Extension to IVDR transition timelines:

What this means to IVDs and what steps is BSI taking to foster IVDR transition

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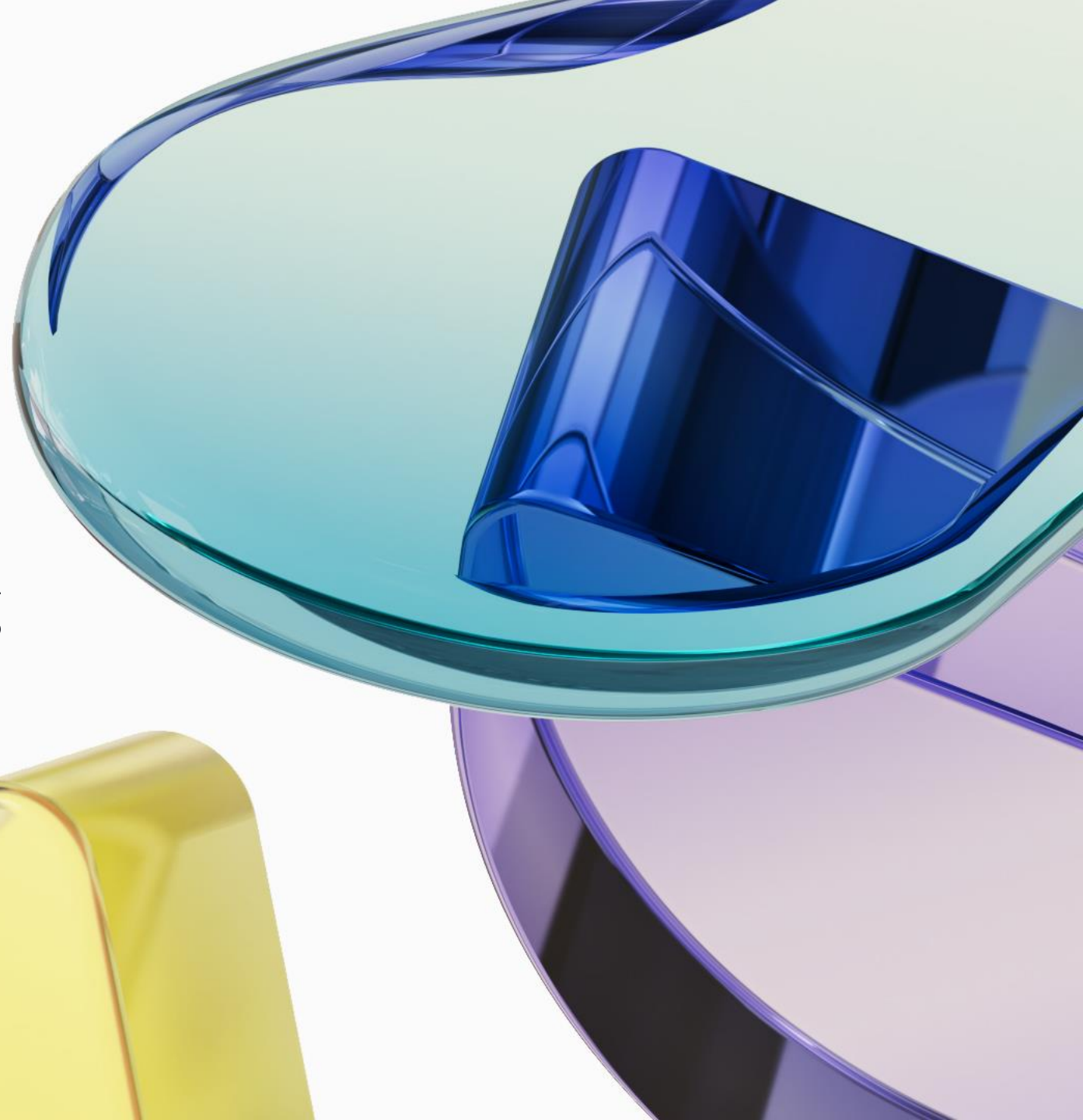
23 April 2024



