Regulatory Updates and IVDR Transition

BSI Webinar; 22 May 2025

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Understanding Regulatory Requirements and IVDR Transition

Introduction

Status Quo of the IVDR and the Notified Bodies

Regulatory Updates for IVDR

Implementation of 2024/1860 (IVDR Extensions)

EUDAMED Update

Q&A

End of presentation

Status Quo of the IVDR and the Notified Bodies

What have Notified Bodies been doing?

Introduction

The situation so far.

Currently.

Currently, we are **26 months** into the IVDR after the original Date of Application (26 May 2022).

Big relief.

Big relief has been seen after publication of Regulation (EU) 2022/112 (transitional provisions).

Meanwhile.

In the meantime, notified bodies (a.o. BSI) have been **very busy** dealing with the applications that were sent in from manufacturers.

Learning Curve.

This road to compliance has been quite “**rocky**” to say the least, leading to a steep learning curve for both manufactures as well as notified bodies.

Past Performance Review Notified Bodies

The developments over the last 2,5 years (after the Date of Application)

Originally

At the time of the original Date of Application (26 May 2022), a total of **270 certificates** were issued and **648 applications** received.

Numbers

The **number** of Notified Bodies have expanded from **8 to 17.** Total number of IVDR certificates have grown to **1163** and applications have grown to **2388** in December 2024.

Timeliness

Notified bodies 50% of NBs: **6-12 months** to issue a new QMS certificate. 67% of the NBs: **13-18 months** to issue a product certificate. This is getting better…

In summary

Considering the limited time and capacity, IVD Notified Bodies managed **to step up** and were able to **improve performance**; we are not where we would like to be, still.

https://health.ec.europa.eu/study-supporting-monitoring-availability-medical-devices-eu-market_en

IVDR Notified body number is increasing…

Search results (12)

NOTIFICATION STATUS Active

LEGISLATION Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Body type	Body Name	Country
NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
NB 0123	TÜV SÜD Product Service GmbH	Germany
NB 0124	DEKRA Certification GmbH	Germany
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0344	DEKRA Certification B.V.	Netherlands
NB 0459	GMED SAS	France
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
NB 0537	Eurofins Electric & Electronics Finland Oy	Finland
NB 2265	3EC International a.s.	Slovakia
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 2962	QMD Services GmbH	Austria
NB 3018	Sertio Oy	Finland

Status 22nd November 2023

Search results (17)

