Rollout of EURLs for IVDR Class D devices

26 September 2024

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Status Quo of the IVDR & Class D Updates

Introduction

Introduction to EU Reference Laboratories for Class D IVD’s

Implementing Regulations in relation to EURLs

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End of webinar

Introduction to EU Reference Laboratories for Class D IVD’s

Legal basis on the involvement of EURLs

Article 100

The European Union reference laboratories

The tasks of the EURLs are laid down in Article 100(2) of Regulation 2017/746.

Advisory ones

Including to provide scientific and technical assistance and opinions to the Commission, the MDCG, the Member States and notified bodies in relation to the implementation of the Regulation, state of the state of specific devices, reference materials and reference measurement procedures, to contribute to the development of CS and of international standards etc.

Related to conformity assessment of Class D devices

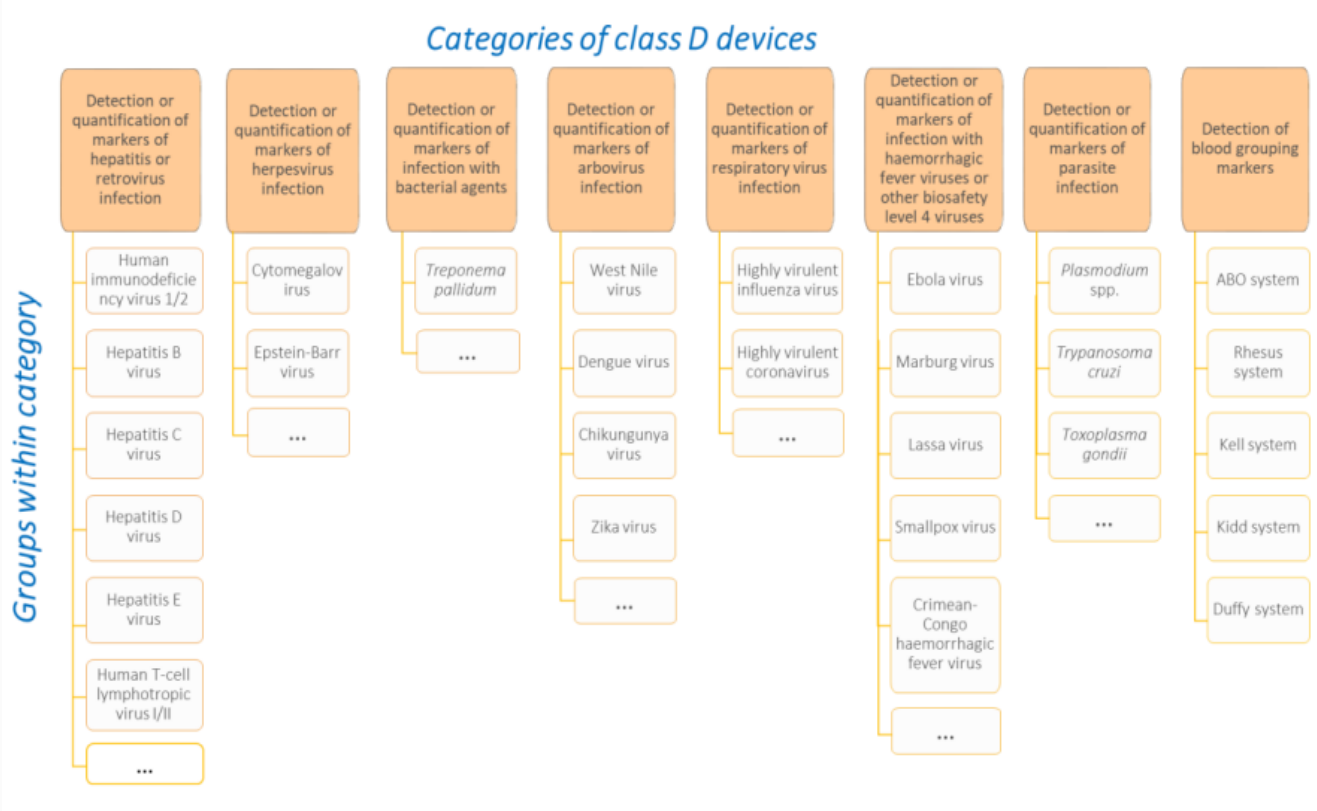
- to verify the performance claimed by the manufacturer and the compliance of class D devices with the applicable CS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in the third subparagraph of Article 48(3);
- to carry out appropriate tests on samples of manufactured class D devices or batches of class D devices, as provided for in the Section 4.12 of Annex IX and in Section 5.1 of Annex XI;

EURLs Designation Journey

July 2022: call for designation of EURLs in 8 categories of class D devices

Specific elements for selection:

- Applicant laboratories must satisfy all criteria (Article 100(4) & Commission Implementing Regulation (EU) 2022/944)
- Combined capacity of all compliant labs in a given category must cover the expected volume of requests for conformity assessments related tasks



https://health.ec.europa.eu/document/download/86752fcd-bc89-4eb0-8f33-643429011db6_en?filename=md_candidate-laboratories_infopack_en.pdf

Designation of EURLs by Regulation (EU) 2023/2713

- On December 6, the European Commission published the Implementing Regulation **(EU) 2023/2713** designating European Union reference laboratories.
- The selected EU reference laboratories have been **designated** to cover the following 4 technical areas: hepatitis and retroviruses, herpesviruses, bacterial agents and respiratory viruses.
- The **5** EU reference laboratories are listed by name in the Annex of Implementing Regulation.
- For technical areas where **no** EU reference laboratories have been designated, the oversight for batch verification will **remain** with the EU Notified Bodies, through alternative means.

