What Class C IVD Device Manufacturers Must Do Now

To Meet Upcoming Deadlines

Alex Laan – Head of IVD Notified Body

Charlotte Hess – Senior Business Development Manager – IVD Lead EMEA

Agenda

Regulatory Updates for IVDR

Class C IVD’s and the IVDR

IVDR extension for Class C IVD’s; application of (EU) 2024/1860

Engagement with BSI on Class C IVD’s before / after 26 May 2026

Meet the BSI IVDR Team!

Q&A

Poll Question 1

Do you already have a contract with a Notified Body?

a) Yes, for IVDR

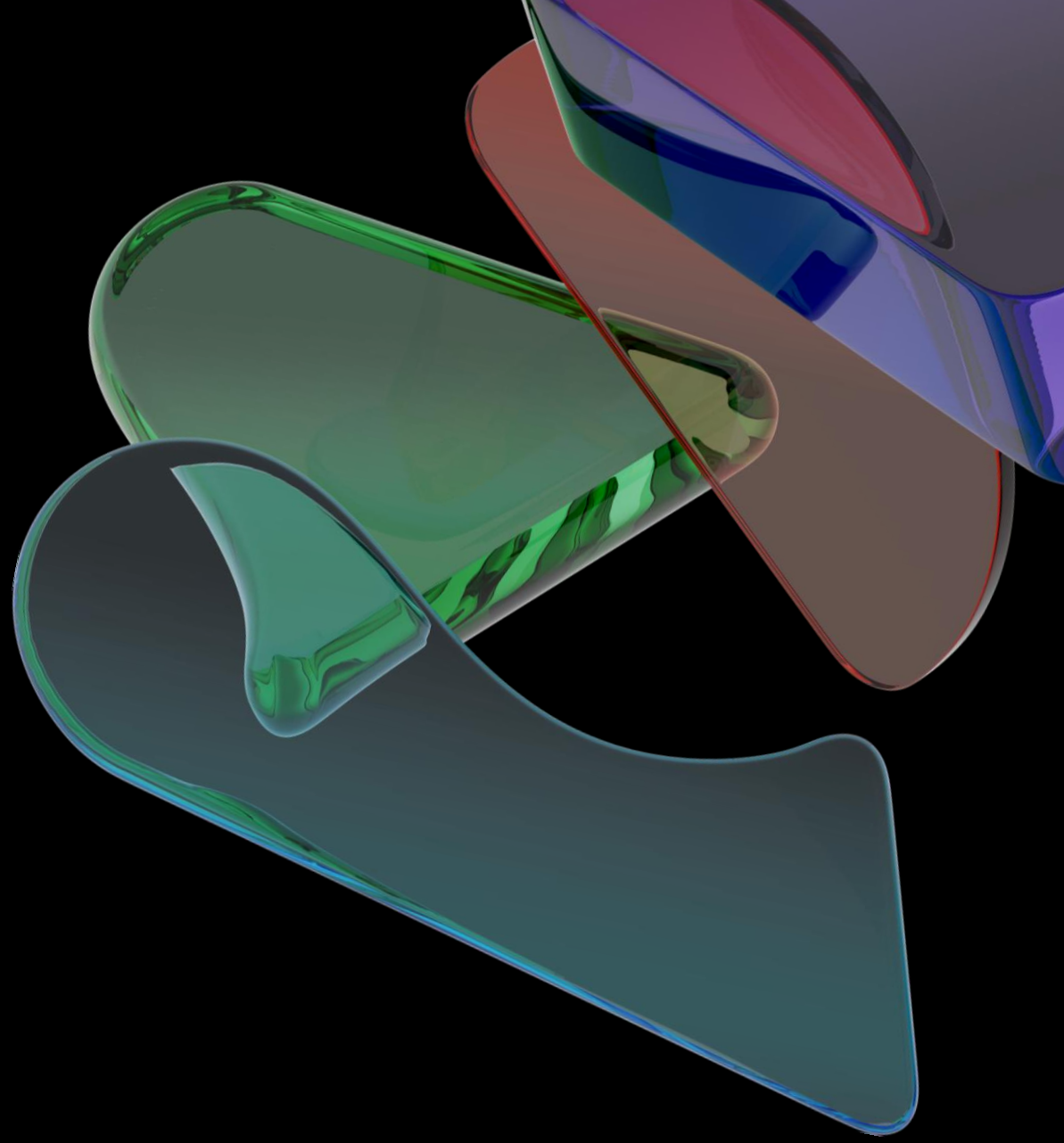
b) For ISO 13485 only

c) No

Regulatory Updates for IVDR

Alex Laan

Head of IVD Notified Body



Introduction

The situation so far.