Agenda

1. Introduction
2. Regulatory background of the proposal
3. Changes to IVDR Transitional Provisions
4. EU 2024/43 and related Q/A
5. Potential scenarios for manufacturers (polls)
6. Questions and Answers

Regulatory Updates EU IVDR – Another proposal

Proposal to amend transitions was published on 23 January 2024

Regulatory Updates EU IVDR – Another proposal

- An exchange of view (EU MS and Industry) was initiated with the European Commission (EPSCO meeting 30 November 2023).
- MS of France and Germany raised concerns on the availability of Class D IVD's, due to rollout of the IVDR. New data from German Industry groups showed risk for a new pending "crunch".
- In addition, member states also raised the point that EUDAMED was lacking and needed to get better oversight of the devices being discontinued.
- Input from Member State authorities and stakeholders has been sought during the MDCG meetings on 10-11 October and 11-12 and 18 December 2023 and related discussions in MDCG subgroups. An extraordinary MDCG meeting with stakeholders (a.o. NB's) was held on 20 December 2023 to discuss issues related to possible amendments to the IVDR.
- EC considered that more time was needed in order to maintain supply of devices to the EU market…
- Leading to the MDR/IVDR amendment DRAFT published in January 2024.

Note: This presentation is based on the current proposal COM(2024)43. Information will be reviewed when the final Amending Regulation is published

Regulatory Updates EU IVDR - Another proposal

Note: The proposal covers both MDR and IVDR (only transitional period for IVDs is further covered in the presentation)

Background

Objectives for the proposal are:

- Ensuring the availability of in vitro diagnostics (IVDR)
- More transparency on medical devices (EUDAMED)
- Prior notice foreseeing the interruption supply of IVDs or medical devices

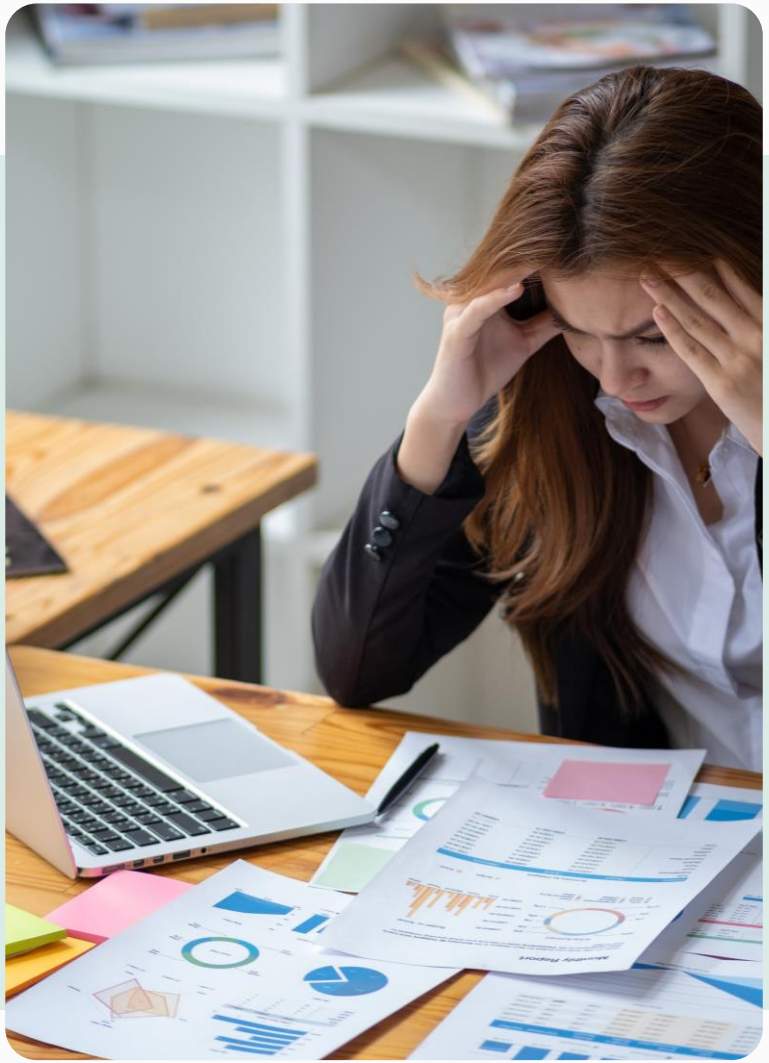
Consideration

Conditions need to be met to benefit from the extended transition timelines.

