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IVDR Amending Regulation (EU) 2024/1860

Frequently asked questions

This guidance has been created taking into account feedbacks from IVD manufacturers. This document provides clarity on the implementation of the **Amending Regulation 2024-1860** with regard to the IVDR (EU) 2017/746, including the transitional provisions covered in Article 110.

Can BSI issue the Notified Body (NB) confirmation letter if the IVDR application is with BSI?

A confirmation letter can be issued as soon as the Amending Regulation comes into force, for those devices that qualify for it. The scope of a Notified Body confirmation letter is to confirm that a specific qualified device or a list of devices are covered by a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR and a signed written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR.

BSI can issue the Notified Body confirmation letter to manufacturers that submitted an application for conformity assessment under IVDR to BSI and that signed a written agreement with BSI, under these scenarios:

- Manufacturers with a legacy device covered by an IVDD certificate issued by BSI or issued by a Notified Body different than BSI.
- Manufacturers with legacy devices self-declared under IVDD and up-classified under IVDR, requiring the involvement of a NB under IVDR.

BSI already has a solid process in place for issuing confirmation letters to those devices that qualify for it. If you need a confirmation letter for your qualifying legacy devices, please contact your Scheme Manager.

For a manufacturer of a legacy device with a valid IVDD certificate that expires after the publication date of the Amending Regulation, where there is no intention to transition to the IVDR, can a confirmation letter be issued by BSI to cover the legacy device until 25 May 2025?

The short answer is: no. A Notified Body confirmation letter cannot be issued in absence of a formal application under IVDR and in absence of a signed written agreement under IVDR. The manufacturer should be able to self-declare its compliance with the conditions in the Amending Regulation before placing legacy devices on the market.

Shall manufacturers expect to have a specific QMS audit or QMS certificate issued to address the QMS requirements in the Amending Regulation?

Manufacturers must put in place a QMS in accordance with Article 10(8) IVDR and must draw up the QMS documentation no later than the 25th May 2025 regardless of the device risk class under the IVDR. The QMS documentation needs to be submitted as part of the application for conformity assessment for any devices which the manufacturer intends to transfer to the IVDR and must be submitted by the relevant deadlines for applications to a Notified Body. BSI will check completeness of documentation submission and will be auditing QMS compliance to the applicable IVDR requirements as part of the surveillance audit as soon as this will become BSI responsibility.

Can legacy devices benefit from the new transitional timelines even if the manufacturer does not intend to transition a device to the IVDR?

Yes, conditional to certain requirements (Art 110(2) and Art.110(3c)), legacy devices can benefit from the new transitional timelines even if there is no intent to transition to the IVDR, although they will not be able to benefit of the full transition but only until the relevant application deadline (26th May 2025 for IVDD certified devices and Class D devices that were self-declared under the IVDD; 26th May 2026 for Class C devices that were self-declared under the IVDD and 26th May 2027 for Class B or class A sterile devices that were self-declared under the IVDD). Please refer to BSI Transition Guidance for more information.

Why are manufacturers expected to notify national competent authorities of the EU that a device will not be progressed under IVDR and withdrawn from the market?

To ensure availability of devices, the Amending Regulation now introduces new requirements in Article 10a that obliges manufacturers to communicate to Member State authorities and healthcare providers whether devices will be discontinued, either temporarily or permanently, in cases where it is reasonably foreseeable that such interruption or discontinuation could result in serious harm or a risk of serious harm to patients or public health in one or more Member States. Manufacturers are required to provide this information six months in advance to competent authorities, as well as to relevant economic operators and healthcare providers. This is done to allow these stakeholders enough time to consider mitigating measures to ensure patient safety and a high level of public health.

Is there a mechanism for ensuring that legacy devices that are not able to benefit from the extended transition timelines in Article 110, do not continue to be placed on the market?

Protection of health and safety of patients, healthcare professionals, and other users are key aspects of the Regulation and oversight of this is guaranteed through the vigilance and through market surveillance of Competent Authorities and, where applicable, through appropriate surveillance activities of Notified Bodies on devices placed on the market.

How can a manufacturer demonstrate that its legacy device benefits from the extension of the transitional period? Will BSI amend the expiry date of relevant directive certificates?

Provided that the conditions laid down in Article 110(2) and Article 110(3) are fulfilled, legacy devices can lawfully be placed on the market. According to MDCG 2022-6, and per Article 110 IVDR Notified Bodies cannot issue new IVDD certificates, or even amend the expiration date of relevant directive certificates. It is expected that the manufacturer should be able to provide a self-declaration to confirm certain devices fulfil the Amending Regulation conditions and can benefit of the extension of the transition until specified date. In addition, a copy of the IVDR application and/or written agreement documentation can also constitute a proof of evidence. BSI, upon specific request from the manufacturer, can provide a Notified Body confirmation letter (see question 1 and 2).