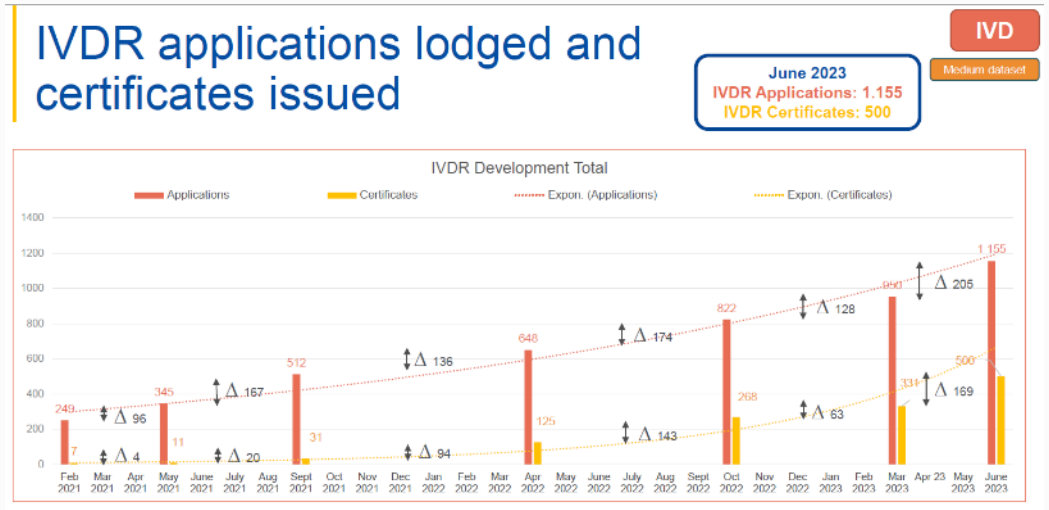
NOTIFICATION STATUS Active

LEGISLATION Regulation (EU) 2017/746 on in vitro diagnostic medical devices

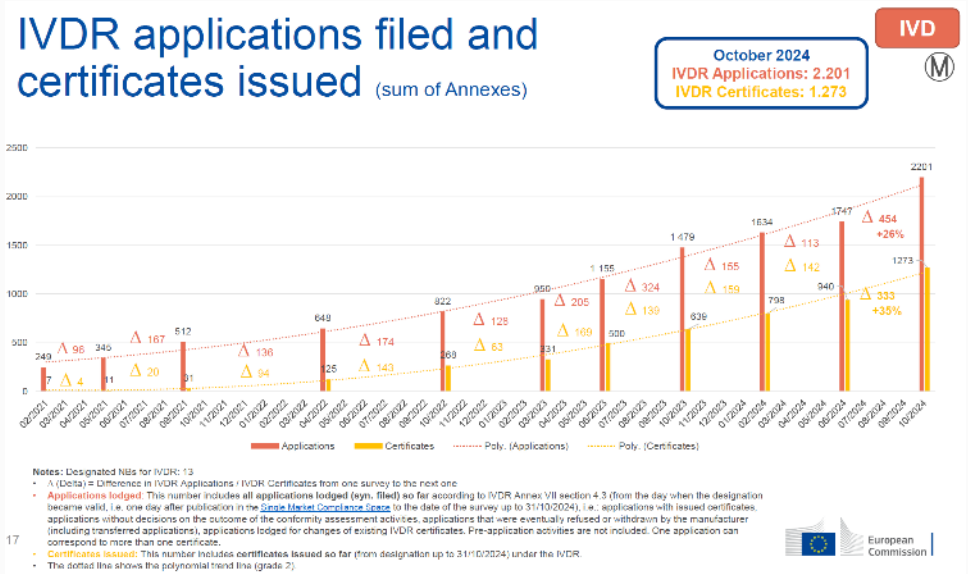
Body type	Body Name	Country
NB 0373	ISTITUTO SUPERIORE DI SANITA'	Italy
NB 0051	IMQ ISTITUTO ITALIANO DEL MARCHIO DI QUALITÀ S.P.A.	Italy
NB 0197	TÜV Rheinland LGA Products GmbH	Germany
NB 0483	MDC MEDICAL DEVICE CERTIFICATION GMBH	Germany
NB 2797	BSI Group The Netherlands B.V.	Netherlands
NB 0318	CENTRO NACIONAL DE CERTIFICACION DE PRODUCTOS SANITARIOS	Spain
NB 0050	National Standards Authority of Ireland (NSAI)	Ireland
NB 0537	Eurofins Electric & Electronics Finland Oy	Finland
NB 0459	GMED SAS	France
NB 2265	3EC International a.s.	Slovakia
NB 2962	QMD Services GmbH	Austria
NB 0124	DEKRA Certification GmbH	Germany
NB 1639	SGS Belgium NV	Belgium
NB 0123	TÜV SÜD Product Service GmbH	Germany
NB 3018	Sertio Oy	Finland
NB 2460	DNV Product Assurance AS	Norway
NB 0344	DEKRA Certification B.V.	Netherlands

Status 30 April 2025

IVDR Certification applications are increasing…



Status 22nd November 2023



Status December 2024

Designated IVDR NBs – current developments

- Current IVDR Notified Body pool is small and is expected not to grow to the same size as MDR Notified Bodies; but **4 new IVDR NB's** have been **added** in the last year.

- Change in transitional provisions (2022 and 2024) have led to the situation that some IVD manufacturers **have withdrawn their initial applications** with the Notified Bodies…be mindful that the EC has communicated that there is not going to come another extension…this is it.

- Class D IVD's can now be independently verified by designated **EU Reference Labs** (EURL) as of 1 October 2024.

- **Positive** development is that the **quality** of IVDR technical documentation and performance evaluation documentation is **steadily improving**.