Appropriate surveillance to be performed by IVDR Notified Bodies on IVDD certified devices, irrespective of expiration date / status.

In short; 2023/607 “fix” is positioned on top of existing transitional timelines.

All IVDR classes are affected, not just Class D.



Objectives for the proposal

Objectives and considerations for the proposal:

Ensuring the availability of in vitro diagnostics (IVDR)

The aim of the proposal is to **ensure availability of safe devices, essential for healthcare. systems, and protect patient care**. The latest available data shows that a high number of IVDs currently on the market has not factored in the new rules (nor has been replaced by other devices), meaning that those devices would no longer be available. The Commission is therefore proposing to extend the transition periods to give manufacturers and notified bodies more time to complete the necessary conformity assessment procedures. This extension will be subject to **conditions**

More transparency on medical devices (EUDAMED

The Commission also proposes measures to enable and accelerate a **gradual roll out** of **EUDAMED**, a database that will contain information about all medical devices and IVDs placed on the EU market.

The mandatory use of **finalised parts** of EUDAMED will support all key players in the implementation of the regulatory framework and enhance transparency for the public

Prior notice foreseeing the interruption supply of IVDs or medical devices

The proposal also introduces a requirement for manufacturers to **give prior notice** to authorities, as well as to distributors or health institutions, if they foresee the interruption of supply of IVDs or medical devices, which **would pose risks** to patient care. This measure would enable healthcare systems to have more time to take action to safeguard patient care

IVDR change of transitional provisions (timeline extension)

- The new Amending Regulation **extends the IVDR transition timelines** while also recognising as valid previously issued IVDD Certificates for the duration of those extended transition timelines.
- This allows manufacturers to **continue placing their devices on the market** based on compliance to the Directive and to IVDR Art 110 provisions, **while transitioning** their devices to the IVDR.
- However, it is important to note that longer transition timelines **apply only** to devices that are **transitioning to the IVDR** while meeting additional specific conditions set out in the Regulation.
- These **conditions** are aimed at ensuring that the manufacturer has taken appropriate steps to transition to the IVDR. In summary:
  - ✓ To **comply with Directive 98/79/EC** and **does not present an unacceptable risk** to the health or safety of patients, users or other persons, or to other aspects of the protection of public health.
  - ✓ No later than **26 May 2025**, the manufacturer has put in place an **IVDR compliant QMS**
  - ✓ No later than **applicable deadlines**, the manufacturer has submitted an **IVDR application** and has signed a **formal written agreement** with a Notified Body
  - ✓ There are **no significant changes** implemented in the design or intended purpose of the device

IVDR change of transitional provisions (timeline extension)

- Given the above conditions, devices covered by IVDD Certificates that were valid as of 26 May 2022, but **expired** prior to the publication of this new amending Regulation benefit from the longer transition timelines **only if the manufacturer had applied for IVDR** and **signed a formal written agreement** prior to the expiry of those Directive Certificates or a **derogation/exemption** has been granted by a Competent Authority under either Article 54 or Article 92 of the IVDR.

- In cases where the manufacturer has their IVDR application with a different Notified Body to the one that issued the Directive Certificate, the Regulation **allows the IVDR Notified Body to take over the appropriate surveillance** of the devices covered the Directive Certificates issued by the other Notified Body, subject to an agreement between the two Notified Bodies and the manufacturer.

- However, the Notified Body designated under Regulation (EU) 2017/746 should **not be responsible** for conformity assessment and surveillance activities carried out by the Notified Body that issued the **original IVDD certificate**.

