Questions and answers regarding prolonged transitional provisions of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR)

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SIEMENS Healthineers

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1. Purpose and Applicability

1.1 Purpose

This Questions and Answers document is intended to support understanding of the extended transitional provisions of the European Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), as set up by **Regulation 2022/112** published on 28 January 2022[3] and amending the IVDR and allowing for a progressive rollout of new requirements for legacy IVD devices under the new legislation.[1,2] The amendment is applicable in all EU member states with immediate effect.

This document is based on the Amending Regulation 2022/112,[3] the Commission's Questions and Answers on the progressive rollout of the IVDR,[4] and also on the experience gained from the transitional provisions under the EU MDR that include a similar concept of stepwise implementation for legacy devices.

1.2 Applicability

This document can be used to foster understanding of the proposed change to transitional provisions allowing a progressive rollout of the IVDR and granting selected IVDD-compliant devices[2] a prolonged transition under the IVDR when certain preconditions are met.

However, this document is not intended to provide in-depth guidance on "old or directive devices" (IVDD-compliant products that were placed on the market prior to the date of application of the IVDR DoA: 26 May 2022).

2. General Questions on IVDR transition phase

2.1 Why were longer transition periods to implement the IVDR granted by the EU policy makers?

Short answer

Due to resources being diverted to address the COVID-19 pandemic and the substantial changes introduced by the IVDR, member states' authorities, health institutions, notified bodies, and economic operators faced challenges in fully meeting the requirements of the IVDR at the date of application on 26 May 2022.

Explanatory information
Due to resources being diverted to address the COVID-19 pandemic and the substantial changes introduced by the IVDR, member states' authorities, health institutions, notified bodies, and economic operators faced challenges in fully meeting the requirements of the IVDR at the date of application on 26 May 2022.

Only a few notified bodies were designated under the IVDR close to the date of application. Therefore, there was a grave shortage of notified body (NB) capacity, making it difficult for manufacturers to conduct the legally required conformity assessment procedures in time. As the designated notified bodies under the IVDR covered only few of the EU member states, the situation was particularly problematic for other member states, which tend to apply to notified bodies in their own or neighboring member states.

If not addressed, this situation would have led to a significant disruption in the supply of a multitude of IVDs on the EU market, both for health institutions and the public.

Originally, Article 110 of the IVDR provided for a prolonged transitional period until 26 May 2024, for IVDs with a certificate issued by a notified body in accordance with the IVDD prior to 26 May 2022. However, only about 8% of all devices in the diagnostics market would have benefited from the original transitional provision.

To address the shortage of notified body capacity more broadly, the EU policy makers agreed on additional transitional periods for devices that must undergo a conformity assessment involving notified bodies for the first time under the IVDR. The amendment differentiates between risk classes, with a transition period until May 2025 for high-risk devices (class D), until May 2026 for class C devices, and until May 2027 for lower-risk devices (class B and A sterile). This approach aims to balance the available notified body capacity with high level of public health protection.

2.2 Is the application of the entire IVDR postponed?

Short answer
No, only transition periods for selected device groups are extended.

Explanatory information
No. The general application date of the IVDR remained unchanged: 26 May 2022. In particular, the IVDR applies from 26 May 2022, to CE-marked IVDs that do not require the involvement of a notified body (i.e., class A non-sterile devices, which represent around 20% of the market, e.g., the majority of IVD instruments, buffers, accessories without critical characteristics, and general culture media) and to "new" IVD products (i.e., those not covered by a certificate or a manufacturer's DoC issued prior to 26 May 2022).

2.3 Do the additional transitional periods compromise public health or patient safety in the EU?

Short answer
No, they safeguard the availability of vital IVD products in the EU after the date of application of the IVDR.

Explanatory information
The additional transitional periods are necessary to avoid disruption in the supply of essential IVDs. Otherwise, the diagnosis of patients and their access to relevant health care could be at risk. It is estimated that about 70% of clinical decisions rely on IVDs.*

Only those products that were on the EU market in accordance with the IVDD prior to 26 May 2022, and which are therefore deemed to be safe and performant, can benefit from the prolonged transitional periods. Starting from the date of application, newly developed and launched IVDs and products that have undergone a significant change in design or intended purpose must fully comply with new IVDR requirements to be CE-marked and placed on the EU market.

Moreover, manufacturers must prepare for the certification procedures under the IVDR as soon as possible. That means that they must adapt their quality management system, products, and technical documentation and apply to a notified body well before the end of the transition periods. In addition, the reinforced requirements under IVDR on PMS, vigilance, and registration also apply from 26 May 2022, to devices that benefit from the transitional periods.

**Rohr U-P, Binder C, Dieterle T, Giusti F, Messina CGM, Toerien E, et al. The value of in vitro diagnostic testing in medical practice: a status report. PLoS ONE. 2016;11(3):e0149856.*
†For the current status of notified body designations, see https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=35

2.4 Why are there so few notified bodies designated under the IVDR prior to the date of application?

Short answer
The main reasons are:

- Strengthened requirements for notified bodies (NB)
- Significantly longer and more complex designation processes
- Decrease in the number of NBs (e.g., caused by resource issues, Brexit)

Siemens Healthineers is among a few manufacturers that have worked from the beginning with two notified bodies that were designated early under the IVDR to ensure timely IVDR compliance and product availability in the EU market.

Please note that class D products require additional approval processes and consequently additional resources, such as designated reference laboratories or expert panels.

Explanatory information
Under the IVDD, 18 notified bodies were designated, versus only 7 notified bodies that were designated under the IVDR in August 2022, and further designations are pending.† The IVDR has significantly reinforced the criteria for the designation and oversight of notified bodies. While this is necessary to ensure a high level of safety and device performance, it also makes it more challenging for a candidate notified body to apply and become designated under the IVDR.

Together with member states' authorities and stakeholders, the EU Commission will closely monitor the situation on the EU market, including notified body capacity and preparedness of manufacturers to submit applications for certification, and consider measures to address the shortage of notified body capacity.

2.5 What is the status of the European medical devices database (EUDAMED)?

Short answer
The European medical devices database EUDAMED is not yet fully functional and operational. Only single modules are ready for voluntary use.

Explanatory information
The European medical devices database, EUDAMED, will provide an overview of all medical devices available in the European Union. It will be composed of six modules: actor registration, unique device identification (UDI) and device registration, notified bodies and certificates, clinical investigations and performance studies, vigilance, and market surveillance. It will integrate different electronic systems with information about medical devices and related companies (e.g., manufacturers).

The development of EUDAMED is progressing, with the first module, actor registration, made available in December 2020. Since October 2021, the second and third modules have been available, namely the UDI/device registration module (which can be used on a voluntary basis) and the certificates and notified bodies module, except for the mechanism for scrutiny and the clinical evaluation consultation procedure functionalities (CECP). The remaining modules, as well as the functionalities for the mechanism for scrutiny and the CECP, will be released when EUDAMED is fully functional.

The European Commission is continuing to work in close cooperation with EU member states on this highly complex project.

2.6 Why has a longer transition time been granted for in-house tests* according to Art. 5.5 IVDR?

Short answer
Due to the COVID pandemic, health institutions need more time for the implementation of the new rules for in-house tests.