- **Consistency** among IVDR Notified Bodies is also improving due to harmonization (NBCG-MED, TEAM-NB) and more engagement with the EC and MDCG and implementing changes in the conformity assessment process a.o. **structured dialogue**.

Regulatory Updates EU IVDR and MDR

Short term and longer-term amendments are coming, also for IVD...

State of Play MDR/IVDR

EU short term initiatives (legislative and non-legislative)

Legislative

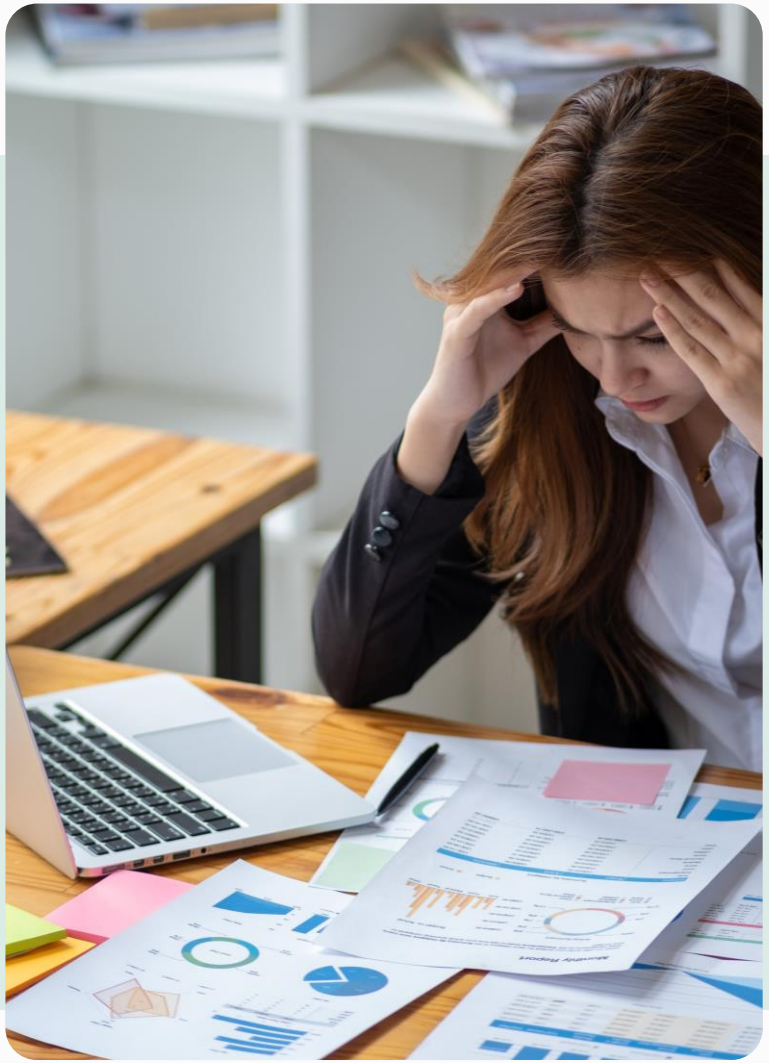
- Implementing regulation for e-IFU's for medical devices -> Planned adoption **Q2 2025**
- Establishment of an Expert Panel on orphan and paediatric devices -> Planned adoption **Q2 2025**
- Reclassification of well-established technologies (WET) -> Planned adoption **Q4 2025**
- Expansion of the list of well-established technologies (WET) -> Planned adoption **Q3 2025**
- Implementing rules regarding requirements to be met by Notified Bodies -> Planned adoption **Q4 2025**

Non-legislative

- Guidance on breakthrough technologies (**BtX**)
- Guidance on **orphan IVDs**
- Guidance on sampling of technical documentation
- Guidance on certificates under conditions
- Guidance on **structured dialogue**
- IMDRF Guidance of **high priority** is expected to be published
- MDSAP mapping activities (NBCG-Med and MDCG)

Regulatory Updates EU IVDR – EU 2024/1860

Note: The EU Act 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.

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.