Currently.

Currently, we are **22 months** into the IVDR after the publication of the amending regulation (EU 2024/1860 (13 June 2024).

Big relief.

Big relief has been seen after when a total of 7 IVDR Notified Bodies have been added, to quench NB capacity constraints.

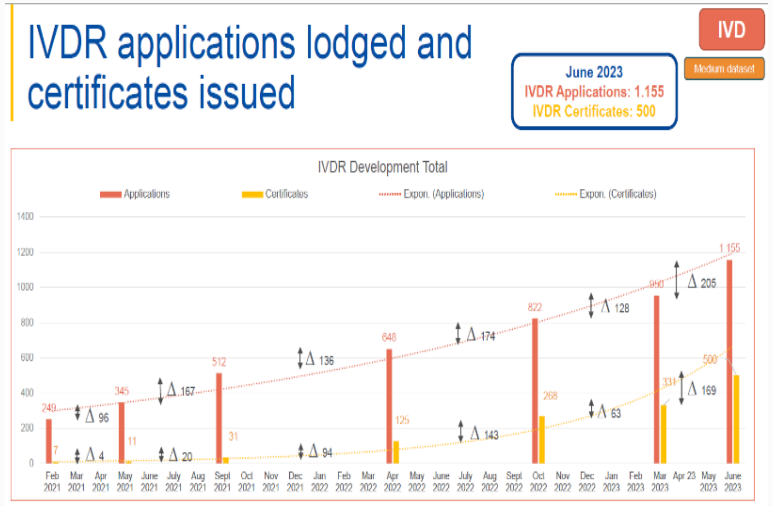
Meanwhile.

In the meantime, the Targeted Evaluation of the IVDR has resulted in a Targeted Proposal to amend the IVDR. And an implementing Act to amend Annex VII got published.

Learning Curve.

This road to compliance has been not quite as “**rocky**” as before, due to the learning curve that seems to flatten for both manufactures as well as notified bodies.

IVDR Certification applications are increasing…



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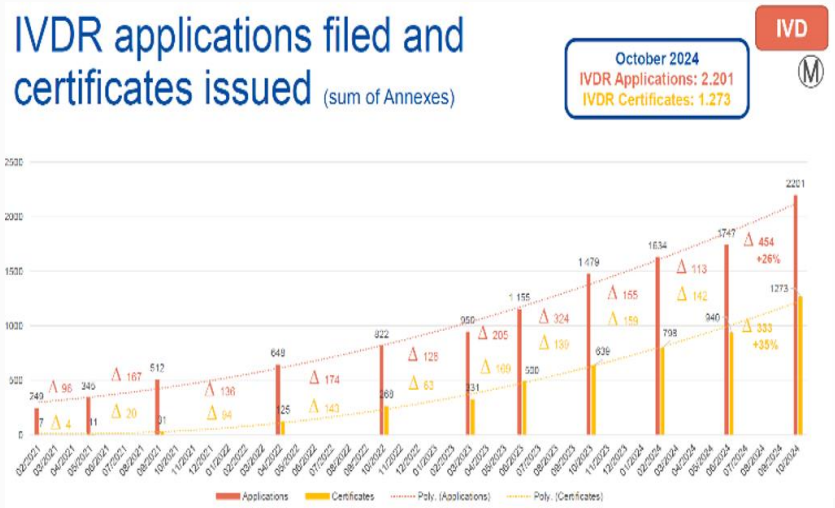