Laboratory	Location	Detection or quantification of markers of hepatitis or retrovirus infection	Detection or quantification of markers of herpesvirus infection	Detection or quantification of markers of infection with bacterial agents	Detection or quantification of markers of respiratory virus infection
Paul Ehrlich Institute	Germany	x	-	-	x
Consortium (SERMAS)	Spain	-	x	x	-
Instituto de Salud Carlos III	Spain	x	x	x	-
Consulting Químico Sanitario SLU	Spain	-	x	x	-
RISE Research Institutes of Sweden AB	Sweden	-	-	-	x

EURLs and their designation

Detection or quantification of markers of hepatitis or retrovirus infection	PEI
	ISCIII
Detection or quantification of markers of herpes infection	Consortium
	ISCIII
	CQS
Detection or quantification of markers of infection with bacterial agents	Consortium
	ISCIII
	CQS
Detection or quantification of markers of respiratory virus infection	PEI
	RISE

EURL Network

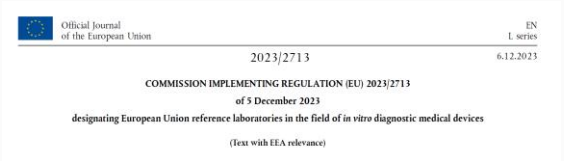
EURL-Network
- Coordination
- Harmonize work
  - Methods
  - Materials
  - Panels
  - Sampels
  - Reports
  - Etc.
- Generic questions

EURL-sub-network
- Scope specific questions
- Harmonize work
  - Methods
  - Materials
  - Panels
  - Sampels
  - Reports
  - Etc.

Implementing Regulations in relation to EURLs

Commission Implementing Regulation (EU) 2023/2713

On 6 December 2023, the long-awaited Implementing Regulation (EU) 2023/2713, was published.


Official Journal of the European Union
EN
L series
2023/2713
6.12.2023
COMMISSION IMPLEMENTING REGULATION (EU) 2023/2713
of 5 December 2023
designating European Union reference laboratories in the field of *in vitro* diagnostic medical devices
(Text with EEA relevance)

The Background Story.

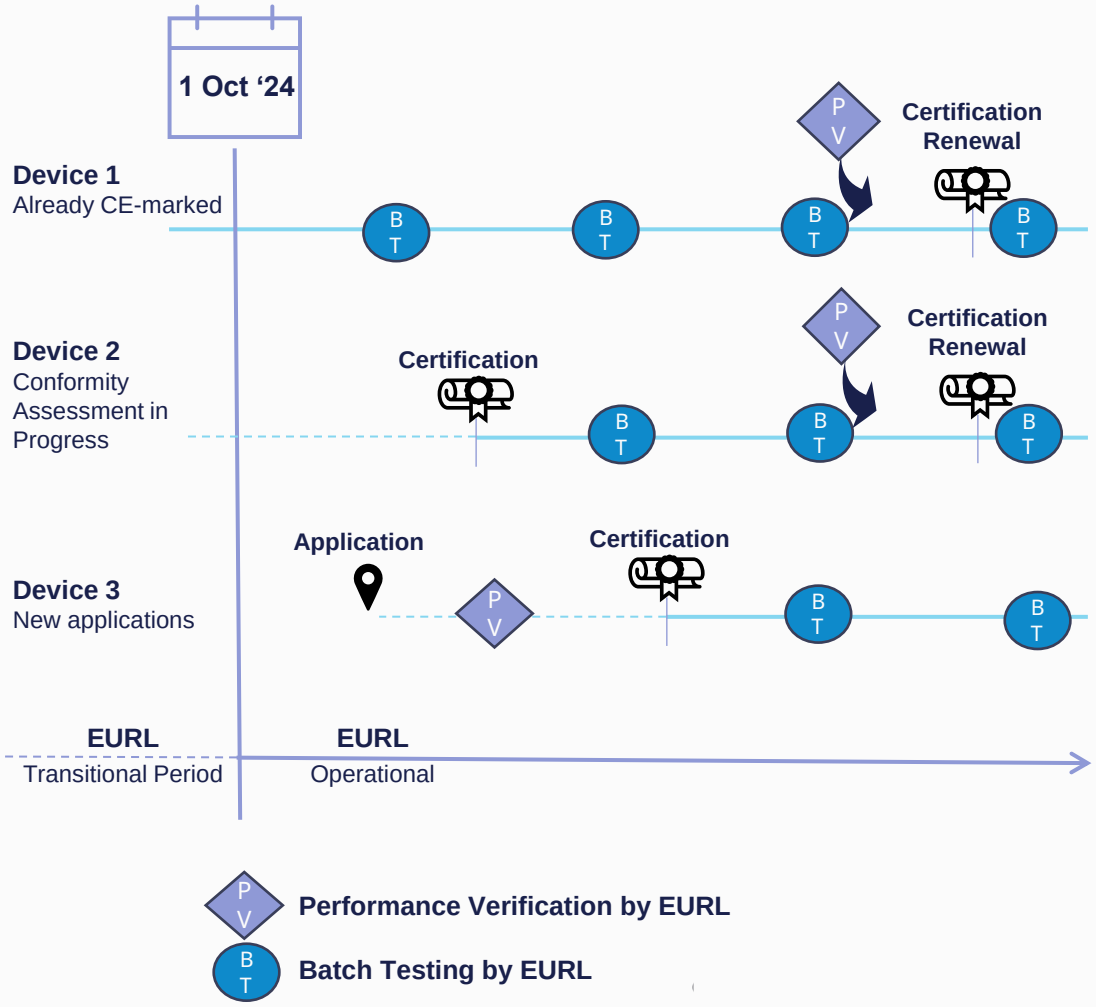
This new Implementing Regulation is (most probably) the last legislative act dealing with the rollout of EU Reference Labs overseeing Class D IVD's per IVDR; previously there were also (EU) 2022/944 and (EU) 2022/945, dealing with fees, tasks, and criteria for EURLs.

In short (EU) 2023/2713 covers the following:

1. Designation of EURLs (5 EU based labs) with an additional transition time to 1 October 2024 that will enable the EURLs to prepare for their duties and produce a solid process; Batch Verification (BV) and Performance Verification (PV).
2. Class D IVD's that already have gone through IVDR CE certification or are in the process of this, will have PV at the first recertification; others will follow the normal process per article 100 IVDR.