26 May 2022

- IVDR PMS and vigilance applies of all IVDs
- No new IVDD certificates issued by NB
- All new products to market under IVDR
- Class A devices must be IVDR compliant

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 actually **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**.

Notified Body Expectations

Condition	Up to the 26 May 202X	From 27 May 202X and up to the 26 Sept 202X	From the 27 Sept 202X until the end of 2027/2028/2029
Legacy device continues to comply with IVDD	✓	✓	✓
Manufacturer to ensure that the appropriate surveillance for the certified legacy devices they intend to place on the market is maintained by the NB*	✓	✓	✓
No significant changes in the design or intended purpose are allowed (MDCG 2022-6)	✓	✓	✓
Legacy device does not present an unacceptable risk	✓	✓	✓
Manufacturer's quality management system in compliance with IVDR Article 10(8)	In place by 26 May 2025	✓	✓
Lodged a formal application for IVDR conformity assessment in respect of the legacy device or in respect of a device intended to substitute that device	Lodged by 26 May 2025/2026/2027		
The manufacturer and the NB (IVDR NB) has signed a formal agreement for IVDR conformity assessment		By the 26 Sept 2025/2026/2027	
*Appropriate surveillance of legacy devices to be placed on the market is transferred to the IVDR NB (where different from the IVDD NB)		By the 26 Sept 2025	Maintenance of appropriate surveillance for eligible legacy devices

The IVDR formal application can be transferred from one NB to another NB even after 26 Sept 202X, maintaining compliance of the legacy devices with the requirement of art.110

Notified Body Expectations

Processes in place to ensure continuous compliance with requirements of amended IVDR art.110

EU Commission Q&A, Q. 7

The manufacturer should be able to provide a **self-declaration** confirming that the conditions for the extension are fulfilled, stating the end date of the transition period

Manufacturer Self-Declaration

We declare that the following devices comply with..

a) Cont. compliance to IVDD

b) No sign changes in design or intended purpose

c) No safety concerns

d) IVDR compliant QMS by 26 May 2025

e) IVDR application by 26 May 202X and written agreement by 26 Sep 202X

XXXXX YYYY/MM/DD

Notified Body Expectations

Does the manufacturer have a process for updating/re-issuing the self-declaration and implementing other actions such as pausing/ ceasing to place legacy devices on the market based on the factors/outcomes/data that affect compliance to the five conditions specified in EU 2024/1860?

Manufacturer Self-Declaration

We declare that the following devices comply with..

a) Cont. compliance to IVDD

b) No sign changes in design or intended purpose

c) No safety concerns

d) IVDR compliant QMS by 26 May 2025

e) IVDR application by 26 May 202X and written agreement by 26 Sep 202X

XXXXX YYYY/MM/DD

Continued compliance with IVDD

Outcomes from NB IVDD appropriate surveillance and NB actions on IVDD certificates

No significant changes

- Change control process outputs
- NB assessment of change history

No unacceptable risk

- Post-market surveillance
- C.A. market surveillance
- NB actions on IVDD certificates – suspensions, scope restrictions etc

IVDR compliant QMS by 26 May 2025

- Outcomes of NB IVDR QMS audits
- CA audits (in the context of Market Surveillance)

IVDR application by 26 May 2025 and written agreement by 26 Sep 2025

IVDR application/IVDR certification refusals, withdrawals, cancellations

Note: Activities for which a NB is involved are not applicable to self-declared IVDD devices

What happens if you do not comply?

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

(a) those devices continue to comply with Directive 98/79/EC;

(b) there are no significant changes in the design and intended purpose;

(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(d) no later than 26 May 2025, the manufacturer has put in place a quality management system in accordance with Article 10(8);

(e) the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, no later than:

(i) 26 May 2025, for devices referred to in paragraph 3a and paragraph 3b, point (a), of this Article;

(ii) 26 May 2026, for devices referred to in paragraph 3b, point (b), of this Article;

(iii) 26 May 2027, for devices referred to in paragraph 3b, point (c), of this Article;

(f) the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII no later than:

(i) 26 September 2025, for devices referred to in paragraph 3a and paragraph 3b, point (a), of this Article;

(ii) 26 September 2026, for devices referred to in paragraph 3b, point (b), of this Article;

(iii) 26 September 2027, for devices referred to in paragraph 3b, point (c), of this Article.