IVDR transition timeline

	IVDR compliant QMS	Formal application lodged	Formal written agreement with a Notified Body signed	Transition deadline
IVDD certified devices[1]	26 May 2025	26 May 2025	26 September 2025	31 December 2027
Class D self-declared[2]		26 May 2026	26 September 2026	31 December 2028
Class C self-declared[2]		26 May 2027	26 September 2027	31 December 2029
Class B and A[2] Sterile self-declared				

Notes

[1] **IVDD certified devices:** IVDD Certification from a Notified Body.

[2] **IVDD self-declared devices:** IVDs on the market under IVDD that did not need a Notified Body Certification.

The sell-off period for self-certified IVDs already placed on the market under the IVDD has been removed. These devices can be made further available on the market without legal time restrictions. For in-house devices, the requirement to justify that an equivalent device is not available on the market is postponed until May 2028.

Note: This summary is based on the current proposal COM(2024)43. Information will be reviewed when the final Amending Regulation is published

Possibilities moving forth

BSI will await the publication of the final amending publication. BSI plans to offer the same solutions for IVD Manufacturers, as we have done for Medical Device Manufacturers, when implementing EU Regulation EU 2023/607:

- IVD Manufacturer are **required** to declare that they **intend to transition** to IVDR and **meet the conditions set**, in order to profit from the extended timelines; this is **mandatory**.
- When the IVD device application has **been submitted** with BSI and has led to **an acceptance and agreement** before the defined transition deadline, the manufacturer can continue to place the device on the market, **under the IVDD**. Transitional provisions will remain (PMS, vigilance per IVDR).
- For legacy IVD devices that are covered by an **IVDD certificate**, the **validity will be extended to 31 December 2027** at the latest. The expiration date on the IVDD certificate will **not change**, however. **Appropriate surveillance** on the legacy devices covered by this certificate will be done by the **accepting Notified Body**.
- BSI already has a **process in place** for issuing **confirmation letters** to those devices that qualify for it and has issued hundreds of confirmation letters so far to aid manufacturers get market access for their qualifying legacy devices. BSI plans to offer **the same service** towards IVD Manufacturers.

Recommendations

In order to make full use of the currently available capacity for completing the IVDR transition, BSI **strongly recommends** that manufacturers who have already made or planned their IVDR applications and documentation submissions with BSI according to January 2022 legislation, **do not deviate** from their plans, and strongly urges other manufacturers who are yet to make their IVDR applications to **submit them as soon as possible** for the following reasons:

- **Only those devices transitioning** to the IVDR benefit from the longer transition timelines and extended validity of the Directive Certificates for those devices.
- Delaying or changing your current planned submissions will mean that the submissions **will be added to the end of the review queue** thus facing the risk of delayed conformity assessment.
- Manufacturers are not allowed to make significant changes to the design or intended purpose of their devices under the Directive **even under the longer transition timelines**.
- For those manufacturers intending to transition their devices to IVDR and are yet to submit their applications, NBs may not be able to process your application in a timely manner **if it is submitted very close to the application cut-off** timelines due to the anticipated rush of last-minute applications thus **facing the risk of not benefitting** from the longer transition timelines.

Q&A and Proposal

EUROPEAN
COMMISSION

Brussels, 23.1.2024
COM(2024) 43 final

2024/0021 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, information obligation in case of interruption of supply and the transitional provisions for certain *in vitro* diagnostic medical devices

(Text with EEA relevance)

EU Commission is currently drafting a Q&A document to support the COM(2024)43 proposal to be released when this will be published on the EUOJ

In late August, the EU Commission published a flowchart to identify whether a medical device is covered by the extended transitional period. It is anticipated that a similar flowchart will be developed for the amending regulation COM (2024)43.