Commission Implementing Regulation (EU) 2023/2713

- The designating act indicate that Class D devices are expected to undergo performance verification and batch testing by the EU Reference Laboratory in accordance with Article 100(2). points a) and b), of the IVDR.
- Transition period from publication until October 1, 2024
- Activities of EU Ref Labs will start from 1st Oct ‘24 (Art 2.2)
- Verification on Performance, as part of conformity assessment, will only be applicable to devices where applications are lodged with NB after 1st Oct ‘24 (Art 2.3) meaning that:
  - Devices under application or already certified prior Oct 24 will have no involvement of EURL in initial conformity assessment for CE marking
  - Batch verification testing will be applicable from Oct 2024 for all Class D devices (already certified/ongoing certification) that fall within the scope of a designated EURL



In the meantime, the EU 1860/2024 amendment was introduced…

This amendment on the transitional provisions of the IVDR has now led to **new questions** for high risk IVD's that are in transit towards IVDR…

Some IVD manufacturers of Annex II List A IVD's may **not be in time** for the extended timelines (= not eligible) that are mentioned in the amendment 1860/2024… A manufacturer **can always apply** with the Notified Body for the IVDR, though, but may not profit from the extended timelines…

Batch verification activities that have been conducted by an independent testing lab (such as PEI) and/or Notified Bodies through "alternative means" are **not addressed in the amendment** (since not in the article 110), meaning these would fall **outside the amendment requirements.**

How are **batch verification activities** going to be carried out for Annex II List A devices when these are covered by an IVDD Certificate that is accepted by the new Notified Body **under appropriate surveillance** after May 26, 2025, for the remaining period until December 31, 2027, when eligible?

Where are the notified bodies and EU Reference Laboratories with the implementation of EU 2023/2713?

IVD Notified Bodies involved in Conformity Assessments of Class D devices are aligning through TEAM-NB and NBCG-Med:

- IVD Notified Bodies are part of the NBCG-Med consortium. Objective is to **share views and harmonize practices** among Notified Bodies. Most are also part of TEAM-NB.
- The IVD Notified Bodies that certify Class D IVD's (10) are part of the Class D working group that **discuss regulatory matters** concerning Class D IVD devices once every two months; covering a.o. PECP's, Common Specifications, Classifications, MDCG / EC Survey results and **Class D oversight through EURLs.**
- **Current focus** for the Class D working group is to **prepare Notified Bodies and EURLs** conformity assessment processes of Class D IVD's before and after October 1, 2024, that fall within the scope of the EURLs.
- This includes preparatory work for existing IVD manufacturers that have **already applied / been certified** under the IVDR.

Harmonization meetings between Notified Bodies and EURLs have been organized…

- EURLs have started to form a network and harmonize their working methods.
- Representatives of the five EURLs have **teamed up** with the Notified Bodies since 9 April; 6 additional meetings have been held, since.
- NBs are actively working with EURLs on general framework agreement, **common workflow**, best practices and harmonized conformity assessment procedures -> reaching the **final** stages.
- NBs will continue to certify devices without designated EURL, according to IVDR, MDCG 2021-4, and conducting the batch verification of devices **by other means and alternative measures** (Team NB/NBCG-Med "*Class D measures in the absence of EU Reference Laboratories- Points to consider for Notified Body approach*")
- NBs have been initiating an **alternative approach** with the European Commission to continue with alternative measures approach for the devices under EURL, for the moment. While **enrolling** EU Reference Laboratories…
- The Commission, after consulting the Member States in the Medical Device Coordination Group, is considering launching a **second call** to cover the remaining technical categories of Class D devices.

Questions that were raised with the EURLs during the harmonization meetings with the Notified Bodies

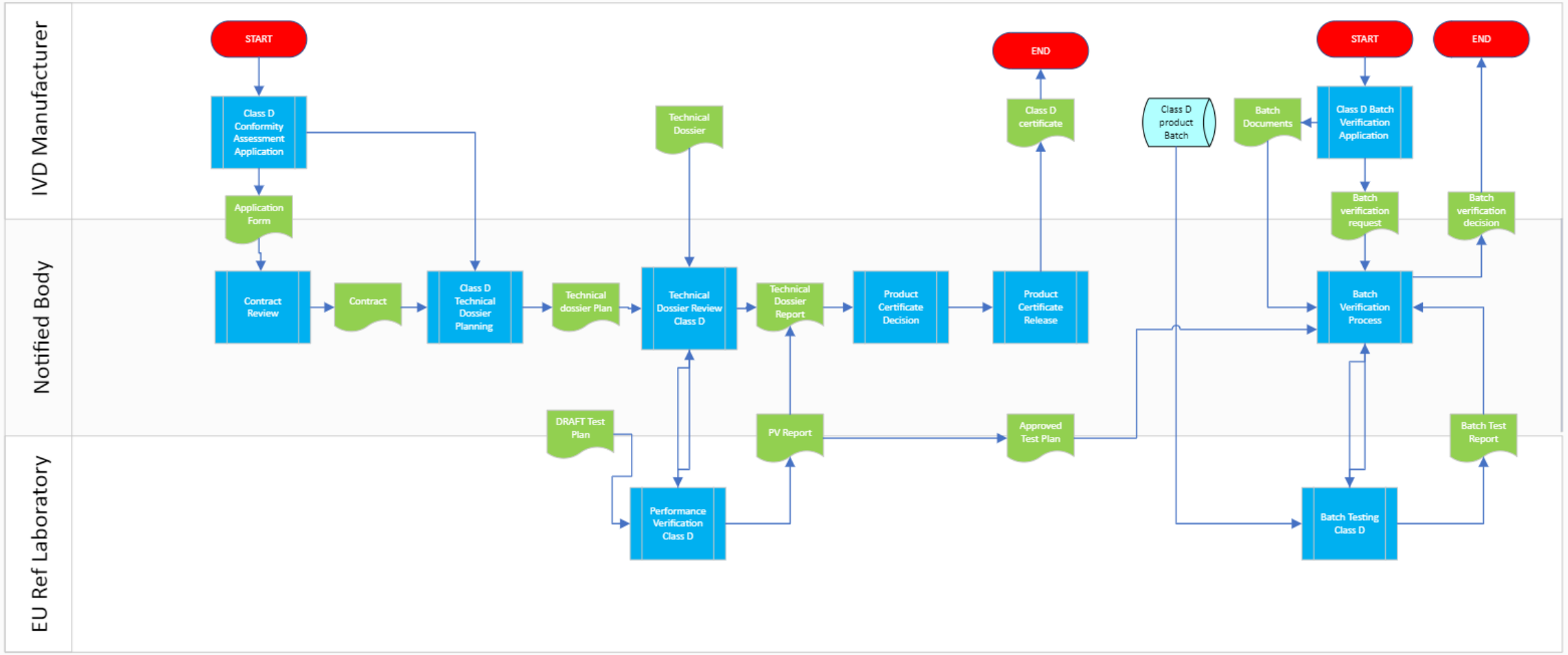
The publication of (EU) 2023/2713 has led to many questions from both Notified Bodies and EURLs:

