50 years RAPS JRA Journal of Regulatory Affairs

From IVDD to IVDR: The interplay between notified bodies and EU reference laboratories

Jennifer Rosendahl, MSc, PhD

Marta Carnielli, PharmD

Panna Vass, MSc, PhD

Karin Agrenius, MSc

The EU In Vitro Diagnostic Medical Devices Regulation (EU IVDR) introduced a new layer of oversight for high-risk Class D in vitro diagnostic (IVD) medical devices by requiring performance verification and batch testing by designated EU reference laboratories (EURLs). This article outlines the transition from the former EU In Vitro Diagnostic Directive (IVDD), under which notified bodies (NBs) conducted device verification using various alternative methods, to the EURL legal framework established under EU IVDR, Article 100. It summarizes EURL designation and technical areas, the development of harmonized agreements and workflows between NBs and EURLs, and the phased implementation of performance verification and batch testing. It also outlines key operational steps, manufacturer obligations, and batch testing criteria.

Keywords – batch testing, EU IVDR, EU reference laboratory, notified body, performance verification

Introduction

Regulation (EU) 2017/746, also known as the EU IVDR, introduced performance verification and batch testing by designated EURLs to strengthen the oversight of high-risk Class D IVDs.[1] The primary goals are to ensure device quality, safety, reliability, and batch consistency both prior to certification and throughout the product lifecycle. Testing of Class D IVDs is performed by designated EURLs, while the notified body remains responsible for the device's conformity assessment. This article reviews the workflow developed between the notified bodies and EURLs and the implementation of testing activities of Class D IVDs at these laboratories, as set forth in Regulation (EU) 2022/944.[2]

Notified bodies are entities designated by EU member states and notified in a dedicated electronic system. They are responsible for conducting conformity assessments for IVDs when required by the EU IVDR. For Class D IVDs, NBs examine the manufacturer's quality management system and technical documentation and issue corresponding certificates to the manufacturer. After receiving the necessary certificates, the manufacturer may affix the CE mark and place their device on the EU market.

Since the publication of the EU IVDR in 2017, the number of IVDR NBs has grown to 19, most of which are designated for Class D IVDs. Although NBs are separate and independent entities, they collaborate closely through the Notified Body Coordination Group, established under Article 45 of the IVDR, as well as the European Association of Medical Devices Notified Bodies, known as Team-NB.

EU reference laboratories are designated by the European Commission for different scopes of class D IVDs. Where an EURL is

Alex Laan, BSc, Dipl-Ing

Tom Patten, MSc

Olga Tkachenko, MSci, PhD

Aisha V. Sauer, MSc, PhD

designated for the scope that covers a given device, the NB must involve the EURL to verify the device's performance before issuing the technical documentation certificate and to conduct batch testing post-certification. In the absence of a designated EURL, NBs may verify the conformity data provided by the manufacturer during conformity assessment through *alternative means*, such as witness testing during audits and batch documentation review.

Regulatory background: From IVDD to IVDR

The concept of verifying or testing batches is not new. Under the IVDD, which was adopted in 1998, NBs were required to perform "verification of manufactured products" for high-risk IVDs listed in Annex II, List A.[3] However, the IVDD did not specify detailed procedures for conducting such verification. Guidance provided by the former NB-MED,[4] an informal coordination group of NBs, outlined the following options:

- Independent batch testing: NBs could directly test samples from product batches, typically through contracted independent laboratories;
- Manufacturer-performed testing with NB materials: NBs could provide reference materials to manufacturers, who would test batch samples according to agreed procedures; and
- On-site witnessed testing: NBs could witness the manufacturers performing batch testing at their facilities in accordance with agreed procedures.

The IVDR was introduced as a more robust and harmonized regulatory framework. Among other changes, it strengthened requirements for clinical evidence for devices, significantly expanded the role of NBs, and strengthened coordination between member state competent authorities. The IVDR also established the legal basis for the designation of EURLs and set forth their roles in independently verifying the performance of high-risk IVDs.

The regulation gives the European Commission discretion as to when and which EURLs are designated. Prior to their designation, in the absence of EURLs, NBs have continued to apply an oversight mechanism (also known as an alternative means) like the one used under the IVDD for batch testing of Class D IVDs.[5]

EURL designation under IVDR

To be designated as an EURL, a candidate laboratory must meet the criteria set out in Article 100(4) of the IVDR, as further detailed in Regulation (EU) 2022/944 on tasks and criteria.[2] These include qualified staff, adequate equipment and reference materials, and an appropriate administrative structure. EURLs must operate independently, maintain confidentiality, and avoid any conflicts of interest, such as financial ties to the medical device/IVD industry, to ensure their impartiality and ability to act in the public interest.

Tasks and criteria

Under Article 100 of the IVDR, EURLs perform the following main tasks regarding IVD Class D devices both before and after market placement:

- Article 100(2)(a): Verify that the manufacturer's claimed performance complies with the applicable common specifications, if such exist, or with other solutions chosen by the manufacturer that ensure a level of safety and performance that is at least equivalent; and
- Article 100(2)(b): Carry out appropriate tests on samples of manufactured Class D devices or on batches of Class D devices, in accordance with Section 4.12 of Annex IX and Section 5.1 of Annex XI of the IVDR.

