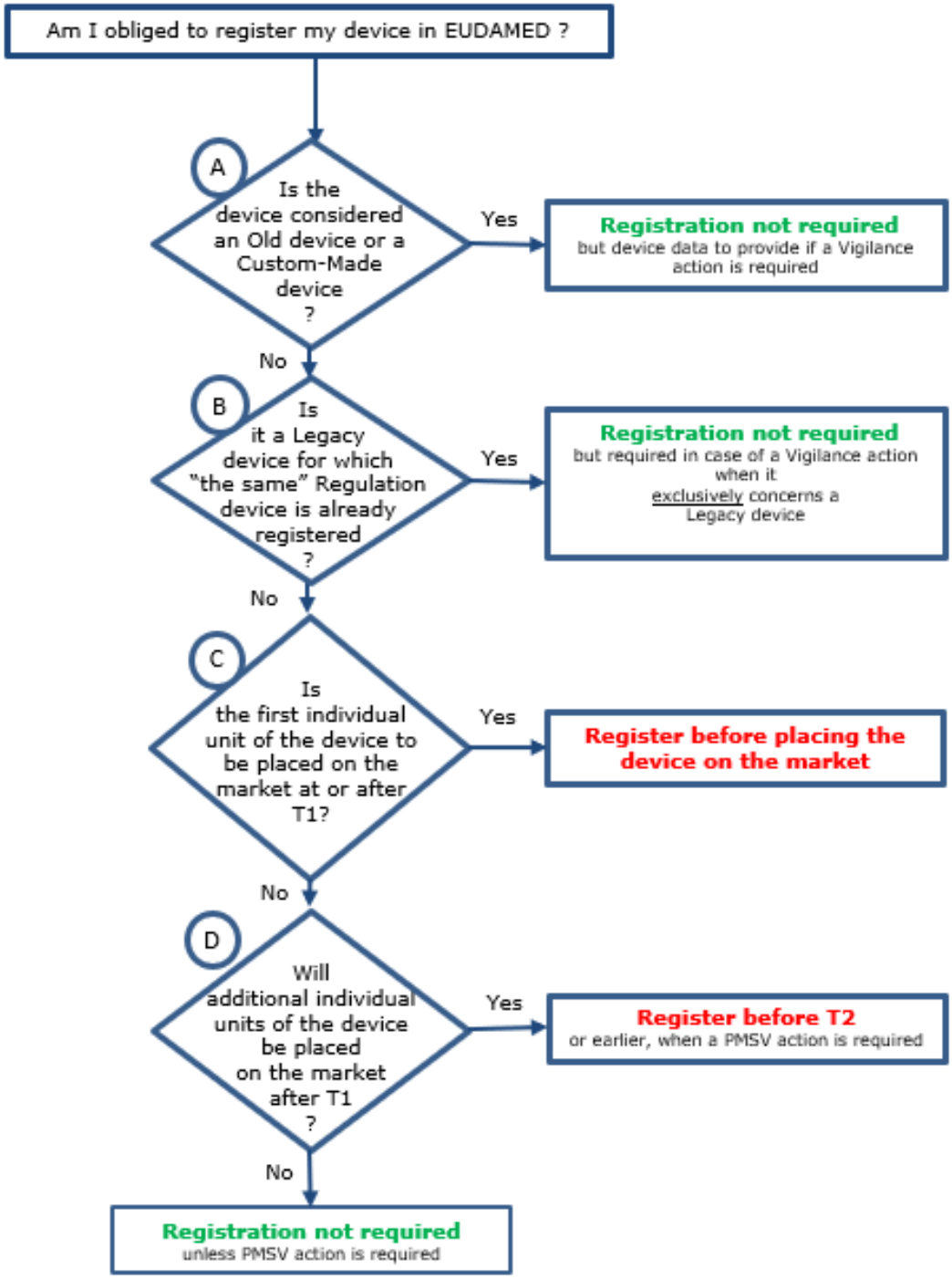
Legacy devices: are Legacy devices under MDR or IVDR,

Regulation devices: are MDR devices or IVDR devices.

<u>Gradual rollout of EUDAMED</u>:

Registration of devices in EUDAMED

- in regular cases on or after T1



Gradual rollout of EUDAMED:

Registration of devices in EUDAMED

- in case of a PMSV action on or after T3