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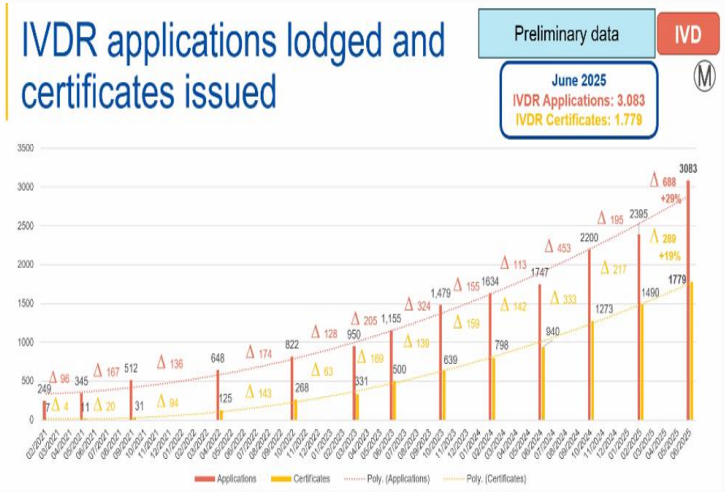

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MDR/IVDR Changes

Short-Term Measures

Legislative Measures

- Expand scope of e-IFU legislation
- Expert panels for Orphan and paediatric devices
- Well-established Technologies (WET) – Reclassification and expansion
- IVDs – expand Common Specifications
- Health Technology Assessments – Joint clinical assessments
- Rules for NBs – Annex VII changes

Non-legislative measures (Guidance)

- Breakthrough devices
- Substantial Changes
- Orphan IVDs
- Sampling of TD
- Certificates under conditions
- Structured Dialogue
- MDSAP mapping activities
- Guidance on substantial changes

Targeted Evaluation

10-year assessment of effectiveness of MDR & IVDR

Longer term changes to MDR & IVDR

Amending legislation – new legislation going through co-decision

Commission has the 'right of initiative' – but substantial input & involvement from Member States & European Parliament

Focus likely to be on:
system governance & centralisation of some functions
availability of products, alternative pathways, clinical evidence requirements
cutting 'red tape', administrative burden & costs

Class C IVD’s and the IVDR

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

What are Class C devices per the IVDR?

- Class C mostly cover IVD’s that represent a **High Individual Risk/Moderate Public Health Risk**, such as Genetic testing, particular blood grouping, cancer diagnostics (oncology panels), infectious disease testing (e.g., Salmonella,), and prenatal screening.

- In accordance with Regulation (EU) 2017/746, devices shall be classified into classes A, B, **C** and D, considering the intended purpose of the devices and their inherent risks (Article 47).

- When IVD’s are **not appropriately classified**, IVD manufacturers may not be able to **comply with the transitional provisional** requirements, risking the removal of the device from the EU market.

- It is recommended to apply **MDCG 2020-16 rev.4**, when classifying IVD’s.

What are Class C devices per the IVDR?

- Per Annex VIII IVDR, Class C devices are covered by rule 2, 3 and 4, but most would be covered under rule 3;

  (a) for detecting the presence of, or exposure to, a **sexually transmitted agent**;

  (b) for detecting the presence in **cerebrospinal fluid or blood of an infectious agent** without a high or suspected high risk of propagation;

  (c) for detecting the presence of an infectious agent, if there is a **significant risk that an erroneous result** would cause death or severe disability to the individual, foetus or embryo being tested, or to the individual's offspring;

  (d) for **pre-natal screening of women** in order to determine their immune status towards transmissible agents;

  (e) for **determining infective disease status or immune status**, where there is a risk that an erroneous result would lead to a patient management decision resulting in a **life-threatening situation** for the patient or for the patient's offspring;

  (f) to be used as **companion diagnostics**;

  (g) to be used for **disease staging**, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

  (h) to be used in **screening, diagnosis, or staging of cancer**;

  (i) for human **genetic testing**;

  (j) for **monitoring of levels of medicinal products**, **substances or biological components**, when there is a risk that an erroneous result will lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;

  (k) for **management** of patients suffering from a **life-threatening disease or condition**;

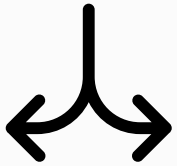
  (l) for screening for **congenital disorders** in the embryo or foetus;

  (m) for screening for **congenital disorders in new-born babies** where failure to detect and treat such disorders

What are Class C devices per the IVDR?