Commission proposal COM(2024)43 in a nutshell

Manufacturer does NOT intend to transition legacy device to the IVDR

Directive Certificate was valid at the time of the publication of the COM(2024)43 on the OJEU	*Directive Certificate expired* prior to the publication of the COM(2024)43 on the OJEU

Manufacturer intends to transition legacy device to the IVDR

Directive Certificate was valid at the time of the publication of the COM(2024)43 on the OJEU	*Directive Certificate expired* prior to the publication of the COM(2024)43 on the OJEU

Commission proposal COM(2024)43 in a nutshell

Conditions for extension of *certificate* validity

Directive Certificate expired prior to the publication of the COM(2024)43 on the OJEU

- certificate not withdrawn prior to expiry
AND
- IVDR contract signed by the expiry date OR Derogation(Art54)/ Exemption(Art92) approved by CA before date of publication

Directive Certificate valid at the time of the publication of the COM(2024)43 on the OJEU

- No additional conditions

Conditions for *devices* to be placed on the market based on the directive certificates (with the extended validity)

- Continued compliance with IVDD (Including maintenance of appropriate surveillance)
- No significant changes (MDCG 2022-6)
- No safety concerns

- Implement IVDR QMS by 26th May 2025
- Apply under IVDR by 26th May 2025 and sign written agreement by 26th Sep 2025

Commission proposal COM(2024)43 in a nutshell

Conditions for self-declared IVDD *devices* to be placed on the market

- Continued compliance with IVDD
- No significant changes (MDCG 2022-6)
- No safety concerns

- Implement IVDR QMS by 26th May 2025
- Apply under IVDR and sign written agreement according to staggered approach based on classification

POLL #1

IVDD certificate CE 123456 expired on 12th January 2024. Class D under IVDR.
No IVDR contract with a NB in place. No derogation/exemption granted by a Competent Authority for legacy device.
Can the legacy device benefit from the extended transitional timelines?

A	No, stop placing on expiry date
B	Yes, up to 26th May 2025
C	Yes, up to 31st Dec 2027

POLL #1

IVDD certificate CE 123456 expired on 12th January 2024. Class D under IVDR.
No IVDR contract with a NB in place. No derogation/exemption granted by a Competent Authority for legacy device.
Can the legacy device benefit from the extended transitional timelines?

A **No, stop placing on the market on expiry date**

B

C

Conditions for extension of *certificate* validity

Directive Certificate expired prior to the publication of the COM(2024)43 on the OJEU

- certificate not withdrawn prior to expiry
AND
- IVDR contract signed by the expiry date OR Derogation(Art54)/ Exemption(Art92) approved by CA before date of publication

Directive Certificate valid at the time of the publication of the COM(2024)43 on the OJEU