**In-house tests, also referred to as laboratory-developed tests, are manufactured and used by a health institution or laboratory and thereby address on a non-industrial scale the specific needs of target patient groups that cannot be met by equivalent CE-marked devices available on the European market. In-house tests are not marketed or transferred to other legal entities and do not bear the CE marking but must comply with the requirements stipulated in Article 5.5 IVDR. In-house devices developed in laboratories can be essential for diagnosis and treatment, especially for rare diseases.*

Explanatory information
Except for the general safety and performance requirements specified in Annex I of the IVDR, in-house devices are exempted from the IVDR, provided the health institution meets several conditions set out in Article 5.5 of the IVDR. Among other things, health institutions must have an appropriate quality management system, comply with the international standard defining the quality and competence requirements for medical laboratories (EN ISO 15189) or other national provisions for the same, and justify that the specific needs of target patient groups cannot appropriately be met by an equivalent in vitro diagnostic medical device available on the market.

Since the outbreak of the pandemic, many health institutions, in particular hospitals, have had to focus their efforts on dealing with COVID-19. The amendment defers the application of most of the conditions to be met by health institutions making in-house devices by 2 years, until 26 May 2024. The requirement for the justification that there is no equivalent CE-marked device available to meet the target patient group's specific needs is deferred even further, until 26 May 2028, as the health institutions will need an overview of CE-marked IVDs available on the EU market to comply with this requirement.

2.7 Is the entire Art. 5.5 for in-house tests postponed?

Short answer
No. Art. 5.5 IVDR point (a) is not postponed.

Explanatory information
According to the amendment, only point (b) to (i) of Article 5.5 IVDR are postponed with different transition times. The transition times are defined as follows:

- Point (a), transfer of IHT to another legal entity: shall apply from 26 May 2022,
  = no additional transition time is granted.
- Points (b), (c), and (e) to (i), implementation of QMS, compliance with ISO 15189, providing information to competent authority, publish public declaration, compiling documentation for class D IHT, review experience from clinical use: shall apply from 26 May 2024,
  = 2 years' additional transition are granted.
- Point (d), justification: shall apply from 26 May 2028,
  = 6 years' additional transition are granted.

2.8 Why is there no prolonged transition for self-declared class A products?

Short answer
Postponement was not deemed necessary for self-declared class A products.

Explanatory information
The conformity assessment of class A devices is performed by the manufacturer and does not require involvement of a notified body. Thus, these products are not affected by the limited number and capacity of notified bodies under IVDR. Therefore, policy makers considered that 5 years' transition was sufficient for manufacturers to transfer these products to IVDR compliance.

2.9 Why was a staggered approach by risk classes over several years introduced?

Short answer
Due to the focus on public health and safety and making the regulatory system workable.

Explanatory information
The higher-risk classes should comply earlier with the new rules since they bear more risk to patients. The stepwise implementation also allows manufacturers and notified bodies to manage the transition with available resources, unlike what would be necessary if thousands of products had to be certified more or less concurrently. Furthermore, time is needed to build up notified body capacity and ensure that notified bodies have the capacity to approve new devices.

2.10 When did the amendment for the prolonged transition phase become effective?

Short answer
28 January 2022.

Explanatory information
The IVDR amendment establishing a prolonged transition was approved by the policy makers in December 2021 and published in the Official Journal of the EU on 28 January 2022, as **Regulation 2022/112.**[3] It became effective on the day of its publication and was immediately legally binding in all EU member states.

3. Detailed questions on the interpretation of the IVDR prolonged transition phase

3.1 What is the length of the transition time?

Short answer
3–5 years, depending on the risk class and device category.

Explanatory information
The length of the transition time differs and depends mainly on the future risk class and device category:

1. IVDR application date remains unchanged: 26 May 2022.
2. Additional transitional periods are granted **only for defined product classes/groups under specified conditions**,* with +3 to +5 years to fully comply with the IVDR.
    a. IVDD devices that have a valid IVDD certification† may be produced and placed on the EU market until 26 May 2025, unless the IVDD certificate expires earlier.
    b. Self-declared IVDD devices that will be in class D under IVDR may be produced and placed on the EU market until 26 May 2025.
    c. Self-declared IVDD devices that will be in class C under IVDR may be produced and placed on the EU market until 26 May 2026.
    d. Self-declared IVDD devices that will be in class B or class A sterile under IVDR may be produced and placed on the EU market until 26 May 2027.
    e. Self-declared IVDD devices that will be in class A under IVDR may not benefit from the prolonged transition and **must fully comply** with the **IVDR** starting from 26 May 2022.
3. No additional grace period is given for self-declared class A devices. Most instruments must comply with the IVDR from 26 May 2022.
4. New devices released after the date of application (26 May 2022) must comply with the IVDR and cannot benefit from the additional grace period.
5. Devices that are significantly changed after the date of application (26 May 2022) cannot continue to benefit from the additional transition and must either comply with the IVDR or the manufacturer must cease placing them on the EU market.
6. Sell-off provisions: After the prolonged transition period ends, +1 year is granted for further distribution of IVDD-compliant devices in the EU.

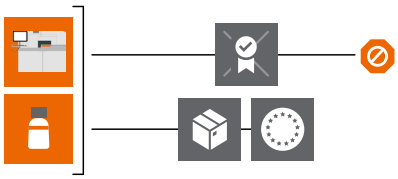
See also the following images:

**The conditions are as follows: valid EC certificate or DoC under IVDD, no significant change, and compliance with selected requirements of the IVDR (PMS, vigilance, and registration)*
†IVDD devices for self-testing and Annex II List A and B devices.

In Vitro Diagnostic Device Regulation (IVDR) transition plan to ensure continuous availability of products

26 May 2022

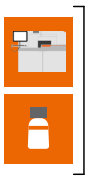
IVDR certification must be achieved for new products and products that significantly changed.



Self-declared class A devices must comply with the IVDR effective on the date of application: 26 May 2022.

Prolonged transition phase of IVDD products

Healthcare providers and patient care will benefit from the additional transitional provisions granted by the legislators, which allow continuing shipping of vital IVD products into the EU for a longer transition period.



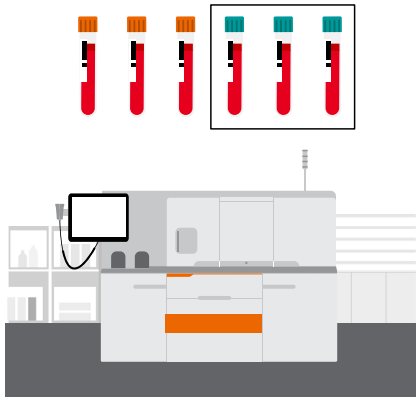
Class B*+	Medium risk for individual patients, e.g., hematology, general chemistry tests	May 2027‡
Class C+	High risk for individual patients, e.g., cancer markers, infectious diseases	May 2026‡
Class D+	High public health risk and high individual risk, e.g., blood safety/high-risk infectious diseases	May 2025‡

Siemens Healthineers will continue to pursue implementation of the IVDR requirements till May 2022 as originally planned, while healthcare providers will benefit from the prolonged transition phase to continue to offer good patient care.

IVDD → IVDR | IVDR transition phase

In Vitro Diagnostic Device Regulation (IVDR): changed regulatory requirements for lab operations,* such as in-house tests (IHT)

Significant change† to intended purpose of a product used on **Siemens Healthineers systems**



Fulfill requirements of Article 5.5 IVDR

IVDR application date for IHT* will not change for new IHT: 26 May 2022.
A prolonged transition phase is granted by legislators for existing in-house tests.

Healthcare providers will benefit from the extended transitional provisions, which allow continuing with existing IHT* for a longer time period.