- How will the **EURLs organize** among themselves in the EURL network? How will processes and procedures be harmonized?
- Transition into batch release for IVDR certified devices on 1st October – Do the **EURLs prioritize these** compared to new applications that come in?
- What will **performance verification** activities look like for EURLs?
- How will EURLs assure that **required laboratory instrumentation** will be appropriately installed, in accordance with manufacturers specifications? And/or, are manually conducted tests considered an alternative for automated tests?
- How do EURLs foresee the **transitioning from IVDD Annex II List A/B** certified devices to IVDR Class Ds (legacy devices)?
- How will **standardization in the batch verifications** for similar devices from different manufacturers within one EURL and between different EURLs be assured?
- How do EURLs interpret requirements for **variants of Class D IVD's** that may be placed on the EU market separately?
- How do EURLs interpret the requirement of **becoming operational** on 1 October per (EU) 2023/2713?

All of these **questions** (and more) will be discussed in the next months, leading up to 1 October 2024.

Where are the notified bodies and EU Reference Laboratories with the implementation of EU 2023/2713?

General work-flow (details may still change)



Where are the notified bodies and EU Reference Laboratories with the implementation of EU 2023/2713?

The following **objectives** are currently being discussed within the Class D Working Group in collaboration with the EURLs

Set-up of a **contract** template dealing with obligations and responsibilities between the Notified Bodies and the EURLs, per EU 2022/945 and MDCG 2022-3

Set-up of a **test plan** template for determining batch testing regimes between the Notified Bodies and the EURLs, per EU 2022/945 and MDCG 2022-3.

Update of internal procedures and working methods that support the operations of batch verification and performance verification activities, per EU 2022/945 and MDCG 2022-3

In addition, Notified Bodies are required to **update** the **certification agreements** to address the specifics of article 100 IVDR and EU 2022/945

EURLs will separately need to define their **verification activity fees** in accordance with IVDR and per EU 2022/944. Notified Bodies will **not** determine the fees of the EURLs

IVD Manufacturers will **not have a direct contract / agreement** with an EURL to cover batch testing and performance verification activities. EURLs will directly liaise with a Notified Body and the latter will **select the EURL** per EU 2022/945 and MDCG 2022-3 (with input from manufacturer).

Potential scenarios for conformity assessment of legacy Class D devices before and after October 1, 2024.

With the introduction of 2023/2713, the following scenarios can occur:

1. Legacy Annex II List A IVD's (certified under 98/79/EC) **that are eligible** to be placed on the EU market, per the **conditions of amendment 2024/1860** will undergo batch verification activities under the regime of the Notified Body responsible for their appropriate surveillance.
2. Legacy devices that were self-declared under the IVDD but are now Class D under the IVDR will need to start their conformity assessment journey by lodging an application with a NB **before May 26, 2025.**
3. IVD's that have started the IVDR conformity assessment with a Notified Body and **are certified before October 1, 2024, >** batch verification process will start through EURL testing; EURL performance verification will happen before recertification, per article 100 IVDR.
4. IVD's that have started the IVDR conformity assessment with a Notified Body and **have not yet been certified before October 1, 2024, >** batch verification process will start through EURL testing; EURL performance verification will happen before recertification, per article 100 IVDR.
5. IVD's that starts the IVDR conformity assessment with a Notified Body **after 1 October 2024 >** EURL performance verification process will start **during the initial technical documentation review**. After successful IVDR certification, the batch verification process will start through the EURL per article 100 IVDR.

New development!

- MDCG 2021-4 has been updated and published, as of 25 September 2024.

- Q7 allows parallel approach after 1 October

Q7. What does the date of application of the designation of EURLs (1 October 2024) mean in practical terms for EURL tasks, and in particular for sample or batch testing according to Article 100(2)(b) IVDR and performance verification according to Article 100(2)(a)?

For each device testing, there are preparatory elements to complete, such as: signing of contracts, shipping of equipment, shipping of device samples, installation activities etc. As the EURL is required to support and carry out these activities as of 1 October 2024, it may not be possible to start the testing itself on this date. Testing should take place, on a case-by-case basis, as soon as all the arrangements such as proper installation and validation of any equipment are in place. While these preparatory elements of the task are being put in place, the notified body can request other testing or evidence from the manufacturer to ensure appropriate batch verification in line with the provisions in Annex IX 4.3, 4.12 or Annex X 3(a) and 5 and Annex VII 4.5.3 IVDR, especially if such arrangements were in place before the application of the EURL designation.

For performance verification, for all class D devices for which a formal application is lodged with the notified body from 1 October 2024, and which fall in scope of the designated EURLs, notified bodies are obliged to contact appropriate EURLs to engage in activities described in Articles 10-12 of Commission Implementing Regulation 2022/944 as part of the conformity assessment procedure. For class D devices for which a formal application is lodged with the notified body before 1 October 2024 but a certificate was not yet issued by that date, the notified body should follow the EURL-related provisions of Section 4.9 of Annex IX or Section 3 (j) of Annex X in the course of the renewal of EU technical documentation assessment certificates and EU type-examination certificates.