Legacy device does not comply with IVDD

If a **Major NCs that could lead to safety or performance concerns** is raised

Surveillance including elements of IVDR Art 110

Audit

The legacy device cannot be placed on the market anymore under Directive as long as the major NC is open, unless justified otherwise

Send Corrective action plan (CAP) to NB

NC close out audit

Major NC adequately addressed: No further actions and the legacy devices can be placed back on the market

Major cannot be closed or CAPA not acceptable: Cancellation/suspension/scope restriction depending on the nature of the non-conformance

What happens if you do not comply?

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

(a) those devices continue to comply with Directive 98/79/EC;

(b) there are no significant changes in the design and intended purpose;

(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(d) no later than 26 May 2025, the manufacturer has put in place a quality management system in accordance with Article 10(8);

(e) the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, no later than:

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(ii) 26 September 2026, for devices referred to in paragraph 3b, point (b), of this Article;

(iii) 26 September 2027, for devices referred to in paragraph 3b, point (c), of this Article.

Significant changes implemented

A **Major NCs** is raised

Send Corrective action plan (CAP) to NB

NC close out audit

Major NC adequately addressed: No further actions, but the subject legacy device(s) may not be marketed anymore (since changes already implemented, and if they cannot be reversed) Cancellation/scope restriction for impacted device(s)

Major cannot be closed or CAPA not acceptable: Suspension/ cancellation of the directive certificate potentially affecting all the legacy devices

Subject device cannot be placed on the market anymore since the change is already implemented

Audit

Significant changes (MDCG 2022-6)
Notification system for changes
Procedure adequate and effective including Art 110

What happens if you do not comply?

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

(a) those devices continue to comply with Directive 98/79/EC;

(b) there are no significant changes in the design and intended purpose;

(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(d) no later than 26 May 2025, the manufacturer has put in place a quality management system in accordance with Article 10(8);

(e) the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, no later than:

(i) 26 May 2025, for devices referred to in paragraph 3a and paragraph 3b, point (a), of this Article;

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(iii) 26 May 2027, for devices referred to in paragraph 3b, point (c), of this Article;

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(i) 26 September 2025, for devices referred to in paragraph 3a and paragraph 3b, point (a), of this Article;

(ii) 26 September 2026, for devices referred to in paragraph 3b, point (b), of this Article;

(iii) 26 September 2027, for devices referred to in paragraph 3b, point (c), of this Article.

Unacceptable risk to health and safety – Art 89 and Art 90 of IVDR

Safety issues leading to **Major NCs**

Send Corrective action plan (CAP) to NB

NC close out audit

Audit

Vigilance procedure and implementation as per IVDR Art 110
Procedures and processes for feedback and maintenance of self-declaration

Subject device cannot be placed on the market until the safety concern is addressed

Major NC adequately addressed: No further actions and the subject device may be placed on the market again

Major cannot be closed or CAPA not acceptable: Cancellation of certificate / scope restriction leading to permanent loss of market access under the Directives

What happens if you do not comply?

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

(a) those devices continue to comply with Directive 98/79/EC;

(b) there are no significant changes in the design and intended purpose;

(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(d) no later than 26 May 2025, the manufacturer has put in place a quality management system in accordance with Article 10(8);

(e) the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, no later than:

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(ii) 26 September 2026, for devices referred to in paragraph 3b, point (b), of this Article;

(iii) 26 September 2027, for devices referred to in paragraph 3b, point (c), of this Article.

After 26 May 2025, IVDR QMS not implemented or ineffective implementation

If a **Major NCs** is raised

Send Corrective action plan (CAP) to NB

NC close out audit

Major NC adequately addressed: No further actions

Major cannot be closed or CAPA not acceptable: Cancellation/suspension of **all** the Directive certificates issued under the same QMS system

Audit

The full IVDR Article 10(8) will be the audit criteria after 26 May 2025 for legacy devices

Legacy devices cannot be placed on the market anymore under Directives as long as the major NC is open, unless justified otherwise

What happens if you do not comply?