No transfer of IHT to another legal entity, laboratory	May 2022
Conditional grace period for IHT,* e.g., implementation of QMS, compliance with ISO 15189, providing information to competent authority, publishing public declaration.	May 2024
Record justification that IHT is needed‡	May 2028

Lab operations can include in-house tests (IHT), lab-developed tests (LDT), research use only (RUO), user-defined methods (UDM), and off-label use of a CE-marked IVD.

†Significant change may include but is not limited to design change, change of intended purpose, specimen type change, adding indications for use, changing/adding testing population. Example: modification of a CE-marked device.*

‡Record justification that IHT is needed: Proof of other specific needs of targeted patients that cannot be met at the appropriate level of performance by the equivalent CE-marked device available on the market.*

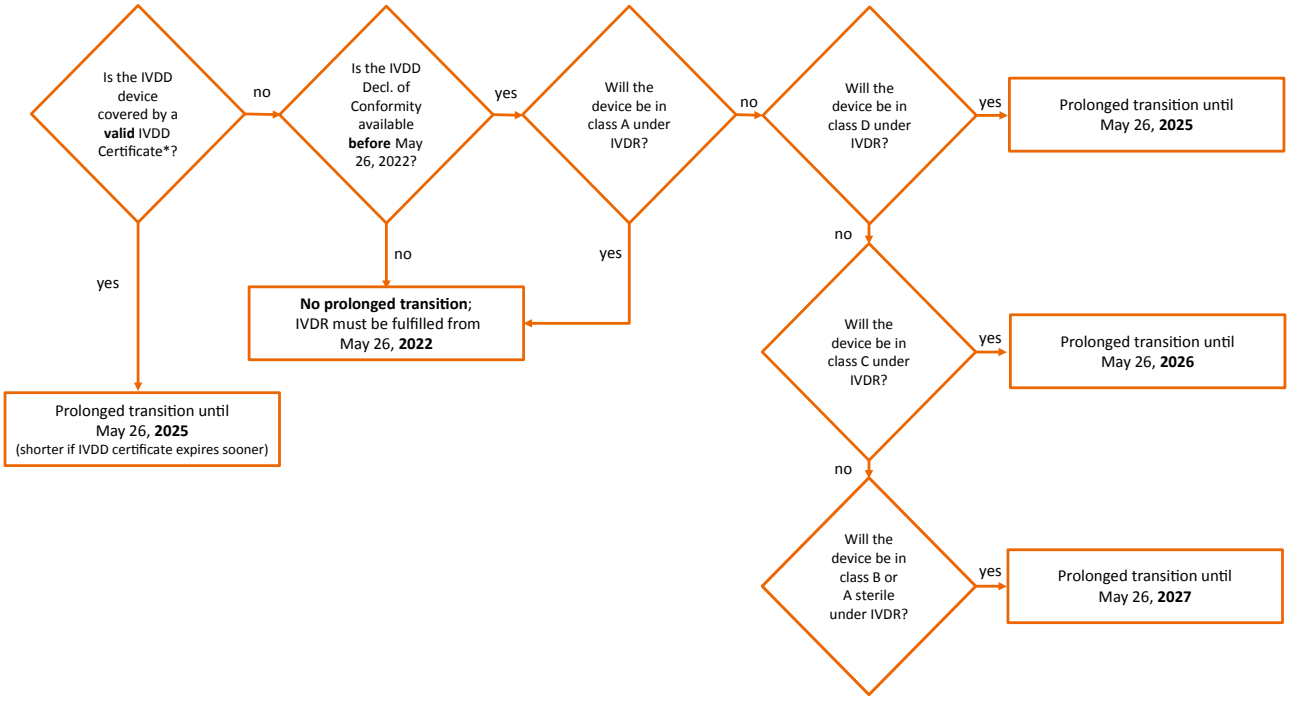
3.2 How do I know which transition time applies to a device?

Short answer

You must consider the device category and the future risk class under the IVDR.

Explanatory information

Use the decision tree below:



3.3 What are the key changes in transition time and sell-off provisions for specific device classes/groups?

Short answer

1. IVDR application date remains unchanged: 26 May 2022.
2. Additional grace periods are granted only for defined product classes/groups under specific conditions: +3 to 5 years to fully comply with the IVDR.

   Conditions: valid EC certificate or DoC under IVDD, no significant change, and compliance with selected requirements of the IVDR (PMS, vigilance, and registration).

   No additional grace periods are given for self-declared class A devices (non-sterile):
   The majority of instruments, buffers, accessories without critical characteristics, general culture media, etc. must fully comply with the IVDR on 26 May 2022.
3. New devices released after the date of application (26 May 2022) must comply with the IVDR and cannot benefit from the additional grace period.
4. Prolonged transition is also granted for so-called "in-house tests/lab-developed tests":
   +2 years and +6 years for the justification.
5. Sell-off provisions: After the grace period ends, +1 year is granted for further distribution of IVDD-compliant devices in the EU.

Explanatory information

The following table contains detailed information on prolonged transition and sell-off provisions per device category and risk class:

**IVDD devices for self-testing and Annex II List A and B devices*

Type	Date of placing on the EU market	Status under IVDD	Possible risk class under IVDR	Deadline for transition to IVDR	Conditions for application	Compliance with PMS, V and registration requirements acc. IVDR from DoA?
Directive devices	**Prior DoA (26 May 2022)**	**Self-declared IVDD products** (General IVDD products without NB)	N/A	N/A	N/A	Only vigilance & registration requirements
		IVDD Annex II list A and B and self-tests (with valid IVDD Certificate with NB)				
Legacy devices	**Starting from DoA (26 May 2022)**	**IVDD Annex II list A and B and self-tests** (with valid IVDD Certificate with NB)	**B**, **C** or **D**	**26 May 2025**	• **Valid IVDD Certificate** issued by NB prior DoA (26 May 2022) • Continued compliance with IVDD • **No significant changes** to design/Intended Purpose • **IVDR req. on PMS, Vigilance and Registration** must be fulfilled	Yes
		Self-declared IVDD products (General IVDD products without NB)	**D** (Up-classified under IVDR with NB)	**26 May 2025**	• **Valid IVDD EU DoC** issued prior DoA (26 May 2022) • Continued compliance with IVDD • **No significant changes** to design/Intended Purpose • **IVDR req. on PMS, Vigilance and Registration** must be fulfilled	
			C (Up-classified under IVDR with NB)	**26 May 2026**		
			B (Up-classified under IVDR with NB)	**26 May 2027**		
			A sterile (Up-classified under IVDR with NB)	**26 May 2027**		
Regulation devices	**Starting from DoA (26 May 2022)**	**Self-declared IVDD products** (General IVDD products without NB)	**A** (Self-declared under IVDR without NB)	**26 May 2022**	**Full applicability of IVDR**	Yes
		New / significantly changed devices (not covered by valid IVDD Certificate or IVDD EU DoC)	**A**, **B**, **C**, **D**			

3.4 Do all self-declared IVDD-compliant devices benefit from the prolonged transition?

Short answer

No. Self-declared IVDD devices that will be in Class A (i.e., remain self-declared under the IVDR) must comply with the regulation from the date of application, 26 May 2022.

Explanatory information

Only self-declared IVDD devices that have a valid Declaration of Conformity issued before the date of application (26 May 2022) and that will be up-classified and require notified body involvement under the IVDR may benefit from the prolonged transition.