Medical Devices

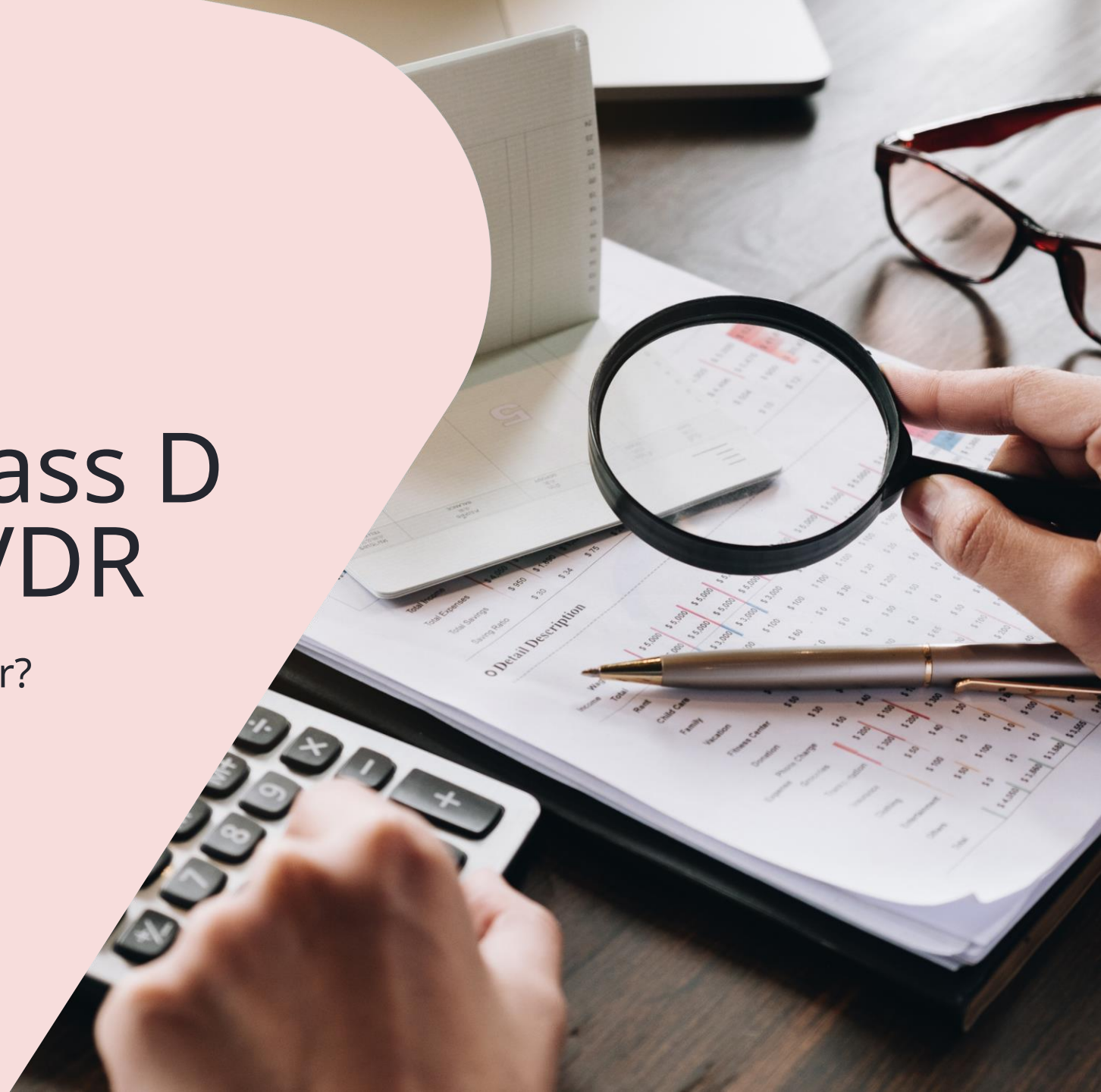
Medical Device Coordination Group Document MDCG 2021-4 Rev. 1

MDCG 2021-4 Rev. 1

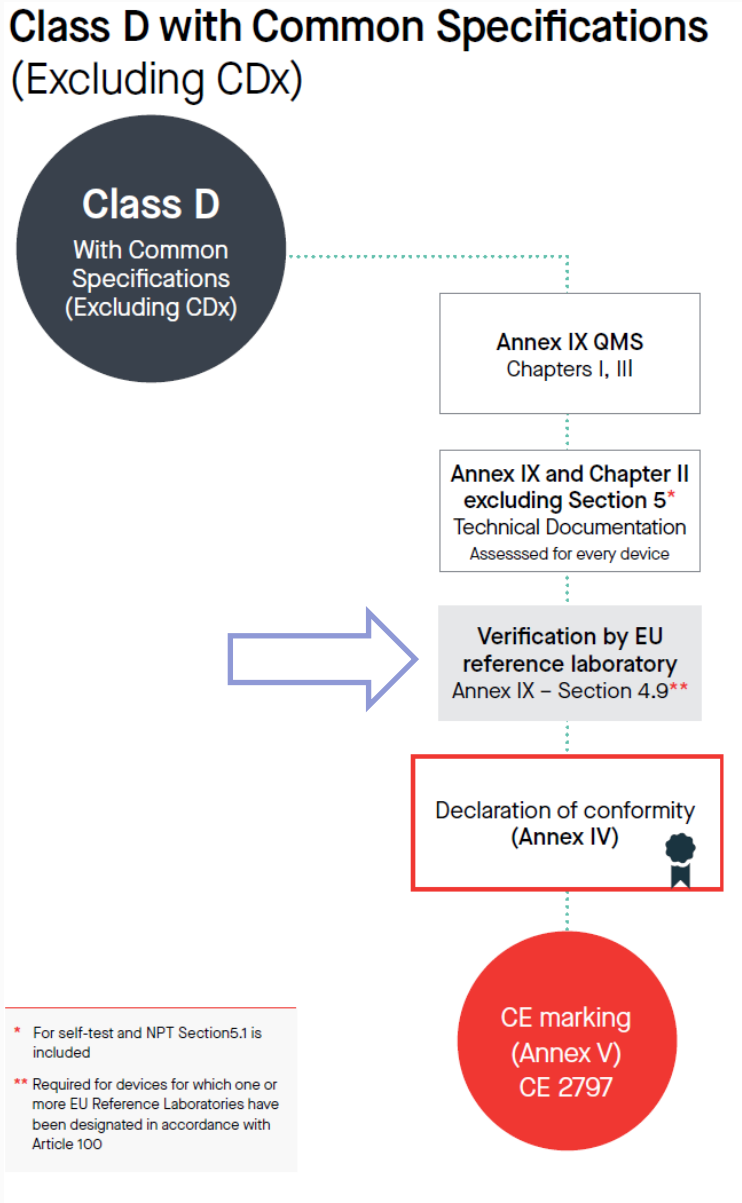
Application of transitional provisions for certification of class D *in vitro* diagnostic medical devices according to Regulation (EU) 2017/746