3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:

(a) those devices continue to comply with Directive 98/79/EC;

(b) there are no significant changes in the design and intended purpose;

(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

(d) no later than 26 May 2025, the manufacturer has put in place a quality management system in accordance with Article 10(8);

(e) the manufacturer or the authorised representative has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that device, no later than:

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(f) the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII no later than:

(i) 26 September 2025, for devices referred to in paragraph 3a and paragraph 3b, point (a), of this Article;

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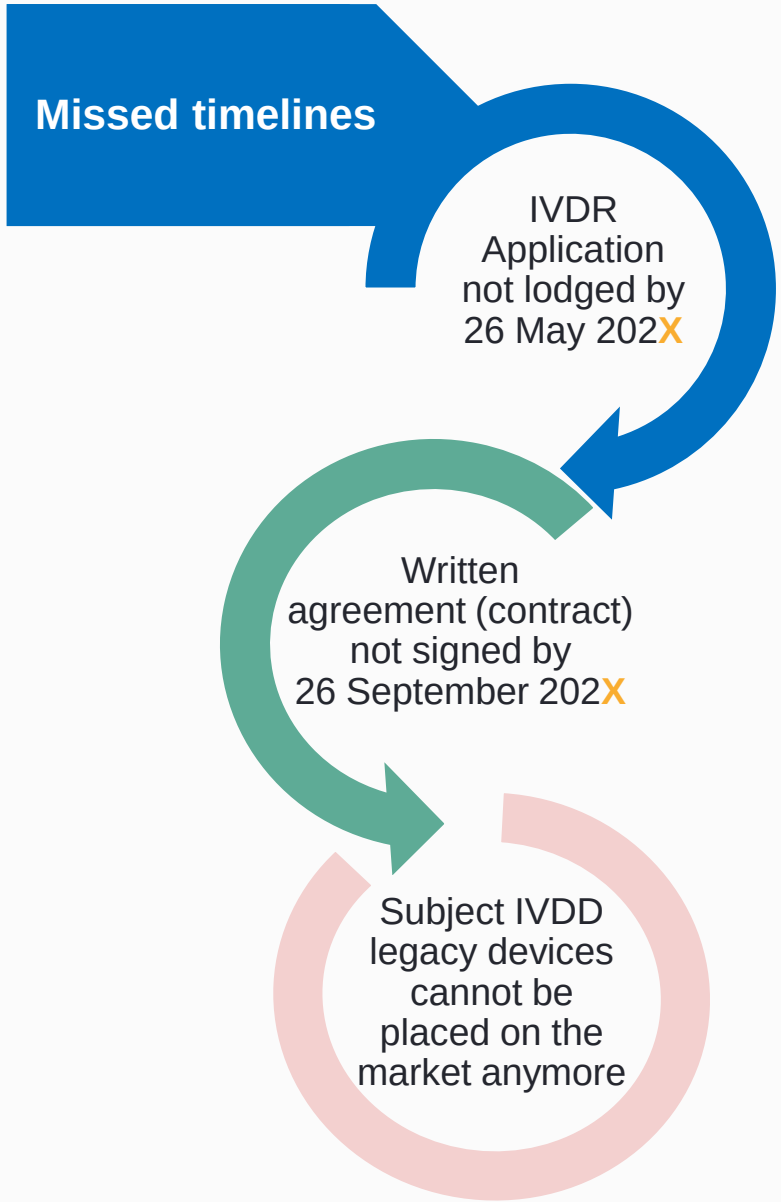

Impact of IVDR refusals/scope restrictions/ cancellations or withdrawals of IVDR application on legacy devices

- *Art 110 (3c). Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met …*

Impact of IVDR refusals/scope restrictions/ cancellations or withdrawals of IVDR application on legacy devices

If the NB refuses to issue an IVDR certificate, restricts the scope of an IVDR certificate or cancels an IVDR certificate etc…