Conformity Assessment Routes per the IVDR that are applicable for Class C devices:

Annex IX Conformity Assessment based on a **Quality Management System** and an Assessment of Technical Documentation.



Annex X/XI Conformity Assessment based on **Type Examination** combined with **Production Quality Assurance**. (not offered by BSI).

- These conformity assessment activities **may** also constitute a consultation with EMA in **case of Companion Diagnostics (CDx).**
- **Legacy** IVD devices that are classified as Class C per the IVDR can **remain on the market** under the IVDD regime until 31 December 2028. But only **conditionally**, when an IVDR application has been sent in by **May 26, 2026**, for the IVDR…and the Notified Body has been able to accept by 26 September 2026…
- More about this in this presentation…

Poll Question 2

Are all your legacy devices already covered under an IVDR Contract?

a) Yes

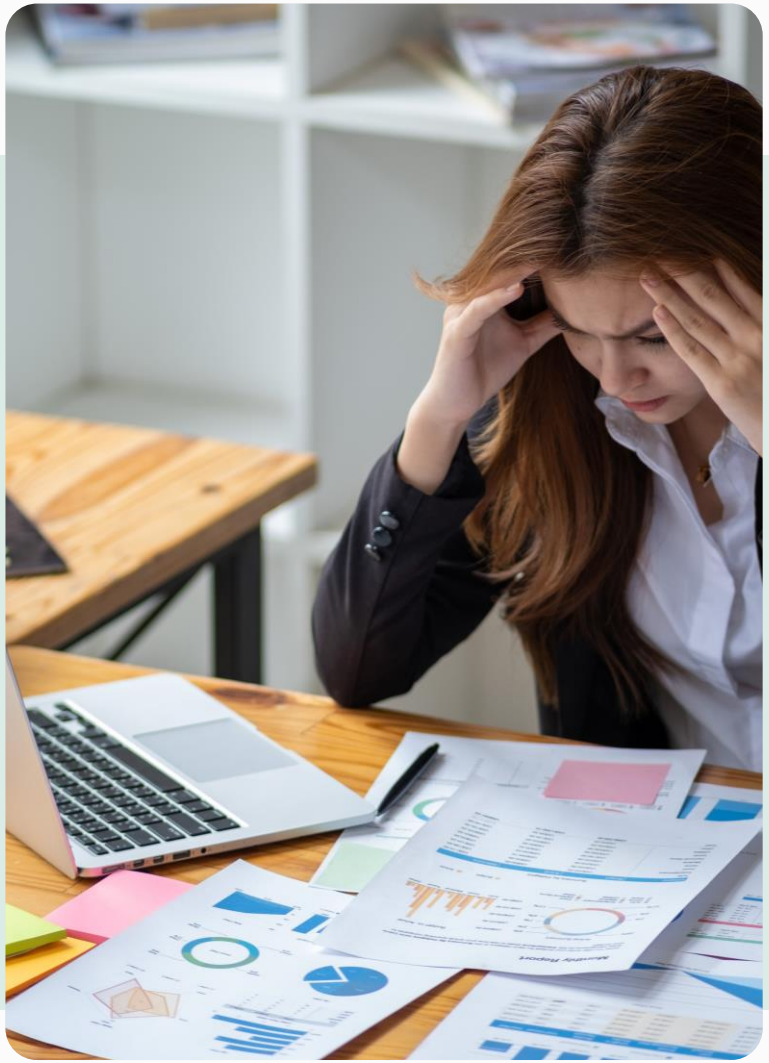
b) No

IVDR extension for Class C IVD’s; application of (EU) 2024/1860

What are the rules...