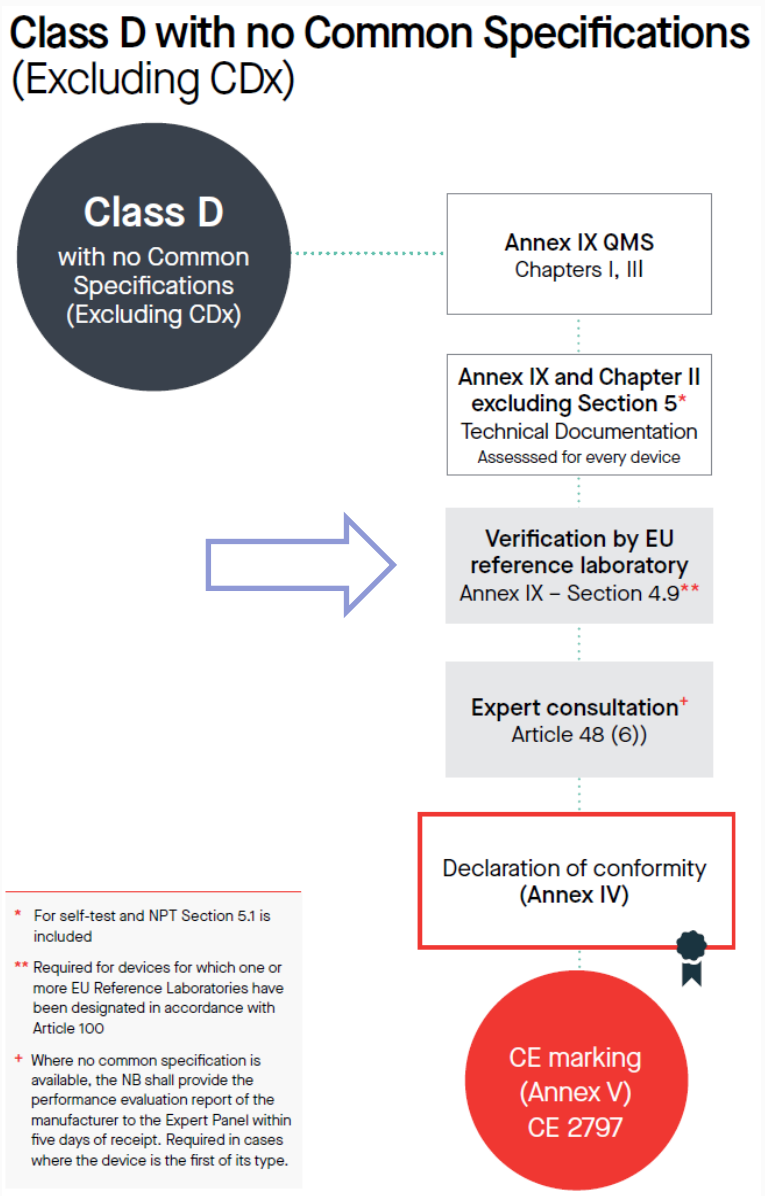
Certification of Class D IVD’s under the IVDR

What is going to change after 1 October?



Class Ds – current process



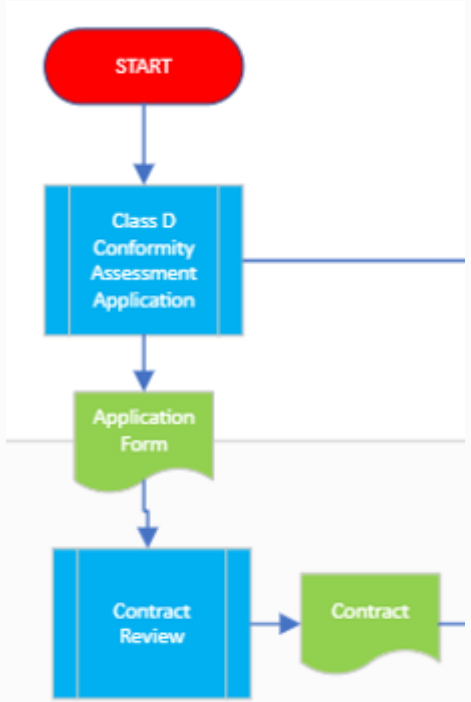


Main changes after October 1:

1. Application review:

- For Class D IVD's that are in application **before 1 October** or have been already **IVDR certified**:
  - Current application/contract remains valid pending the enrolment of the EURLs.
  - Once a **general framework agreement** has been set-up between BSI and the applicable EURL, preparations will start to enrol the EURL process; an **updated** certification agreement, with updated terms and agreement specific for Class D devices will be offered to the affected client. An EURL will be selected, based on the technical scope and capacity. The client will be involved in the selection process.

- For Class D IVD's that will be in application **after 1 October**:
  - A **new** certification agreement containing specific Class D terms and conditions will be shared with the client.
  - When an application is **approved**, and the certification agreement (with Class D specific terms and conditions) is signed, an EURL will be selected by BSI based on the technical scope and capacity. The client will be involved in the selection process.