Self-declared IVDD devices that remain self-declared and will not require NB involvement under the IVDR (class A) may **not** benefit from the prolonged transition and must comply with the IVDR from the date of application (26 May 2022). For example, the majority of IVD instruments, buffers, accessories without critical characteristics, and general culture media that will be class A under the IVDR must comply with the entire IVDR from 26 May 2022.

3.5 Must IVDD devices that benefit from the prolonged transition be registered in the European medical device database (EUDAMED)?

Short answer
Yes, as soon as the EUDAMED is fully operational.

Explanatory information
In principle, the registration in EUDAMED is also mandatory for IVDD devices that benefit from the prolonged transition.[10] However, the registration can be only performed when the EUDAMED is fully operational. Until then, the registration requirements of the IVDD continue to apply, but in addition, voluntary use of the finalized EUDAMED modules is possible.[5,9,10,11,12,13,15,16]

Please consider that in some EU member states, the use of finalized EUDAMED modules may be mandatory and must be followed (e.g., in Germany) prior to full EUDAMED functionality.

3.6 Must economic operators who market IVDD devices that benefit from the prolonged transition be registered in the European medical device database (EUDAMED)?

Short answer
Yes, as soon as EUDAMED is fully operational.

Note: This applies to manufacturers, authorized representatives, and importers only. Distributors are **not** required to be registered in EUDAMED at all.

Explanatory information
Registration in EUDAMED is also mandatory for economic operators (e.g., legal manufacturer, authorized representative, and importer) who market IVDD devices that benefit from the prolonged transition in the EU.

However, registration can be only performed when EUDAMED is fully operational. Until then, the registration requirements of the IVDD continue to apply, but voluntary registration in EUDAMED is possible and desirable.[12,13]

Please consider that in some EU member states, the use of finalized EUDAMED modules may be mandatory and must be followed (e.g., in Germany).

Distributors are not required to register in EUDAMED; it is in fact not possible for them to do so. However, distributors may be required to register in local databases in the EU member state where they are based.

Detailed information is provided in the dedicated Medical Device Coordination Group (MDCG) Guidance MDCG 2022-8[9] and further guidelines.[5,10,11,12,13,15,16]

3.7 Is a Unique Device Identification (UDI) required for IVDD devices that benefit from the prolonged transition?

Short answer
The IVDR does not require UDI for IVDD devices that benefit from the prolonged transition. Siemens Healthineers has UDIs in place for the majority of products.

Explanatory information
Art. 110.3 does not require UDI for "legacy devices" (IVDD-compliant devices that benefit from the prolonged transition).[9]

3.8 Can self-declared IVDR devices (class A) benefit from the prolonged transition?

Short answer
No.

Explanatory information
Art. 110.3 does not require UDI for "legacy devices" (IVDD-compliant devices that benefit from the prolonged transition).[9]

3.9 Do self-declared IVDR devices (class A devices that cannot benefit from the prolonged transition) require an IVDR compliance certificate?

Short answer
No.

Explanatory information
Regarding class A (non-sterile) IVDs, the manufacturer is responsible for compliance with the IVDR. In accordance with Art. 48.10, the following preconditions must be met to place products on the EU market:

- Manufacturers of class A devices shall draw up the technical documentation set out in Annexes II and III IVDR, and
- Shall declare the conformity of their products by issuing the EU declaration of conformity.

In addition, manufacturers must fulfill the obligations specified in Art. 10 IVDR, including the requirements for QMS (Art. 10.8), but there is no requirement for a quality management system certified by a notified body for self-declared class A devices (non-sterile). All higher device classes require quality management system certification by a notified body under IVDR.

However, the verification of IVDR compliance of class A devices (QMS and/or technical documentation) can be performed by European authorities at any time.

3.10 What are the transitional provisions for devices marketed together in a kit box?

Short answer
It depends on whether the kit components are devices on their own.

Explanatory information
There can be two scenarios that determine the length of the transition:

Case 1: The kit component (e.g., assay, calibrator, control, buffer solution) is an IVD product on its own, is independently classified, and has its own Declaration of Conformity, labeling, etc.

Each kit component has its individual transition that depends on the risk class/category of the component, e.g., a buffer solution in class A has no prolonged transition and must fully comply with the IVDR from 26 May 2022, even if it is packaged and sold together in a kit box with an assay that is in class B that may benefit from the prolonged transition until 26 May 2027. Since the class A component in the kit box is a device on its own and classified independently, it cannot benefit from the prolonged transition granted only to legacy devices that are in higher risk classes.

Case 2: The kit component (e.g., assay, calibrator, control, buffer solution) is not an IVD product on its own but is classified in the same class as the assay to which it belongs to (e.g., class B or higher). The kit component does not have its own Declaration of Conformity, labeling, etc.

Prolonged transition is allowable, and its length depends on the risk class/category of the kit. The complete IVDR must be fulfilled by the end of the transition time granted for the device class/group, e.g., IVDD devices covered by a valid certificate or Class D: May 2025, Class C: May 2026, Class B: May 2027.

General implementation rules on classification of IVDs should be followed (see relevant MDCG guidance documents: [6,7])

3.1. Application of the classification rules shall be governed by the intended purpose of the devices.

3.2. If the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.

3.3. Accessories for an in vitro diagnostic medical device shall be classified in their own right separately from the device with which they are used.

3.4. Software, which drives a device or influences the use of a device, shall fall within the same class as the device.

If the software is independent of any other device, it shall be classified in its own right.

3.5. Calibrators intended to be used with a device shall be classified in the same class as the device.

3.6. Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes shall be classified in the same class as the device.

3.11 Who assigns and confirms the future IVDR risk class assigned to self-declared IVDD devices that may benefit from the prolonged transition?

Short answer
The (legal) manufacturer must assign the risk class. There is no further confirmation or verification required during the prolonged transition.

Explanatory information
The (legal) manufacturer must choose the appropriate risk class that will apply to the device under the IVDR based on its intended purpose.

Dedicated MDCG Guidance documents on classification of IVDs should be followed, MDCG 2020-16[6] and MDCG 2019-11 for software only IVD products.[7] There is no further confirmation or verification by the NCA, or NB required by Art. 110.3 IVDR during the transition period.

However, the (legal) manufacturer shall duly justify and document the chosen risk classification and keep it at the disposal of competent authorities.

Consider that the NCA or other relevant authority, e.g., customs, may at any time request the justification for benefiting from the prolonged transition, e.g., when the device is registered or imported/distributed in EU during the transition.

3.12 Can an IVDD device that benefits from the prolonged transition be significantly changed during the transition period?

Short answer
No.

Explanatory information
Per Article 110.3, a significant change to the design and/or intended purpose of IVDD device that benefits from the prolonged transition would invalidate the precondition for using the extended transition time. In such case, the (legal) manufacturer must either make the device IVDR-compliant or stop CE marking under IVDD based on the prolonged transition (which means that the device may no longer be placed on the EU market).[8]

3.13 What is considered a significant change to the design and intended purpose of IVDD device that benefits from the prolonged transition?

Short answer
No further details are defined in the IVDR. The manufacturer must define it in the quality management system, taking into consideration the official guidance providing interpretation of this restriction.[8]

Explanatory information
The IVDR does not provide any definition or guidance regarding which changes would be considered significant and which would not. Thus, it is the responsibility of the (legal) manufacturer to define in its QMS which changes to the design and intended purpose would be considered significant and which would not. The official guidance document (MDCG 2022-6,[8]) that provides clarification on the concept of "significant changes in the design and intended purpose" under IVDR Article 110[3] should be taken into account, a case-by-case assessment must be performed when product changes arise during the prolonged transition, and the (legal) manufacturer must diligently justify and document its decision. The justification must be kept available for competent authorities for verification.