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

Considerations

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 IVDR 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]				
Class B and A[2] Sterile self-declared		26 May 2027	26 September 2027	31 December 2029

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

- 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

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

Transition Timeline

Applicable to class C devices that were self-declared. IVDD self-declared devices: IVDs on the market under IVDD that did not need a Notified Body Certification.

26 May 2026

Formal Application lodged

Contact your selected Notified Body **beforehand** to be given access to the used application portal or forms

Prepare to have the following information available

- Person responsible for Regulatory Compliance (PRRC)
- EU authorized Representative
- Device Intended Use / Purpose
- Risk classification
- All applicable classification rules
- Justification for classification
- EMDN and IVDR Codes
- Technical File Number

Transition Timeline

Applicable to class C devices that were self-declared. IVDD self-declared devices: IVDs on the market under IVDD that did not need a Notified Body Certification.

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IVDR Intended Purpose

→ Refer to Annex I 20.4.1 c)

- Very prescriptive under IVDR
- Devices risk class and codes
- Applicable to all devices of all risk classes (incl. calibrators & controls

(c) the device's intended purpose:

(i) what is detected and/or measured;

(ii) its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, prediction companion diagnostic);

(iii) the specific information that is intended to be provided in the context of:

— a physiological or pathological state;

— congenital physical or mental impairments;

— the predisposition to a medical condition or a disease;

— the determination of the safety and compatibility with potential recipients;

— the prediction of treatment response or reactions;

— the definition or monitoring of therapeutic measures;

(iv) whether it is automated or not;

(v) whether it is qualitative, semi-quantitative or quantitative;

(vi) the type of specimen(s) required;

(vii) where applicable, the testing population; and

(viii) for companion diagnostics, the International Non-proprietary Name (INN) of the associated medicina product for which it is a companion test.

Transition Timeline

Applicable to class C devices that were self-declared. IVDD self-declared devices: IVDs on the market under IVDD that did not need a Notified Body Certification.

26 May 2026

Formal Application lodged

Contact your selected Notified Body **beforehand** to be given access to the used application portal or forms

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Transition Timeline

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26 May 2026

Formal Application lodged

Contact your selected Notified Body **beforehand** to be given access to the used application portal or forms

Prepare to have the following information available

- Person responsible for Regulatory Compliance (PRRC)
- EU authorized Representative
- Device Intended Use / Purpose
- Risk classification
- All applicable classification rules
- Justification for classification
- **EMDN and IVDR Codes**
- Technical File Number

Codes

Make sure to assign relevant codes

- **EMDN-Code:** assign the most suitable EMDN code to your device. For IVDs, the code will start with a ‘W’ and we need at least 6 digits. (European Medical Device Nomenclature (EMDN))
- **IVP-Code:** displays required knowledge in examination procedures. Assign at least 1 per device
- **IVR-Code:** reflects the design and intended purpose of the device. Assign the most suitable to your device
- **IVS-Code:** provides information about the specific characteristics of the device. Assign 0 to several if appliable

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		
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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

Transition Timeline

Applicable to class C devices that were self-declared. IVDD self-declared devices: IVDs on the market under IVDD that did not need a Notified Body Certification.

26 September 2026

Formal written agreement with a Notified Body signed

There is a set of documents that need to be supplied with the signed contract

- Sample draft Declaration of Conformity (as per Annex IV of MDR/IVDR) for the highest classification device included in the application
- Quality Policy
- Quality Objectives
- Quality Manual
- PMS Procedure
- Sample PMS plan for the highest classification device (or groups of devices) included in the application
- Vigilance reporting procedures covering incident reporting, field actions, periodic summary reporting, and trend reporting
- A description of the procedures in place for keeping PMS plans, PMCF plans (PMPF plans for IVDs) and vigilance procedures up to date
- Sample performance evaluation plan for the highest classification device (or groups of devices) included in the application
- Procedures for keeping the performance evaluation plans up to date taking into account the state of the art
- Sample Post Market Performance Follow-up (PMPF) plan for the highest classification device (or groups of devices) included in the application

Application Checklist

Signed contracts can only be accepted if the Application Checklist is completed.