If a manufacturer has lodged an IVDR application for certain devices with BSI, who will be responsible of the appropriate surveillance during the transition period?

The Amending Regulation allows the IVDR Notified Body to take over the appropriate surveillance of devices certified under the Directive from the Notified Body that issued the Directive certificates under a tri-partite (transfer) agreement. The transfer of appropriate surveillance to the IVDR NB must be completed no later than the 26 September 2025. A tri-partite (transfer) agreement will be set up and approved between the manufacturer, BSI and the Directive Notified Body. BSI will inform clients when the process for transferring the appropriate surveillance of legacy devices is in place. If you intend to transfer the appropriate surveillance of any of your legacy devices currently certified through another NB to BSI, please contact your BSI Account Manager or Scheme Manager as soon as possible to allow the transfer activities to be completed before the 26 September 2025 deadline, as defined in the Amending Regulation.

What should be included in the formal application under IVDR lodged by the manufacturer?

The application should include the documents listed in the relevant conformity assessment as referred to in Annexes IX to XI of the IVDR. It should be noted that a full review of the technical documentation at the application and prior to the conclusion of the written agreement, is not required. However, the application must clearly identify the manufacturer and the list of devices covered by the application and intended to be transferred to the IVDR and, where applicable, the device(s) intended to substitute a legacy device. The information submitted with the application needs to allow the Notified Body to verify the qualification of the products as IVDs, their respective classification and the chosen conformity assessment procedure. When lodging the application, the manufacturer should provide and agree with a Notified Body a timeline for possible submission of the technical documentation and any other relevant information for the conformity assessment activities in due time.

If a manufacturer aims to submit an IVDR application (and signed a written agreement with a NB) for a substitute device of a legacy device, does it mean the legacy device cannot benefit from the extended transitional timelines?

The transitional period provided for in Article 110(3a) and (3b) IVDR can apply to a legacy device that is being replaced by a substitute device under IVDR.

This means that, in case the IVDR application and signed contract cover a substitute device of a legacy device, the legacy device can benefit from the extended transitional timelines. It is the responsibility of the manufacturer to determine the device that is intended to substitute a legacy device and to explain the link to the substituted legacy device.

Will the Notified Bodies/BSI also do appropriate surveillance of devices that were self-declared under the IVDD, after the 26th of September 2025?

No, appropriate surveillance by Notified Bodies only affects the legacy IVD devices that are covered by a previously issued IVDD CE Certificate.

Will the amendments affect the original timelines in relation to the IVD devices that were presented under the Amending Regulation (EU) 2022/112?

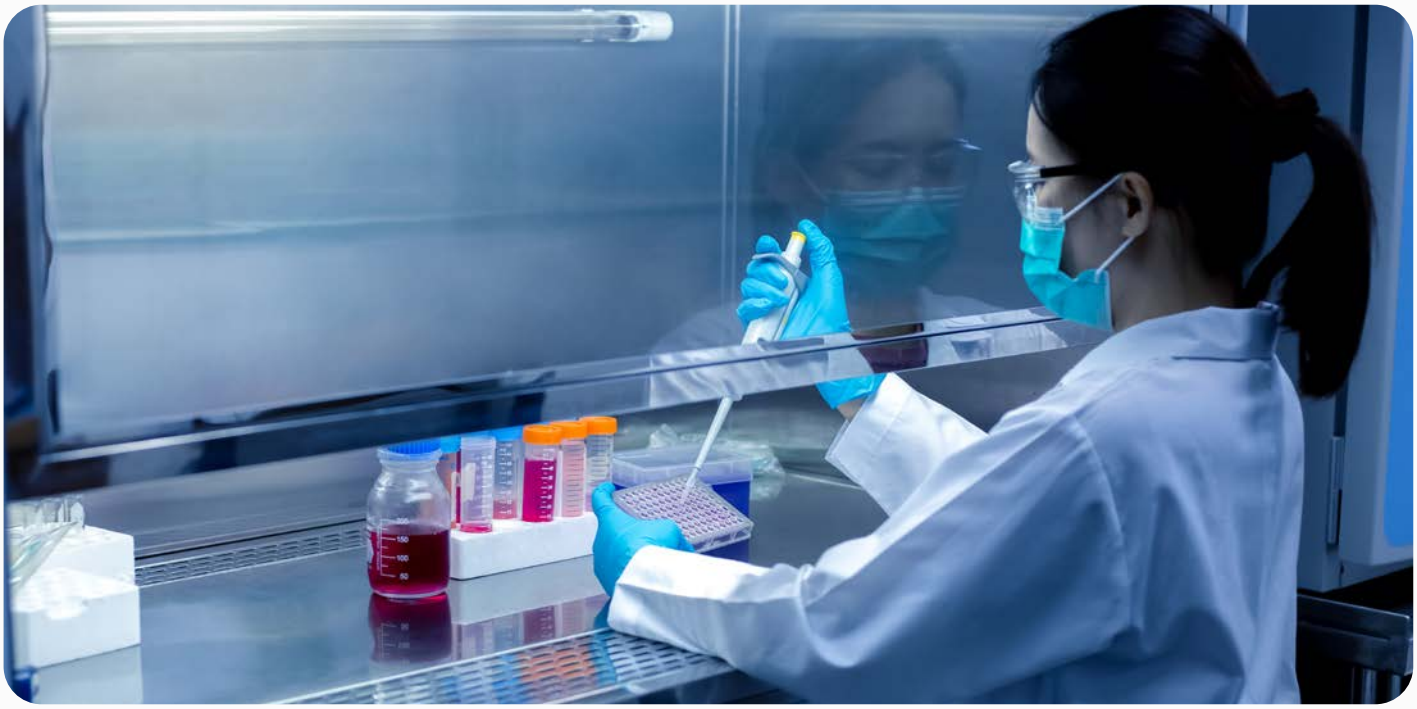
It depends.