- No additional conditions

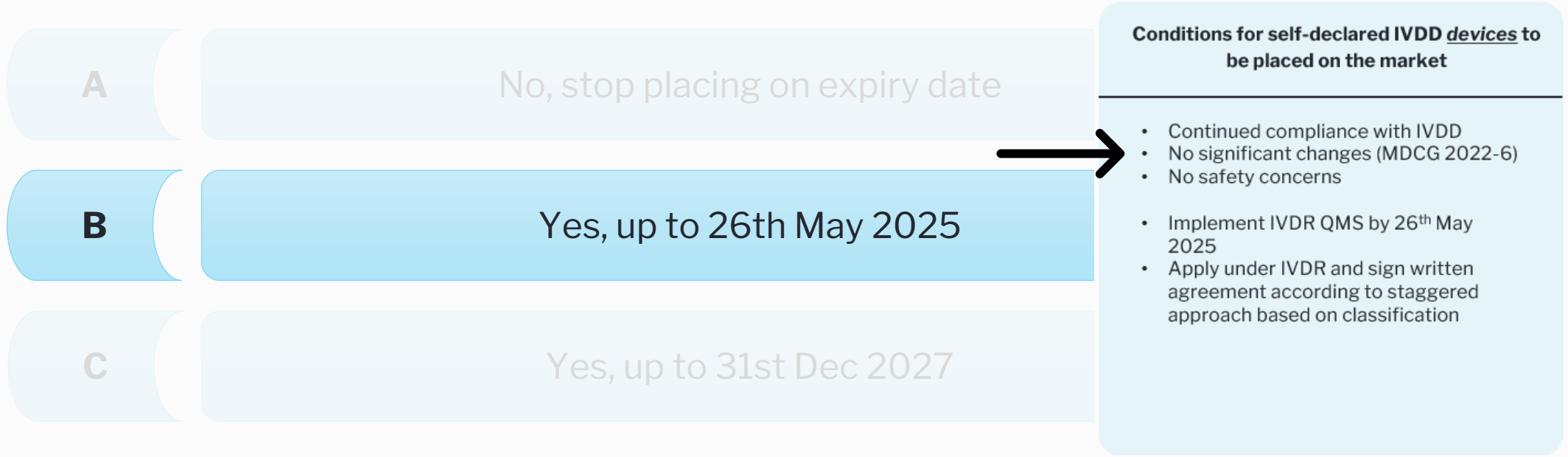
POLL #2

IVDD self-declared with a DoC signed by 26th May 2022. Class D under IVDR.
No IVDR contract with a NB in place and no intention to transition to IVDR.
Can the legacy device benefit from the extended transitional timelines?

A	No, stop placing on expiry date
B	Yes, up to 26th May 2025
C	Yes, up to 31st Dec 2027

POLL #2

IVDD self-declared with a DoC signed by 25th May 2022. Class D under IVDR.
No IVDR contract with a NB in place and no intention to transition to IVDR.
Can the legacy device benefit from the extended transitional timelines?



POLL #3

IVDD self-declared with a DoC signed by 25th May 2022. Class D under IVDR.
No IVDR contract with a NB in place. Intention to transition to IVDR.
Can the legacy device benefit from the extended transitional timelines?

A	No, stop placing on expiry date
B	Yes, up to 26th May 2025
C	Yes, up to 31st Dec 2027

POLL #3

IVDD self-declared with a DoC signed by 25th May 2022. Class D under IVDR.
No IVDR contract with a NB in place. Intention to transition to IVDR.
Can the legacy device benefit from the extended transitional timelines?

Conditions for self-declared IVDD *devices* to be placed on the market

- Continued compliance with IVDD
- No significant changes (MDCG 2022-6)
- No safety concerns

- Implement IVDR QMS by 26th May 2025
- Apply under IVDR and sign written agreement according to staggered approach based on classification

A

B

C Yes, up to 31st Dec 2027, if additional conditions are satisfied

POLL #4

IVDD certificate CE 123456 expires after the date of publication of COM(2024)43.
Class D under IVDR. No IVDR contract with a NB in place and no intention to transfer to IVDR.
No derogation/exemption granted by a Competent Authority for legacy device.
Can the legacy device benefit from the extended transitional timelines?

A	No, stop placing on the market on expiry date
B	Yes, up to 26th May 2025
C	Yes, up to 31st Dec 2027, if additional conditions are satisfied