Documents in draft version are acceptable

MDR, IVDR CE application Checklist

Instructions for Manufacturers: Please complete the table below with the corresponding document references for the items specified and provide **English language** copies of the actual documents as attachments along with the signed BSI contract.

Document Type	Document References
Sample draft Declaration of Conformity (as per Annex IV of MDR/IVDR) for the highest classification device included in the application	
Quality Policy	
Quality Objectives	
Quality Manual	
PMS Procedure	
Sample PMS plan for the highest classification device (or groups of devices) included in the application	
Vigilance reporting procedures covering incident reporting, field actions, periodic summary reporting, and trend reporting	
A description of the procedures in place for keeping PMS plans, PMCF plans and vigilance procedures up to date	
Specific to IVDR Applications	
Sample performance evaluation plan for the highest classification device (or groups of devices) included in the application	
Procedures for keeping the performance evaluation plans up to date taking into account the state of the art	
Sample Post Market Performance Follow-up (PMPF) plan for the highest classification device (or groups of devices) included in the application	
Note: For self-testing, near-patient testing devices that are class B, class C or class D, if practicable and required, BSI may request an example of the device during the conformity assessment process.	

Notified Body Expectations

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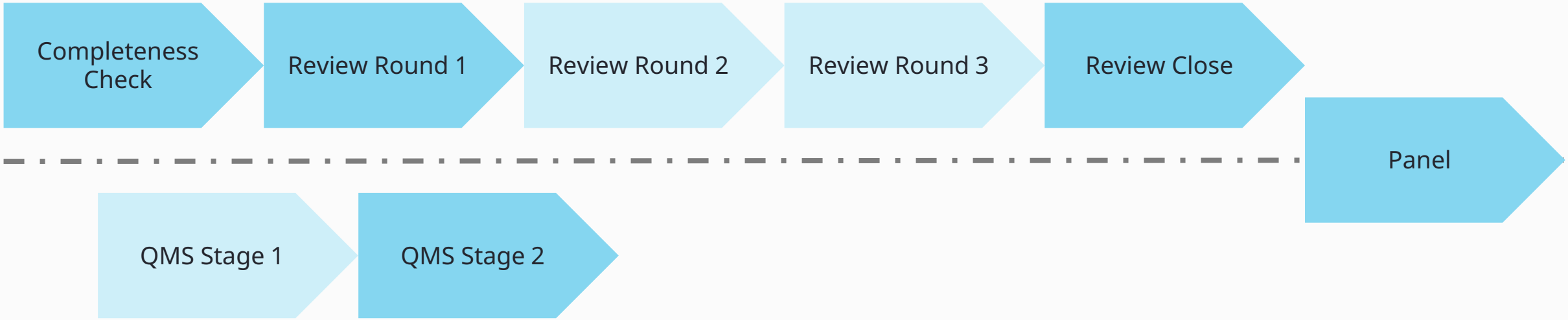
The IVDR formal application can be transferred from one NB to another NB even after 26 Sept 202X, maintaining compliance of the legacy devices with the requirement of art.110

IVDR Review Process

The Review Process consists of a (or multiple) technical file assessment(s) and a Quality management system audit. Both can run in parallel.



Darker blue = mandatory, applicable to all. Lighter blue = if required

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;