For those legacy devices that satisfy the conditions in the Amending Regulation, Article (3c) of the IVDR states that, the transitional timelines are extended up to the 31 December 2029.

If the manufacturer does not intend to transition a legacy device to the IVDR, these timelines apply (provided that the conditions laid down in Article 110(3c) IVDR are fulfilled):

- IVDD certified legacy devices: 26 May 2025.
- Self-declared IVDD legacy devices classified as class D under IVDR: 26 May 2025.
- Self-declared IVDD legacy devices classified as class C under IVDR: 26 May 2026 (provided that a QMS compliant with the requirements as per Article 10(8) IVDR is put in place by the 26 May 2025).
- Self-declared IVDD legacy devices classified as class B or A sterile under IVDR: 26 May 2027 (provided that a QMS compliant with the requirements as per Article 10(8) IVDR is put in place by the 26 May 2025).

It must be noted that the previous Amending Regulation will be superseded by the new Amending Regulation.



Will the IVDR amendment affect the implementation/rollout of the new EURL legislation for the EURLs that will be involved in the oversight of Class D IVDs?

We expect the impact of the IVDR amendment on the implementation of the new EURL legislation to be limited. We anticipate that the new conditional timelines in the amendment will help smooth out the implementation of the EURLs. Hence, IVDD Annex II List A devices can be placed on the market for a longer period now, which does take pressure off the conformity assessment process.

Are manufacturers allowed to make changes to their devices under the Directives for a longer period under the Amending Regulation?

The Amending Regulation does still allow manufacturers to make changes to devices under IVDD **if such changes do not constitute a significant change in design or intended purpose, per Article 110.** While it is possible to make some changes to devices under the IVDD, BSI strongly recommends that manufacturers make progress in transitioning their devices to IVDR rather than consider making changes under the IVDD. Approval of changes under IVDD will be strictly limited to those changes that are demonstrated to be essential and without which there could be challenges with market availability of safe devices to patients.

Will these amendments affect the way BSI prioritize their technical documentation assessments? In other words, since there is now less stress on the conformity assessment process, will BSI apply a different focus, not based on classification?

BSI has always operated on a first-in-first-out basis and plans technical documentation reviews based on the certification schemes and agreement set up with manufacturers; this will not change. Any submissions already received will be placed in the current queue and conformity assessments completed as and when resources (with the appropriate competencies) become available. We strongly recommend that manufacturers do not request to postpone these reviews to ensure timely completion of assessments. Changes to existing submissions could result in delays in scheduling. Any new submissions received will continue to be added to the end of the current queue.

If a manufacturer already has an IVDR application with BSI. Is it possible to change the contract from Dedicated service to Standard service for Technical Documentation reviews?

It is possible to change from a Dedicated service to Standard service for Technical Documentation reviews, irrespective of the implementing regulation. However, BSI will treat these changed service level reviews as "new" and will issue an "Amendment Agreement to Contract" with a Standard service for the impacted devices only. Such devices moving to the Standard service will be added to the end of the current queue of reviews already in place by that date. Manufacturers that opt in for Standard service will then not get the same service level as indicated for Dedicated service.