Significant changes to IVDD devices covered by certificates must be submitted to the NB for verification and approval before the change may be implemented.

3.14 What happens if an IVDD device benefiting from the prolonged transition has a significant change?

Short answer
The device may no longer benefit from the prolonged transition.

Explanatory information
The options listed below apply upon implementation of a significant change.[8] The (legal) manufacturer may:

- Make the device IVDR-compliant and continue placing it on the EU market under the IVDR, or
- Apply to each targeted EU member state for an exemption according to Article 54 IVDR, Derogation from the conformity assessment procedures. If the exemption is granted, the (legal) manufacturer may continue placing it on the market in the respective EU countries without CE mark based on the derogation approval, or
- Stop CE-marking the device under IVDD based on the prolonged transition (since placing it on EU the market is no longer permitted).

3.15 May an IVDD device benefiting from the prolonged transition continue to benefit if it has only a significant change in the design and no change in the intended purpose?

Short answer
No.

Explanatory information
The wording of Art. 110.3 might suggest that both restrictions would need to apply at the same time to invalidate the prolonged transition: significant changes in the design and intended purpose. But the interpretation by policy makers has clarified that if there is a significant change in either the design or the intended purpose, the prolonged transition can no longer be used (see CAMD guidelines, question 15[5] and MDCG Guidance 2022-6[8]).

3.16 May an IVDD device benefiting from the prolonged transition continue to benefit if it has only a significant change in the design and no change in the intended purpose?

Short answer
No.

Explanatory information
Only significant changes to the design and/or intended purpose would invalidate the prolonged transition as defined in Art. 110.3.[8] In general, QMS changes do not significantly affect the design and/or the intended purpose of devices and therefore would not invalidate the prolonged transition.

However, each change must be carefully assessed case-by-case by the (legal) manufacturer and, if necessary, verified with the NB involved. Further guidance on assessment of significant changes during the transition period is provided in the MDCG guidance 2022-6.[8]

3.17 May IVDD devices that benefit from the prolonged transition continue to be produced and placed on the EU market after the date of application (26 May 2022)?

Short answer
Yes, until the end of the prolonged transition.

Explanatory information
All IVDD devices that benefit from the prolonged transition (class A, B, C, and D) may continue to be produced and placed on the EU market after the date of application (26 May 2022) until the end of the prolonged transition period defined for the respective product risk class:

- IVDD devices that have valid IVDD certification may be produced and placed on the EU market until 26 May 2025.
- IVDD devices that are IVDR class D may be produced and placed on the EU market until 26 May 2025.
- IVDD devices that are IVDR class C may be produced and placed on the EU market until 26 May 2026.
- IVDD devices that are IVDR class B or class A sterile may be produced and placed on the EU market until 26 May 2027.

Refer also to the MDCG guidance document related to the prolonged transition (MDCG 2022-8).[9]

3.18 What are the prerequisites to benefit from the prolonged transition?

Short answer
Devices must have been approved under the IVDD before the date of application (26 May 2022), and self-declared IVDD devices require up-classification under the IVDR.

Explanatory information
IVDD devices must fulfill the following prerequisites to benefit from the prolonged transition:

- **Self-declared IVDD products** (so called "general IVDs" without NB) that:
  - Have been approved under the IVDD and have a valid DoC issued before the DoA (26 May 2022), and
  - Will be up-classified under IVDR and will require NB involvement.
- **IVDD Annex II list A and B devices and self-testing devices that:**
  - Have been approved under the IVDD and are covered by a valid IVDD certificate(s) issued by a NB before the DoA (26 May 2022).

Detailed information is provided in the dedicated MDCG Guidance MDCG 2022-8.[9]

3.19 Which requirements apply during the prolonged transition?

Short answer
- Continued compliance with IVDD,
- No significant change to the device, and
- IVDR requirements on PMS, vigilance, and registration must be fulfilled starting from DoA.

Explanatory information
IVDD devices that benefit from the prolonged transition must fulfill the following requirements:

- From DoA (26 May 2022), they must continue to comply with the applicable requirements of the IVDD,[2]
- There may not be a significant change to design and/or intended purpose,[8] and
- IVDR requirements on post-market surveillance (PMS), vigilance, and registration of economic operators and devices must be fulfilled instead of the corresponding IVDD requirements starting from the DoA (26 May 2022).

MDCG guidance document (MDCG 2022-8) is available that addresses this topic in detail.[9]

3.20 Must IVDD devices that benefit from the prolonged transition and will be in class C or D have the Summary of Safety and Performance during the transition?

Short answer
No.

Explanatory information
Art. 29 IVDR is not explicitly mentioned in the transitional provisions stipulated in Art. 110.3 IVDR and is therefore not applicable until the device is transferred to IVDR compliance. See also dedicated MDCG guidance (MDCG 2022-8).[9]

3.21 What types of IVDD certificates may remain valid and allow the use of the prolonged transition?

Short answer
All types of IVDD certificates may remain valid during the prolonged transition, e.g., the European Community (EC) Certificate and the European Community (EC) Design Examination Certificate.

Explanatory information
All types of certificates issued by notified bodies under the IVDD may remain valid until the date indicated on them, but until 26 May 2025, at the latest, and allow use of the prolonged transition:[5]

- EC Design-Examination Certificate (Annex III section 6, Annex IV, section 4 and section 6 IVDD)
- Certificate of Conformity (Annex VI IVDD)
- EC Type Examination Certificate (Annex V IVDD)
- EC Certificate Full Quality Assurance System (Annex IV excluding sections 4 and 6 IVDD)
- EC Certificate Production Quality Assurance (Annex VII IVDD

Detailed information is provided in the dedicated MDCG Guidance MDCG 2022-8.

3.22 Is a DoC issued according to IVDD considered a certificate?

Short answer
No.

Explanatory information
The DoC is a compliance statement issued by the (legal) manufacturers. Certificates are issued by an NB.[5,9]

3.23 Must the IVDD DoC covering legacy devices be updated and contain a statement or memo about the allowable prolonged transition under Art. 110.3?

Short answer
No.

Explanatory information
Neither the IVDR nor the associated guidance documents contain a requirement that the IVDD DoC of a legacy device must contain any additional statement or memo about the allowable prolonged transition defined in Article 110.3 IVDR.[9]

Note: This approach is also aligned with the related MDCG guidance for medical devices that defines the content of the DoC for legacy devices and does not require any "transitional" statement so far (see p. 3ff of the MDCG 2020-2 guidance[14]).

3.24 May a new version of an IVDD DoC be signed and issued after the DoA due to a non-significant change?

Short answer
Yes, but certain limitations and preconditions must be considered.

Explanatory information
There is no clear guidance or interpretation from legislators and notified bodies on this topic. The MDCG guidance pertaining legacy devices only requires that in order to benefit from the prolonged transition, the Declaration of Conformity (DoC) under the IVDD must have been drawn up prior to the date of application 26 May 2022.[9]

When an update of the IVDD DoC is needed to due to non-significant change after the IVDR Date of Application (DoA) (26 May 2022), there could be different options, considering where applicable the opinion of the NB involved in the IVDD conformity assessment:

1. Issuing an amendment to the IVDD DoC describing the change, or
2. Issuing a new version of the IVDD DoC (see the preconditions on the next page).