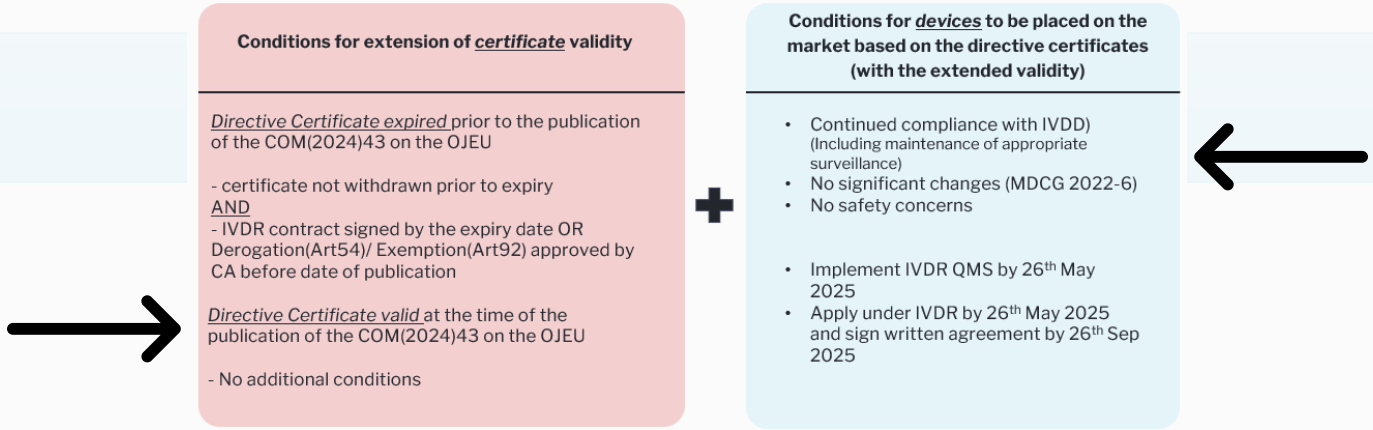
POLL #4

IVDD certificate CE 123456 expires after the date of publication of COM(2024)43.
Class D under IVDR. No IVDR contract with a NB in place and no intention to transfer to IVDR.
No derogation/exemption granted by a Competent Authority for legacy device.
Can the legacy device benefit from the extended transitional timelines?