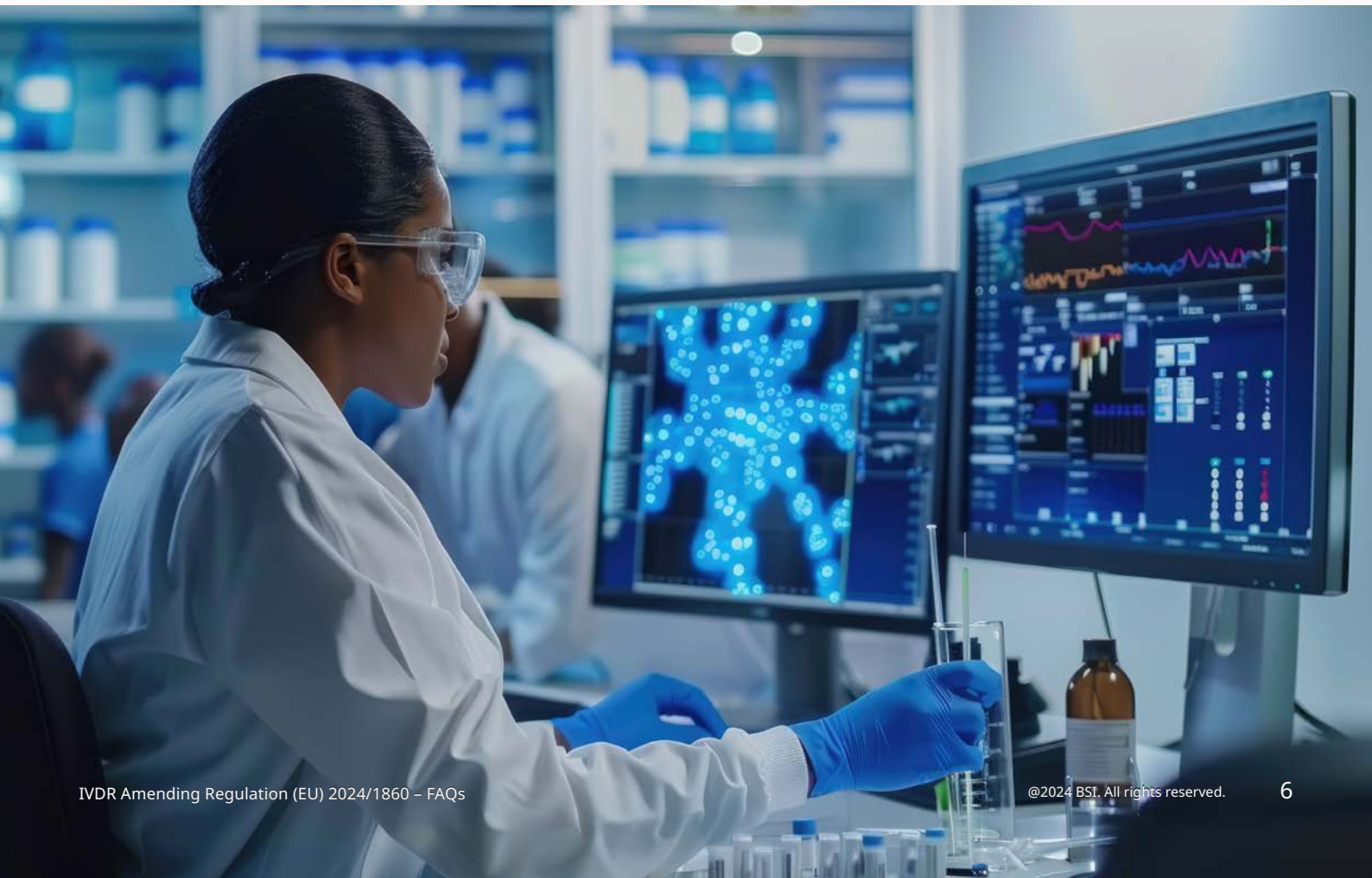
Does BSI anticipate improved capacity as a result of this change?

Since MDR and IVDR were published, BSI has grown 18% CAGR (Compounded Average Growth Rate) every year. BSI continues to adapt its resources plan based on the changes being experienced in the medical device legislations.

The Amending Regulation certainly provides additional relief to Notified Bodies in terms of the longer transition timelines. BSI is also constantly working on streamlining its processes and introducing new IT systems to increase efficiency and capacity. BSI will consider new requests in areas where it has capacity available. Please contact the Sales Teams for any enquiries on this matter.

If IVDR certificates have been already issued and the manufacturer is ready to make changes to the IVDR certified devices, will reviews of changes be deprioritized so that BSI can focus on initial applications only?

All IVDR work will be given equal priority. BSI is operating business as usual with any IVDR conformity assessment type, including changes, being scheduled as first-in-first-out.



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