In case of solution 2, if a new version of an IVDD DoC should be issued after the IVDR DoA (26 May 2022), the following limitations and preconditions should be considered:

- The IVDD-compliant device must be allowed to benefit from the prolonged transition (e.g., not possible for the majority of IVDD instruments that are in class A and remain self-declared under the IVDR),
- There must be an IVDD version of the DoC for this product with the same device identification/ reference number that was signed before the IVDR DoA (26 May 2022),
- There is no significant change to the design and/or intended purpose of the product, and
- The new version of the IVDD DoC signed after the IVDR DoA should include the information that the update is due to a non-significant change and based on the provisions of Art. 110.3 and 112 of the IVDR, e.g.,
  This Declaration of Conformity is updated pursuant to article 110.3 in conjunction with article 112 second paragraph of the Regulation (EU) 2017/746 (IVDR) and changes have been evaluated according to MDCG 2022-6 Guidance on significant changes regarding the transitional provisions under article 110.3 IVDR.

Note: In case of requests by NCAs or customers, it may be necessary to provide the latest version of the IVDD DoC signed prior to the IVDR DoA together with the updated IVDD DoC issued after the DoA.

3.25 Is it possible to change IVDD certificate(s) after the Date of Application?

Short answer
No, but a written confirmation describing the non-significant change can be issued by the Notified Body.

Explanatory information
Valid IVDD certificates issued by the NB prior to the DoA (26 May 2022) may not be changed. However, non-significant changes to the content of the IVDD certificate can be considered. The certificate should not be amended, but the responsible notified body may confirm in writing, after having reviewed the manufacturer's description of the (proposed) change, that the implementation of the change does not represent a significant change in design or intended purpose under IVDR Article 110(3), e.g., name change of a production site, and that the related IVDD certificate remains valid. Such written confirmation corrects or complements information on an existing certificate but does not represent the issuance of a: supplemented certificate," since this is prohibited. In case of requests from authorities, the manufacturer should number such letters received from the notified body and submit them together with the certificate.[8]

3.26 If an IVDD device is covered by two certificates, must both certificates remain valid during the transition?

Short answer
Yes.

Explanatory information
All relevant IVDD certificates that are relevant for a specific device must be valid in order to benefit from the prolonged transition, e.g., the EC certificate and the design examination certificate.

However, this does not exclude the possibility that during the transition period, an EC certificate for the manufacturer's approved quality management system issued in accordance with the IVDD, which has become invalid, is replaced by an IVDR EU quality management system certificate, provided that the EC design examination certificate or the EC type examination certificate issued under the IVDD remains valid.[8]

3.27 If an IVD product is covered by a valid IVDD certificate and will also be up-classified under the IVDR, which prolonged transition applies?

Short answer
An IVDD device covered by a NB certificate issued under the IVDD may only use the transition period until 26 May 2025, irrespective of the device class under the IVDR.

Explanatory information
If an IVDD device is covered by a NB certificate (e.g., IVDD devices for self-testing) the transitional provisions for this group of devices apply until 26 May 2025.

This deadline applies independent of the risk class under the IVDR. In other words, it is not relevant if an IVDD-compliant device covered by an IVDD certificate will be up-classified under the IVDR or not. In this case, the prolonged transition until 26 May 2025, is relevant.

Longer transition periods are only granted for self-declared IVDD devices that will be up-classified and require NB involvement for the first time under the IVDR.

Some explanatory examples of different transitional provisions:

- Urine analysis test that is self-declared under the IVDD and will be up-classified in class B under IVDR: Prolonged transition until 26 May 2027, may be used.
- COVID test that is self-declared under the IVDD and will be up-classified in class D under IVDR: Prolonged transition until 26 May 2025, may be used.

  COVID test for self-testing that is covered by a valid NB certificate under IVDD that will also be up-classified in class D under the IVDR: Prolonged transition until 26 May 2025, may be used.
- Pregnancy test that is self-declared under the IVDD and will be up-classified in class B under IVDR: Prolonged transition until 26 May 2027, may be used.

  Pregnancy test for self-testing that is covered by a valid NB certificate under IVDD that will also be up-classified in class B under the IVDR: Prolonged transition until 26 May 2025, may be used.
- Clinical chemistry analyzer that is self-declared under the IVDD and will remain self-declared in class A under IVDR: No prolonged transition is granted. This device must comply with the IVDR from the DoA, 26 May 2022.

  Blood gas analyzer that is self-declared under the IVDD and will be up-classified in class C under IVDR: Prolonged transition until 26 May 2026, may be used.

3.28 Which post-market surveillance and vigilance requirements of the IVDR must be fulfilled by the manufacturer?

Short answer
All relevant requirements set out in Chapter VII of the IVDR on post-market surveillance and vigilance apply to legacy devices and must be fulfilled instead of the corresponding IVDD requirements.

Explanatory information
In particular, MDCG guidance 2022-8[9] outlines that the following requirements apply from the DoA (26 May 2022) to the IVDD-compliant devices (legacy devices) using the prolonged transition:

- Post market surveillance requirements that should apply to legacy devices:
  - Art. 78 and 79 IVDR (including applicable parts of Annex III Technical Documentation on Post Market Surveillance), except for aspects related to pre-market requirements, e.g., Art. 78(3) (d),
  - Art. 80 IVDR as a minimum requirement unless a manufacturer of legacy devices that will fall under class C or D voluntarily chooses to prepare a PSUR pursuant to Art. 81, and
  - Annex XIII Part B IVDR, since it further develops the requirement of Annex III, section 5 IVDD, except for the performance evaluation report, in line with the IVDR as is it is a pre-market requirement not applicable to legacy devices.
- Vigilance that should apply to legacy devices:
  - Art. 82, 83, and 84

However, use of the EUDAMED database (Art. 87 IVDR) for reporting is not mandatory until full functionality of the database is established.[9,13]

For legacy devices covered by certificates issued under the IVDD, the notified bodies that issued the respective certificates should conduct appropriate surveillance in accordance with Art. 110(3).5 IVDR, which essentially means a continuation of the surveillance activities under the IVDD.[9]

3.29 Who is responsible for verification if the post-market surveillance and vigilance requirements of the IVDR are fulfilled during the transition?

Short answer
The national competent authorities (NCA) and, where applicable, the NB are involved under IVDD.

Explanatory information
The responsibility for the verification depends on the device category:

- For self-declared IVDD compliant devices: the NCAs in the EU member states
- For Annex II List A or B devices and IVDD devices for self-testing: the NCAs in the EU member states and the notified body involved in the conformity assessment under IVDD.

The NB that issued the IVDD certificate shall continue to be responsible for the appropriate surveillance of all the applicable requirements relating to the IVDD devices it has certified. This should be agreed on between the NB and the (legal) manufacturer on a contractual basis (see CAMD guidelines question 15[5] and MDCG Guidance 2022-6[8]).

3.30 Is it allowed to switch IVDD devices that may benefit from the prolonged transition before the end of the prolonged transition?

Short answer
Yes.

Explanatory information
The (legal) manufacturer may decide to use the entire prolonged transition or to bring the device to IVDR compliance earlier, or even not to use the prolonged transition at all.

3.31 Would this mean that the Declarations of Conformity under IVDD must be issued before 26 May 2022, to allow the respective IVD product to benefit from the prolonged transition?

Short answer
Yes.

Explanatory information
Since the IVDD was officially repealed on 26 May 2022, it not possible to issue a DoC stating compliance with the IVDD after this date. Only IVDD DoCs issued before this date may remain valid and allow use of the prolonged transition for defined product device classes/groups under specified conditions as stipulated in Art. 110.3 IVDR.[9]

3.32 Which transitional provisions apply for IVDs with "combined" intended use that are assigned in different risk classes?