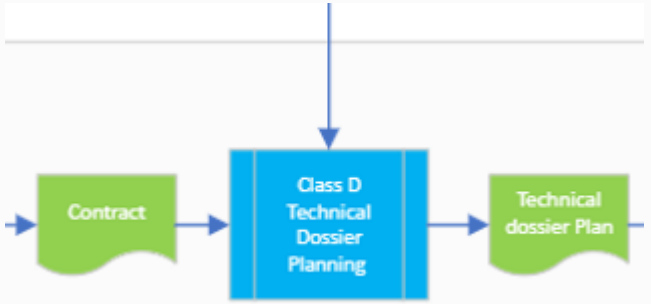


Main changes after October 1:

2. Technical Documentation Planning:

- For Class D IVD's that are in application **before 1 October** or have been already **IVDR certified**:
  - Information will be extracted from the existing technical documentation to prepare for planning EURL testing activities, in this order:
    1. Batch criteria setting (if not already done previously)
    2. Batch testing requirements
    3. Data to support Performance Verification
  - EURL will be selected, and testing will be planned for in accordance with pre-agreed arrangements.

- For Class D IVD's that will be in application **after 1 October**:
  - Information will be extracted from the existing technical documentation to prepare for planning EURL testing activities, in this order:
    1. Data to support Performance Verification
    2. Batch criteria setting
    3. Batch testing requirements
  - EURL will be selected, and Performance Verification will be planned in parallel with the Technical Documentation assessment. Batch criteria and batch testing will start after positive Performance Verification opinion and, resulting, issue of the Class D certificate.

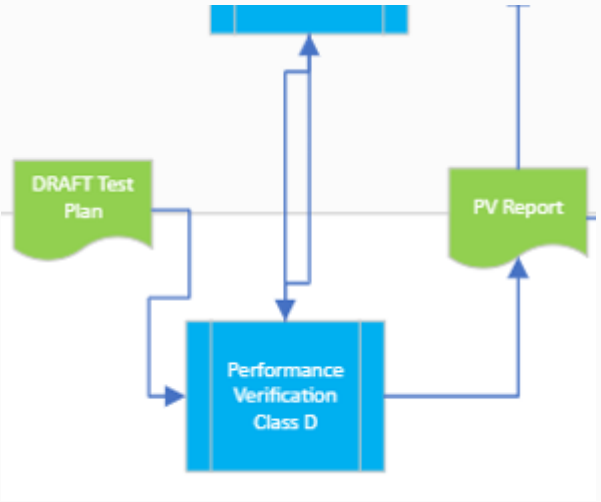


Main changes after October 1:

3. Performance Verification activities:

- For Class D IVD's that are in application **before 1 October** or have been already **IVDR certified**:
  - For Class D IVD's that have **already been IVDR certified**, Performance Verification will need to start and successfully be concluded before the expiration date on the IVDR Product Certificate.
  - For Class D IVD's that **are in application before 1 October**, but IVDR certificate has **not** been issued yet; Performance Verification will need to be agreed with the client and EURL on case-by-case basis. Contact your scheme manager. Ensure compliance to any applicable **Common Specifications (CS)** as these will feed into the EURL test plan and be prepared to discuss batch release schedule for your Class D devices.

- For Class D IVD's that will be in application **after 1 October**:
  - The Performance Verification activity will be planned in parallel with the Technical Documentation review.
  - Batch criteria and batch testing will start after positive PV opinion and, resulting, issue of the Class D certificate. Ensure compliance to any applicable CS for EURLs Performance Verification and Notified Body assessment. Batch testing criteria to be confirmed before certificate is issued.



Main changes after October 1:

4. Batch testing criteria setting / test plan:

- For Class D IVD's that are in application **before 1 October** or have been already **IVDR certified**:
  - For Class D IVD's that have **already been IVDR certified**, batch testing criteria may have already been set / determined. This depends if the (legacy) device have already gone through batch testing previously, and whether significant changes were introduced in the device or testing lab.
  - For Class D IVD's that have previously not been batch tested, batch testing criteria shall be determined. This will be requested with the selected EURL.
  - For Class D IVD's that **are in application before 1 October**, but IVDR certificate has **not** been issued yet; Batch testing criteria will need to be determined by the EURL. This will be requested with the selected EURL.
  - For all above scenarios, batch testing details will end in an approved batch test plan with the NB.

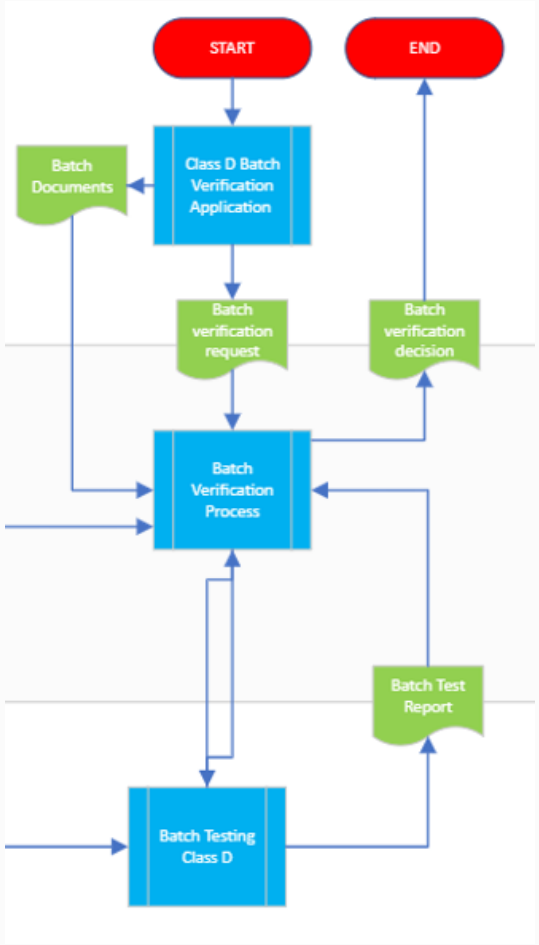
- For Class D IVD's that will be in application **after 1 October**:
  - Batch testing criteria and batch testing will start after positive PV opinion and, resulting, issue of the Class D certificate. This will be requested with the selected EURL.
    Batch testing details will end in an approved batch test plan with the NB.