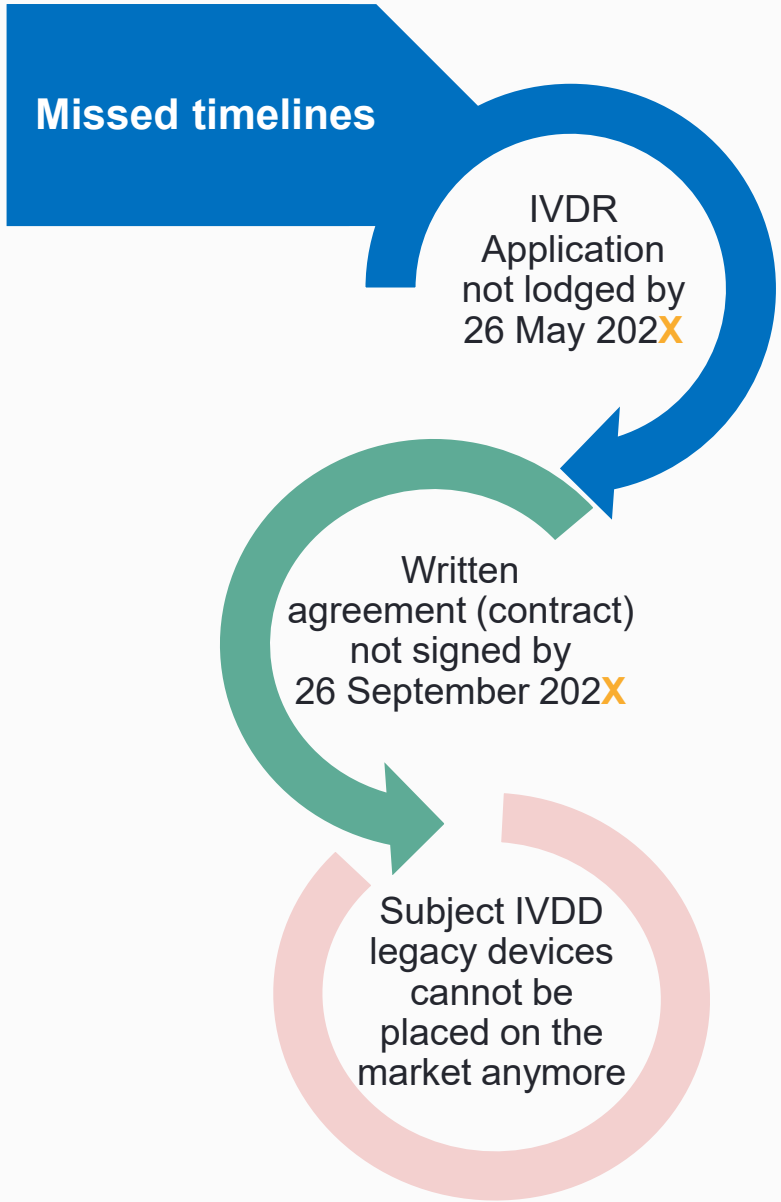
(iii) 26 May 2027, for devices referred to in paragraph 3b, point (c), of this Article;

(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.



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.

Key MDCG Guidance Documents

- **MDCG 2020-16 rev 4** - *Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746*
- **MDCG 2021-14** - *Explanatory note on IVDR codes*
- **MDCG 2024-11** - *Guidance on qualification of in vitro diagnostic medical devices*
- **MDCG 2019-13 -** *Guidance on sampling of MDR Class IIa / Class IIb and IVDR Class B / Class C devices for the assessment of the technical documentation*

Poll Question 3

When is your technical file due to be ready?

a) 2026

b) 2027

c) 2028

d) Don’t know

The IVD Team

Multidisciplinary expertise behind
every conformity assessment

The World's Leading IVD Notified Body Team of Experts

The BSI IVD team brings together senior scientific, clinical, regulatory, and industry specialists spanning leadership, technical assessment, clinical oversight, scheme management, certification, and operations. The team includes:

Global and Associate Global Heads of IVD

Internal clinicians and clinical oversight experts

Head of IVD Notified Body

Scheme Managers and Certification Specialists

Technical Team Managers and QMS assessors

IVD Regulatory Leads (EU and UK) and Operations support

Principle and Senior Technical Specialists

The World's Leading IVD Notified Body Team of Experts

Our depth of experience spans IVD R&D, clinical laboratories, manufacturing, quality systems, and regulatory affairs, including:

650+
cumulative years of industry experience

215+
cumulative years of BSI / Notified Body experience

Our IVD team is globally distributed, supporting manufacturers like you worldwide.