Short answer
The highest risk class in the combined intended purpose determines the allowable transition time.

Explanatory information
The portion of the intended purpose associated with the highest risk class drives the determination which transition time applies: This interpretation is based on the principle that if several classification rules apply to the same device, the rule resulting in the higher classification shall apply (see IVDR Annex VIII implementing rule 1.9).[6,7]

Example:

Syphilis test has a combined intended purpose for screening (A) and individual diagnosis (B):

A. Screening blood and tissue donations for syphilis, which falls under class D according to rule 1, and

B. Diagnosing syphilis, a sexually transmitted agent, in the individual, which falls under class C according to rule 3a.

This device was self-declared under the IVDD and must be up-classified under IVDR in accordance with implementing rule 1.9 to the highest applicable class, in this case class D. The highest applicable risk class also determines the longest allowable transition, **26 May 2025**, for self-declared IVDD-compliant devices that will be in class D under the IVDR.

3.33 Must IVDD devices that benefit from the prolonged transition be made IVDR-compliant after the end of the prolonged transition?

Short answer
No, if the manufacturer decides to stop selling the device in the EU.

Explanatory information
The (legal) manufacturer decides if and how long a specific product will be made available on the EU market, and there is no legal obligation that the IVDD-compliant device must be made IVDR-compliant, even if it benefits from the prolonged transition. It means that the (legal) manufacturer may place an IVDD device on the EU market until the end of the allowable prolonged transition and then stop selling it. However, establishing compliance with the IVDR is required if the (legal) manufacturer intends to continue to market the device on the EU market beyond the allowable prolonged transition.

3.34 Who can verify and/or control the compliance of IVDD devices that benefit from the prolonged transition?

Short answer
Self-declared IVDD devices: competent authority

Annex II List A or B devices or IVDD devices for self-testing: notified body and competent authority

Explanatory information
- **Self-declared IVDD devices:** The competent authority of the EU member state where the manufacturer or the EU authorized representative has its registered place of business is responsible for market surveillance of self-declared IVDD devices and may inspect or request compliance documentation or information from the respective economic operator established on its territory.
- Annex II List A or B devices or IVDD devices for self-testing:
    - The NB that issued the IVDD certificate continues to be responsible for the appropriate surveillance and verification that the manufacturer and, where applicable, the authorized representative meets the preconditions to use the prolonged transition.
    - The competent authority of the EU member state where the manufacturer or the EU authorized representative has its registered place of business is responsible for market surveillance and may inspect or request compliance documentation or information from the respective economic operator established on its territory.

3.35 What do the so-called "sell-off" provisions (Art. 110.4 IVDR) specify?

Short answer
These provisions define how long IVDD-compliant devices may remain in the distribution chain in the EU. The lengths depend on the device class/group.

Explanatory information
It is intended by policy makers to limit the time during which IVDD-compliant devices that have already been placed on the EU market (either before the DoA or based on the prolonged transition after the DoA) may remain in the distribution chain and be made available on the EU market. The length of the allowable sell-off period is defined for each device class/group. For further details, refer to MDCG guidance MDCG 2022-8.[9]

To identify the correct sell-off provisions, you must determine if the IVDD-compliant device was placed on the EU market before or after the date of application: 26 May 2022:

- **IVDD-compliant devices that were placed on the EU market prior to the DoA are called "directive devices" or "old devices" and can be distributed until 26 May 2025.**

  These products must be officially transferred to the possession of the end users before this date. Otherwise, the economic operator (manufacturer, importer, or distributor) must remove the IVDD-compliant products from the European distribution chain.

For IVDD-compliant software classified as an IVD, this means in particular:

- **Software on a data carrier (e.g., USB stick, DVD, etc.) or that is part of the instrument or user interface that is considered placed on the EU market prior to the DoA** (e.g., the carrier with the software is in an EU warehouse) may be distributed within the EU until 26 May 2025. After this date, no further distribution in the EU is allowed.
- **Software on a cloud that is considered as placed on the EU market,** i.e., that was made available to EU customers prior to the DoA, may be made available to new/additional EU customers (e.g., by providing them a license key/access) until 26 May 2025. After this date, no new EU customers can be provided with access to this software. Note: Customers that obtained access to the software before 26 May 2025, may continue to use it without restrictions.

- **IVDD-compliant devices that were placed on the EU market after the DoA are called "legacy devices" and can be distributed on the EU market for one more year after the end of the prolonged transition period.**

  For detailed sell-off dates that apply for specific devices classes/categories, see the last column in the table below. These products must be officially transferred to the possession of the end users before their sell-off dates. Otherwise, the economic operators must remove the IVDD-compliant products from the European distribution chain.

  Example: A self-declared IVDD-compliant device that will be up-classified to class B under IVDR: This device may benefit from the prolonged transition and be placed on the EU market until 26 May 2027, and it can be distributed within the EU until 26 May 2028. This device must be transferred to the ownership of the end user by 26 May 2028. If not, it must be removed from the European distribution chain.

After 26 May 2028, no IVDD-compliant devices (neither hardware nor software) may be made available or put into service in the EU. If such devices are still within the supply chain by this date, i.e., are not in the possession of or have not reached the end user (e.g., the hospital or lab), they are no longer marketable.

This provision primarily addresses the "making available" of IVDD-compliant devices once they have been placed on the EU market, e.g., within the supply chain.

Please also note that these provisions are not intended to apply to devices that are in the stock of the end users (e.g., hospital or lab), second-hand sales of IVDD-compliant devices, or refurbished devices. Once a device has been made available to the end user, the availability of this device on the EU market is no longer regulated by the IVDR (unless the device would be subject to a significant change). There are no restrictions on end users selling or further marketing their IVDD devices.

For more information regarding general concepts on marketing of devices on the EU market, e.g., placing on the market or making available, consult the interpretative guidelines stipulated in the Blue Guide.[17]

Type	Date of placing on the EU market	Status under IVDD	Max. deadline for selling off IVDD products
Directive devices	**Prior DoA (26 May 2022)**	**Self-declared IVDD products** (General IVDD products without NB)	**26 May 2025**
		IVDD Annex II list A and B and self-tests (with valid IVDD Certificate with NB)	
Legacy devices	**Starting from DoA (26 May 2022)**	**IVDD Annex II list A and B and self-tests** (with valid IVDD Certificate with NB)	**26 May 2026**
		Self-declared IVDD products (General IVDD products without NB)	**26 May 2026**
			26 May 2027
			26 May 2028
			26 May 2028
Regulation devices	**Starting from DoA (26 May 2022)**	**Self-declared IVDD products** (General IVDD products without NB)	N/A
		New/significantly changed devices (not covered by valid IVDD Certificate or IVDD EU DoC)	

3.36 Which IVDR requirements apply to importers and distributors of IVDD devices that benefit from the prolonged transition?

Short answer
Only the IVDR requirements for Registration, Post Market Surveillance, and Vigilance apply to importers and distributors during the transition period.

Explanatory information
Starting from the date of application, 26 May 2022, importers and distributors selling IVDD-compliant devices that benefit from the prolonged transition must comply with the following IVDR requirements instead of the corresponding IVDD requirements:

- **Importers and distributors:** fulfillment of Post Market and Vigilance requirements of the IVDR
- **Importers:** registration in EUDAMED. However, as long as EUDAMED is not fully operational, its use is voluntary and the registration requirements of the IVDD continue to apply (unless national legislation in the EU member states regulates it differently).
- **Distributors:** registration in the national database in the EU member state where they have their registered place of business, if applicable.