A — No, stop placing on the market on expiry date

B — Yes, up to 26th May 2025

C



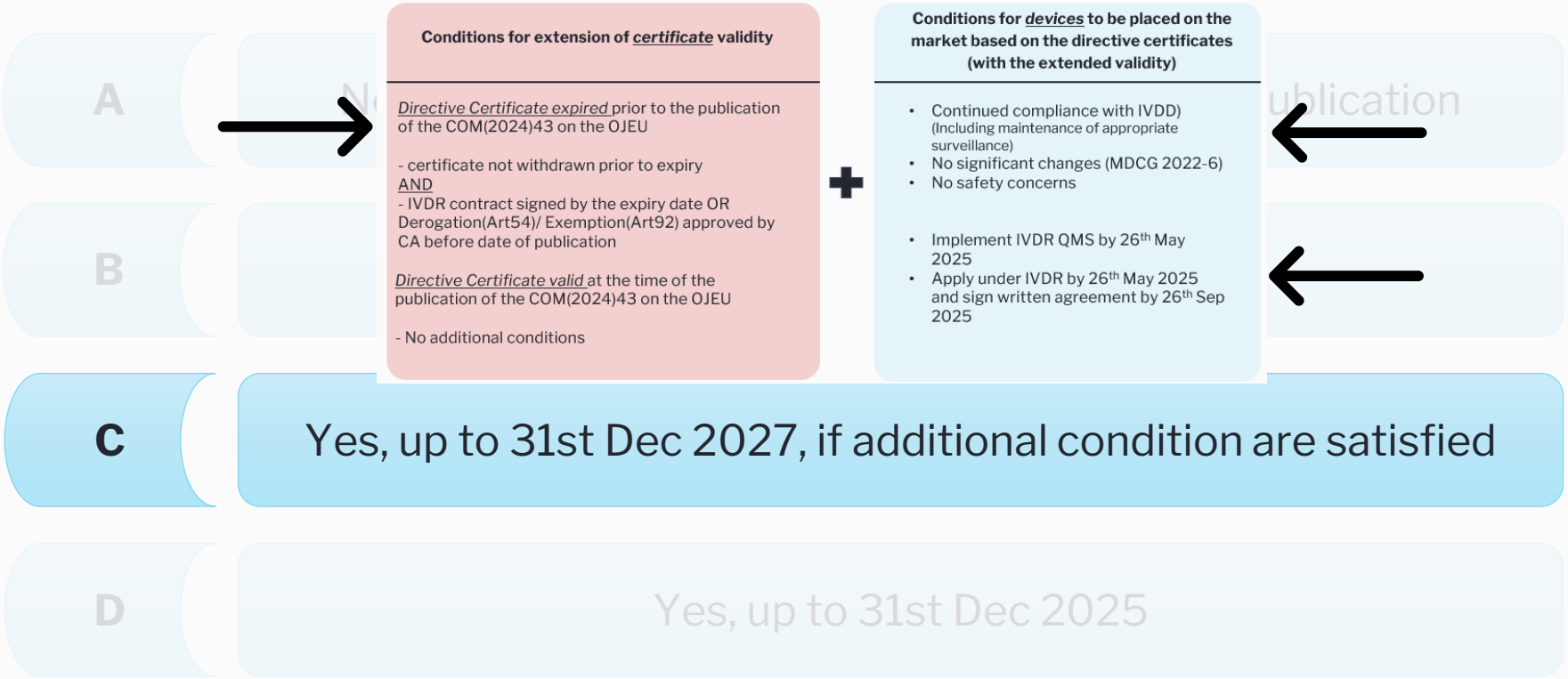
POLL #5

IVDD certificate CE 123456 expired on 12th February 2024. Class D under IVDR.
IVDR contract signed with a NB in January 2024. No derogation/exemption granted by a Competent Authority for legacy device.
Can the legacy device benefit from the extended transitional timelines?

A	No, stop placing on the market on the date of publication
B	Yes, up to 26th May 2025
C	Yes, up to 31st Dec 2027, if additional conditions are satisfied
D	Yes, up to 31st Dec 2025

POLL #5

IVDD certificate CE 123456 expired on 12th February 2024. Class D under IVDR.
IVDR contract signed with a NB in January 2024. No derogation/exemption granted by a Competent Authority for legacy device.
Can the legacy device benefit from the extended transitional timelines?



POLL #6

IVDD certificate CE 123456 expires after the date of publication of COM(2024)43.
Class C under IVDR. No IVDR contract with a NB in place. No derogation/exemption granted by a Competent Authority for legacy device.
Can the legacy device benefit from the extended transitional timelines?

A	No, stop placing on the market on expiry date
B	Yes, up to 31st Dec 2029, if additional conditions are satisfied
C	Yes, up to 31st Dec 2028, if additional conditions are satisfied
D	Yes, up to 31st Dec 2027, if additional conditions are satisfied

POLL #6

IVDD certificate CE 123456 expires after the date of publication of COM(2024)43.
Class C under IVDR. No IVDR contract with a NB in place. No derogation/exemption granted by a Competent Authority for legacy device.
Can the legacy device benefit from the extended transitional timelines?

A

B

C

Conditions for extension of *certificate* validity

Directive Certificate expired prior to the publication of the COM(2024)43 on the OJEU

- certificate not withdrawn prior to expiry
AND
- IVDR contract signed by the expiry date OR Derogation(Art54)/ Exemption(Art92) approved by CA before date of publication

Directive Certificate valid at the time of the publication of the COM(2024)43 on the OJEU

- No additional conditions

Conditions for *devices* to be placed on the market based on the directive certificates (with the extended validity)

- Continued compliance with IVDD) (Including maintenance of appropriate surveillance)
- No significant changes (MDCG 2022-6)
- No safety concerns

- Implement IVDR QMS by 26th May 2025
- Apply under IVDR by 26th May 2025 and sign written agreement by 26th Sep 2025

D Yes, up to 31st Dec 2027 if additional conditions are satisfied

Final remarks

Important points to remember

Do not postpone/delay your IVDR plans!

Manufacturers are responsible for placing legacy devices on the market lawfully

- **Ensure** compliance with proposal conditions, request the NB to continue/transfer appropriate surveillance
- **Stop** placing on the market **if** conditions are not met

Deadlines for all classes of legacy devices transitioning to IVDR

- **26 May 2025/2026/2027**: application under IVDR
- **26 Sept 2025/2026/2027**: sign IVDR written agreement
- **Appropriate surveillance** for IVDD certified devices

IVDR Technical Documentation submission

- Provide a TD submission **plan** to the NB
- **Stick to** the planned submission date
- Refer to EU Commission dashboard for average time to certification

Where can I find additional information?

You can visit our IVDR dedicated webpage to access additional resources to support you.

Stay tuned to access upcoming guidance.

If you have additional questions, you can email us at medicaldevices@bsigroup.com