Pan-European and global Notified Body experience across EU IVDR, UKCA, and international markets

Our geographic spread supports local regulatory insight combined with global consistency

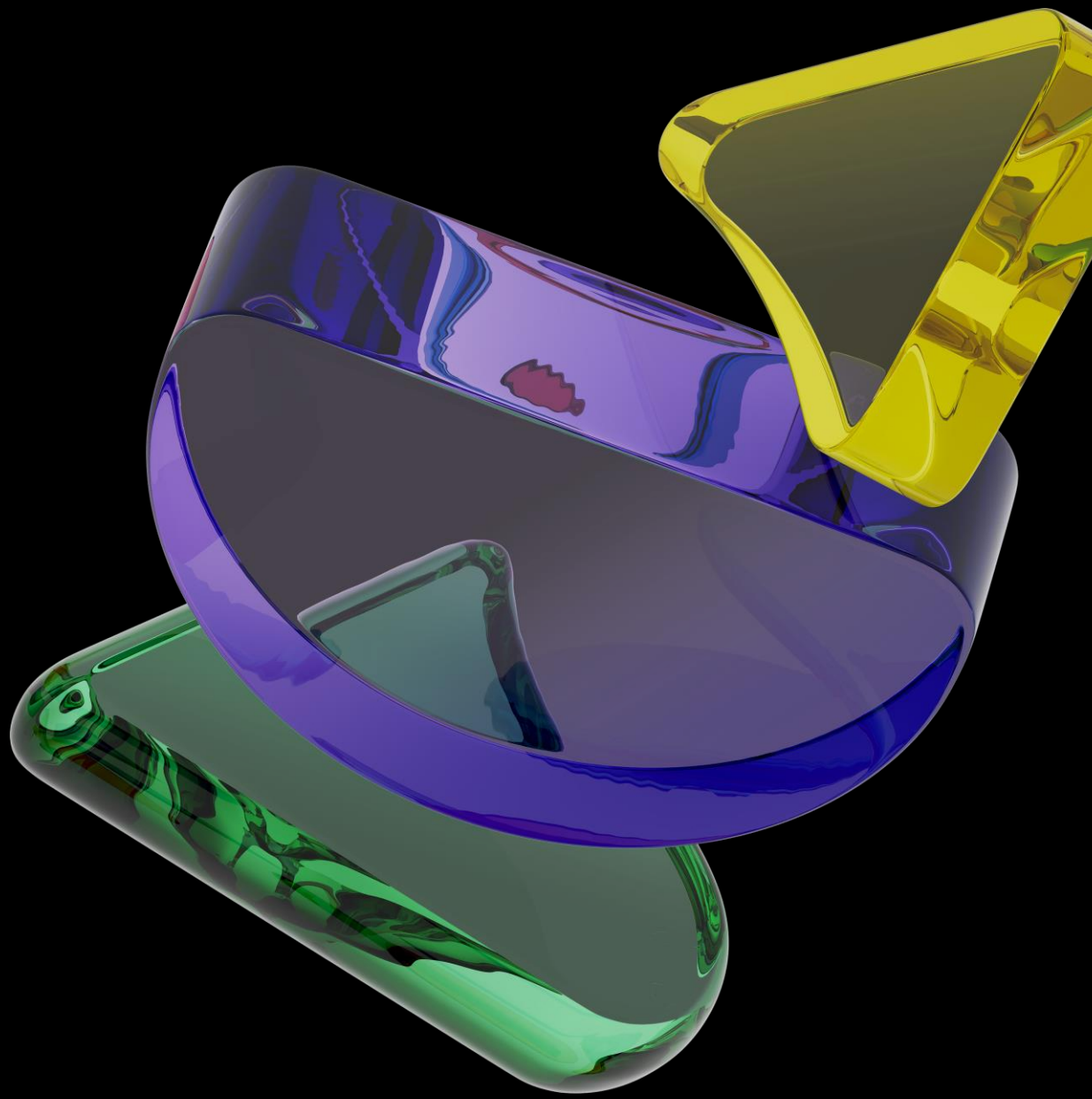
What this means for our clients

- Deep scientific credibility
- Hands on industry experience
- Notified Body authority
- Global regulatory insight

This allows BSI to support you with **practical, proportionate, and trusted conformity assessment,** helping products reach and remain on the market with confidence under IVDR.

Contact us to discuss your IVDR journey

Thank you



Q&A

Ask our experts.