As a general rule: IVDR requirements that are not related to post-market surveillance, vigilance, or registration should in principle not apply to importers and distributors for legacy devices benefiting from the prolonged transition. However, importers and distributors may choose to follow any of the IVDR requirements for legacy devices on a voluntary basis. Detailed information is provided in the dedicated MDCG Guidance MDCG 2022-8[9] and further guidelines.[5,9,10,11,12,13,15,16]

3.37 Can manufacturers be compelled to use the prolonged transition?

Short answer
No.

Explanatory information
The (legal) manufacturer is responsible for the appropriate planning and facilitation of the conformity assessment of its devices. If the (legal) manufacturer has a Notified Body (NB) that is designated under the IVDR, devices can be approved anytime provided there is successful completion of the conformity assessment by the manufacturer and the NB. However, the EU Commission and designating authorities in member states may compel the NB to prioritize the conformity assessments of certain devices, such as new or significantly changed IVDs, or class D devices. Thus, close alignment with the NB on the conformity assessment timelines is essential.

3.38 Is there an EU-wide guidance in place on the implementation of the prolonged transition?

Short answer
Yes.

Explanatory information
There are several guidance documents in place that may assist stakeholders when using the prolonged transition:

Consider that some of the documents are dedicated to medical devices, but the implementation guidelines can be applied to IVDs:

- EU Commission's questions and answers on the progressive roll-out of the new In Vitro Diagnostic Medical Devices Regulation[4]
- CAMD guidance "frequently asked questions on IVDR transition"[5]
- MDCG 2022-8 Regulation (EU) 2017/746 - application of IVDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC[9]
- MDCG 2022-6 Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR [8]
- MDCG 2020-16 Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746[6]
- MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR[7]
- MDCG 2021-27 Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746[15]
- MDCG 2022-12 - Harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional (under the IVDR)[13]
- MDCG 2019-5 Registration of legacy devices in EUDAMED[10]
- 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[11]
- MDCG 2020-15 MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States[12]
- MDCG 2020-2 rev. 1 Class I Transitional provisions under Article 120 (3 and 4) - (MDR); (medical device-specific)[14]

3.39 Does the mutual recognition agreement between Switzerland and the EU continue to apply for devices under the IVDR transitional provisions?

Short answer
No.

Explanatory information
The European Commission notice on the EU-CH MRA[18] indicates that the mutual recognition agreement chapter on IVD ceased to apply starting from the date of application of the IVDR: 26 May 2022.

4. References

1. European Regulation (EU) 2017/746 on in vitro diagnostic medical devices
2. European Directive 98/79/EC on in vitro diagnostic medical devices
3. REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/746 as regards transitional provisions for certain in vitro diagnostic medical devices and deferred application of requirements for in-house devices
4. EU Commission's questions and answers on the progressive roll-out of the new In Vitro Diagnostic Medical Devices Regulation
5. CAMD FAQ – IVDR Transitional provisions
6. MDCG 2020-16 Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746
7. MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR
8. MDCG 2022-6 Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR
9. MDCG 2022-8 Regulation (EU) 2017/746 – application of IVDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2022 in accordance with Directive 98/79/EC
10. MDCG 2019-5 Registration of legacy devices in EUDAMED
11. 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
12. MDCG 2020-15 MDCG Position Paper on the use of the EUDAMED actor registration module and of the Single Registration Number (SRN) in the Member States
13. MDCG 2022-12 – Harmonised administrative practices and alternative technical solutions until EUDAMED is fully functional (under the IVDR)
14. MDCG 2020-2 rev. 1 Class I Transitional provisions under Article 120 (3 and 4) – (MDR)
15. MDCG 2021-27 Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746
16. MDCG 2019-5 Registration of legacy devices in EUDAMED
17. The Blue Guide on the implementation of EU product rules 2022
18. European Commission notice on the EU-CH MRA

5. Disclaimer

Information provided in this document was compiled to the best of our ability to ensure that the interpretations provided are sound.

However, we cannot provide any guarantee that the information is correct, and we don't accept any legal responsibility for it.

The interpretations provided in this document are for information purposes only. Any consideration of the information is the reader's own responsibility and is not meant to substitute for specific legal advice.

Please consider that the ultimate interpretation of legal requirements lies with the courts.

This document may be changed or amended at any time without notice to ensure that the information is kept up to date or if further official guidance or court decision will be available.

6. Definitions and Abbreviations

Term/Abbreviation	Definition
Art.	Article
Basic UDI-DI	Basic Unique Device Identification – Device Identifier
CAMD	Competent Authorities for Medical Devices A group of National Competent Authorities from all EU member states that provides implementation guidance on the EU legislation for medical devices.
CS	Common Specification
Directive Devices, also called "old devices"	IVDD-compliant products that were placed on the market PRIOR to the date of application (DoA) of the IVDR (26 May 2022)
DoA	Date of Application (of the IVDR: 26 May 2022)
DoC	Declaration of Conformity issued by the (legal) manufacturer
EC	European Community
EU	European Union
EUDAMED	European Medical Devices Database (under development by the European Commission) (EUDAMED public access)
EURL	European Reference Laboratory
IVDD	European Directive 98/79/EC on in vitro diagnostic medical devices ("old legislation")
IVDR	European Regulation (EU) 2017/746 on in vitro diagnostic medical devices ("new legislation")
Legacy Devices	IVDD-compliant products that are placed on the market between the date of application of the IVDR (26 May 2022) until end of the prolonged transitions according to 110(3) IVDR, under certain conditions: 1. A valid IVDD certificate issued prior to DoA is available, or an EU DoC is available for self-declared IVDD devices that are up-classified under IVDR, 2. Continued compliance with IVDD, 3. No significant change in Design or Intended Purpose is allowed after DoA (this would trigger immediate transfer to IVDR compliance), and 4. Post-market surveillance, vigilance, and registration requirements according to IVDR apply starting from DoA.
MDCG	Medical Device Coordination Group A group of experts from all EU member states led by the EU Commission that deals with key issues related to the medical devices sector and provides implementation guidance on the EU legislation for medical devices.
NB	Notified body
NCA	National competent authority(ies) in EU member states
PMS	Post-market surveillance
QMS	Quality management system
Regulation Devices	IVDR-compliant products (could be new products, significantly changed IVDD devices, or IVDD products transferred to IVDR compliance)
UDI-DI	Unique Device Identification – Device Identifier

At Siemens Healthineers, we pioneer breakthroughs in healthcare. For everyone. Everywhere. By constantly bringing breakthrough innovations to market, we enable healthcare professionals to deliver high-quality care, leading to the best possible outcome for patients.

Our portfolio, spanning from in-vitro and in-vivo diagnostics to image-guided therapy and innovative cancer care, is crucial for clinical decision-making and treatment pathways. With our strengths in patient twinning, precision therapy, as well as digital, data, and artificial intelligence (AI), we are well positioned to take on the biggest challenges in healthcare. We will continue to build on these strengths to help fight the world's most threatening diseases, improving the quality of outcomes, and enabling access to care.

We are a team of 66,000 highly dedicated employees across more than 70 countries passionately pushing the boundaries of what's possible in healthcare to help improve people's lives around the world.

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
Phone: +49 9131 84-0
siemens-healthineers.com

Published by
Siemens Healthcare Diagnostics Inc.
Laboratory Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5005
USA
Phone: +1 914-631-8000