If the manufacturer withdraws the IVDR application/cancels the certificate or restricts the scope of an IVDR certificate

The IVDR written agreement in relation to those affected devices is terminated

Potential impact on related legacy devices based on when the IVDR refusals/scope restrictions/cancellations or withdrawals of IVDR application happens

Impact of IVDR refusals/scope restrictions/ cancellations or withdrawals of IVDR application on legacy devices

IVDD certificate expired on or before 8 July 2024

No IVDR application lodged before the IVDD certificate expiry date

The extended transitional period ceases to apply for the impacted legacy devices

If legacy devices are covered by a **derogation/exemption** granted by a C.A. [IVDR Art.54 or Art.97(1)] **before 9 July 2024**

Up to the 26 May 2025

The extended transitional period continues to apply provided that an IVDR application is lodged by the 26 May 2025 and the IVDR written agreement is signed by the 26 Sept 2025

From the 27 May 2025

The extended transitional period ceases to apply for the impacted legacy devices since no IVDR application can be lodged after 26 May 2025 for benefitting from the extended timelines

Impact of IVDR refusals/scope restrictions/ cancellations or withdrawals of IVDR application on legacy devices

IVDD certificate expired on or after 9 July 2024

Up to the 26 May 2025

The extended transitional period continues to apply provided that an IVDR application is lodged by the 26 May 2025 and the IVDR written agreement is signed by the 26 Sept 2025

From the 27 May 2025

The extended transitional period ceases to apply for the impacted legacy devices since no IVDR application can be lodged after 26 May 2025 for benefitting from the extended timelines

Impact of IVDR refusals/scope restrictions/ cancellations or withdrawals of IVDR application on legacy devices

IVDD Self-declared up-classified under IVDR

If legacy devices are covered by a **declaration of conformity signed before the 26 May 2022**

Up to the 26 May 202X	From the 27 May 202X
The extended transitional period continues to apply provided that an IVDR application is lodged by the 26 May 202X and the IVDR written agreement is signed by the 26 Sept 202X	**The extended transitional period ceases to apply** for the impacted legacy devices since no IVDR application can be lodged after 26 May 202X for benefitting from the extended timelines

Recommendations to Manufacturers

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.

EUDAMED

Where is Eudamed at?

Eudamed

- What is Eudamed? IT system outlined in MDR and IVDR to manage:
  - UDI database
  - Registration of devices
  - Registration of economic operators
  - Notified bodies and certificates
  - Performance studies
  - Vigilance and post market surveillance
- Original language of MDR and IVDR required that all required modules of Eudamed become mandatory at the same time.
- Due to ongoing delays with completion of the modules, these requirements have been updated to allow for a gradual roll out of Eudamed as each modules becomes available.

Eudamed (rollout)

EUDAMED Modules	Available for voluntary use	Planned OJEU publication date	Period after notice that they become mandatory
Actors	AVAILABLE	Jul 2025	6 months
Vigilance	Q4 2024	Jan 2026	6 months
Clinical Investigation & Performance studies	Q3 2026	Q2 2027?	> 6 months for CI/PS module < 5 years (the coordinated assessment will become mandatory for all Member States when a sponsor submits a single application)
Market surveillance	Q4 2024	Jul 2025	6 months
UDI/Device	AVAILABLE	Jul 2025	6 months
NB & Certificate	AVAILABLE	Jul 2025	6 months

Phased introduction of EUDAMED modules - Forecast

EUDAMED modules declared functional:

- Actor
- UDI/Devices
- NBs and certificates
- Market surveillance

Mandatory use of Moduled:

- Actor
- UDI/Devices
- NBs and certificates
- Market surveillance

Vigilance and PMS module declared functional

Mfrs complete the registration of MDR/IVDR devices and legacy devices

Mandatory use of Vigilance and PMS module

Module for NBs and certificates:
NBs must complete certificate registration, including validated SS(C)P uploads

https://health.ec.europa.eu/document/download/04ce2012-97df-4dd0-8a39-d4f6993b9e16_en?filename=md_eudamed_roadmap_en.pdf

Q&A

Thank you for joining us today