Main changes after October 1:

5. Batch testing activities:

- For Class D IVD's that are in application **before 1 October** or have been already **IVDR certified**:
  - For Class D IVD's that have **already been IVDR certified**, batch testing activities through EURL will be initiated in accordance with pre-agreed arrangements with the selected EURL, per approved test plan.
  - For Class D IVD's that **are in application before 1 October**, but IVDR certificate has **not** been issued yet; batch testing activities will be planned in accordance with the selected EURL, per approved test plan.
  - Until EURLs are operational, batch verification of Class D IVD's will be carried out through alternative means.

- For Class D IVD's that will be in application **after 1 October**:
  - The **batch criteria setting** activity will be planned and conducted **after positive** Performance Verification opinion and successful technical documentation review, per approved test plan.
  - **Batch testing activity** will be planned and conducted **after positive** Performance Verification opinion / batch testing criteria setting has been concluded and, resulting, issue of the Class D certificate, per approved test plan.



VoMP / Alternative measures (Class D / IVDR)

For Class D devices that **do not** fall under the oversight of EURLs, the BSI Class D technical specialist will remain to review the following for **IVDR certified Class D devices (alternative measures):**

- Review manufacturers batch documentation, including labelling and QC batch release testing;
- Review witnessed testing report if applicable;
- Review testing laboratory testing report if applicable, including EURLs once designated;
- Specialist provides the manufacturer a “Verification of Manufactured Product Notification” letter / certificate;
- Class D specialists reviews the manufacturers batch release documentation against the approved test plan;

For Class D devices that **do** fall under the oversight of EURLs, but in the situation that after 1 October, and the EURL is **not yet operational for the device concerned** the BSI Class D technical specialist will **remain to verify the batches** in **accordance with alternative measures**. Once the EURL **is operational** and able to accept test requests from the NB, the batch verification in accordance with alternative measures **will be stopped**. The transition will be planned after engaging with the client.

Notified Body activities after October 1 to support Class D conformity assessments

Potential scenarios for conformity assessment of legacy Class D devices before and after October 1, 2024.

With the introduction of 2023/2713, the following scenarios can occur:

1. Annex **II List A devices** certified under the IVDD (98/79/EC) that are eligible for extended timelines under EU 2024/1860 > **will undergo batch verification activities** under the regime of the Notified Body responsible for their appropriate surveillance.
2. IVD's **that have been certified under the IVDR** as Class D **before October 1, 2024**; a batch testing regime will need to be agreed upon with the EURLs within the designated scope. When applicable (and possible), the existing batch testing regime with the former ITL can continue under the IVDR for the Class D IVD after October 1, 2024. **Performance Verification ≤ Recertification**.
3. IVD's **that have not yet been certified under the IVDR**, but an application has been filed **before October 1, 2024**, a batch testing regime will need to be agreed upon with the EURLs within the designated scope. When applicable (and possible), the existing batch testing regime with the former ITL can continue under the IVDR for the Class D IVD after October 1, 2024. **PV ≤ Recertification.**
4. IVD's **of which an application has been submitted** with the Notified Body for Class D IVDR, **after October 1, 2024**, a performance verification request will be prepared with the EURL, **once the technical documentation is submitted** and reviewed by the Notified Body. Batch testing regime will be determined after the Performance Verification at the end of the certification process.

Focus Area Class D Conformity Assessments

The Notified Bodies, European Commission and EURLs involved with certifying Class D devices will focus on the following…

The Commission, after consulting the Member States in the Medical Device Coordination Group, is considering launching a **second call towards EU Laboratories** to cover the remaining categories of class D devices.

EURLs that have been designated in December 2023 are **getting together** to form a network and **harmonize their working methods** to support the conformity assessment process for Class D IVD's.

Notified Bodies **continue to certify devices** without designated EURL according to MDCG 2021-4; conducting the **batch verification** of devices by alternative means for the other categories not covered by EURLs.

This year, IVD Notified Bodies will prepare for **EURL implementation** for **Class D IVD's** and IVDR **proposed amendment** (EUDAMED, transitional provisions IVDR)…

Notified Bodies are working on a **common agreement**, **best practices** and **harmonized** conformity assessment procedures for Class D IVD's.

So, the road to compliance will remain **"rocky",** nevertheless, Notified Bodies will dedicate their time to make this work before and after October 1, 2024.

What can IVD manufacturers do to prepare?

What can manufacturers do to prepare for the implementation of the EURLs oversight process.

- The publication of (EU) 2023/2713 and short implementation timeframe has led to challenges for both existing IVD manufacturers that have placed their devices on the EU market and new IVD manufacturers.
- IVD manufacturers can do the following when preparing for the implementation of EURL oversight process, depending on the scenario that applies to them.
  - In general: when manufacturers have a clear intention to transition to the IVDR for their Class D IVD's; **apply as soon as possible** with an IVD Notified Body that is designated for Class D's (and your device). When manufacturers apply before October 1, 2024, performance verification can happen **at a later date** in the certification cycle.
  - IVD manufacturers of **legacy devices** that have their devices covered under **Annex II List A IVDD certificate and** are eligible for extension timeline per updated article 110 per EU 1860/2024; discuss the possibility with the Notified Body to transit IVDD and IVDR devices in parallel. Discuss compliance plan for the devices to meet common specifications per IVDR.
  - IVD manufacturers that have had their Class D IVDs already **certified** by the Notified Body through alternative means under the IVDR; prepare compliance for meeting common specifications and discuss batch testing criteria to feed into the EURL test plan.
  - IVD manufacturers that have **applied** their Class D IVD with a Notified Body **before October 1, 2024**, will need to discuss with their Notified Body a plan for compliance with common specifications and batch testing criteria. Since these will be verified during the initial technical dossier assessment of the IVD.
  - In short; **get in contact** with your Notified Body and discuss your plans!

General recommendations to Manufacturers

In order to make full use of the currently available capacity, 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 encouraged to submit IVDR applications, especially for the Class D devices, knowing that after 1 October 2024, the process will get **more formal** with the involvement of the EURLs: Performance Verification -> Batch Criteria Setting -> Batch testing.

- When your Class D IVD is already certified or in IVDR application with BSI; please **contact** your Scheme Manager for further details.

Questions, anybody?

Thank you for joining us today