EURLs also perform advisory tasks under Article 100(2), including:

- Providing scientific and technical assistance, as well as advice regarding the state of the art;
- Contributing to the development of appropriate testing and analysis methods for conformity assessment and market surveillance, as well as contributing to the development of best practices for the performance of conformity assessment procedures;
- Recommending suitable reference materials and reference measurement procedures of higher metrological order; and
- Contributing to the development of common specifications and of international standards.

Article 100(5) specifies additional activities that the EURLs must carry out as a network, including coordinating methods, procedures, and processes, establishing and maintaining a peer review system, and conducting regular proficiency tests.

Calls for designation

In 2022, the European Commission launched a first call for the designation of EURLs for Class D IVDs. These EURLs could be designated in eight different scopes: hepatitis or retrovirus infection, herpesvirus infection, infection with bacterial agents, arbovirus infection, respiratory virus infection, infection with hemorrhagic fever viruses or other biosafety level 4 viruses, parasite infection, and blood grouping markers.

The call outlined a selection process in line with Article 100(1) of the IVDR. The selection had two stages: an assessment of the candidate laboratories' applications by a relevant authority in their EU member state, followed by an assessment by the European Commission. On 5 December 2023, the Commission designated four single laboratory organizations and one consortium as EURLs through Regulation (EU) 2023/2713.[6] These entities became the first to be operational within the EURL network, each with a defined scope(s) relating to specific categories of infectious agents.

A second call for further applications was launched in 2024. Following a similar assessment, the scopes of designation was expanded in December 2025 through Regulation (EU) 2025/2526,[7] amending Regulation (EU) 2023/2713 to include parasite infection markers and blood grouping tests. As of early 2026, five EURLs cover six of the eight scopes for Class D IVDs (**Table 1**). Another call for designation to

Table 1. Designated EU reference laboratories by country and markers

Designated reference laboratory	Country	Markers
Paul Ehrlich Institut	Germany	Hepatitis or retrovirus infection Respiratory virus infection Blood grouping
Consulting Químico Sanitario	Spain	Herpesvirus infection Infection with bacterial agents Parasite infection Blood grouping
Instituto de Salud Carlos III	Spain	Hepatitis Herpesvirus infection Infection with bacterial agents Parasite infection
Consortium coordinated by Servicio Madrileño de Salud[a]	Spain	Herpesvirus infection Infection with bacterial agents
Research Institutes of Sweden	Sweden	Respiratory virus infection Blood grouping

[a]The consortium is comprised of three hospitals: Hospital General Universitario Gregorio Marañón, Hospital Universitario La Paz, and Hospital Universitario Ramón y Cajal.

expand the current EURL pool is expected to be completed by the second half of 2026.

If more than one EURL is designated for a category of devices, those EURLs will form a subnetwork. The subnetworks produce and maintain up-to-date common procedures for performance verification and batch testing for the devices within the category. The designated EURL subnetworks are:

- **Hepatitis or retrovirus infection –** Paul-Ehrlich Institut, Germany; Instituto de Salud Carlos III
- **Herpesvirus infection –** Consulting Químico Sanitario; Instituto de Salud Carlos III; and Servicio Madrileño de Saluda, which is comprised of three hospitals: Hospital General Universitario Gregorio Marañón, Hospital Universitario La Paz, and Hospital, Universitario Ramón y Cajal
- **Infection with bacterial agents –** Consulting Químico Sanitario; Servicio Madrileño de Saluda; Instituto de Salud Carlos III
- **Arbovirus infection –** No designated EURLs
- **Respiratory virus infection –** Paul Ehrlich Institut, Germany; Research Institutes of Sweden
- **Infection with hemorrhagic fever viruses or other biosafety level 4 viruses –** No designated EURLs
- **Parasite infection –** Consulting Químico Sanitario; Instituto de Salud Carlos III
- **Blood grouping markers –** Research Institutes of Sweden; Paul Ehrlich Institut, Germany; Consulting Químico Sanitario

While the EURLs are located in specific EU member states, they serve the entire EU. This means that any NB can request an EURL to carry out performance verification or batch testing for any device and manufacturer, regardless of the country in which they are located, provided that the device is within the EURL's designation scope.

EURLs and NBs in cooperation

Operationalizing EURLs

Together, these five EURLs form a network intended to ensure scientific robustness, regulatory harmonization, and increased confidence in IVD performance across the EU. Their designation is followed by a transition period during which designated laboratories establish networks and harmonized procedures, and manufacturers and NBs adapt their processes to include EURL testing. The EURLs assume their conformity assessment tasks in Article 100(2) of the IVDR at the end of the transition period, specified in the corresponding designation acts.

Prior to the first EURLs becoming operational in October 2024, NBs continued to utilize the previously established approach for batch testing (i.e., verification by alternative means). As of 1 October 2024, NBs are required to engage designated EURLs for devices within the scopes of hepatitis or retroviruses, herpesviruses, bacterial agents, and respiratory viruses for both performance verification and batch testing. EURLs designated for parasites and blood grouping assume their conformity assessment tasks from 1 May 2026. In line with Regulation (EU) 2023/2713, performance verification requirements are implemented in phases depending on whether the manufacturer submitted the device's conformity assessment application to the notified body before or after 1 October 2024 or 1 May 2026, respectively.

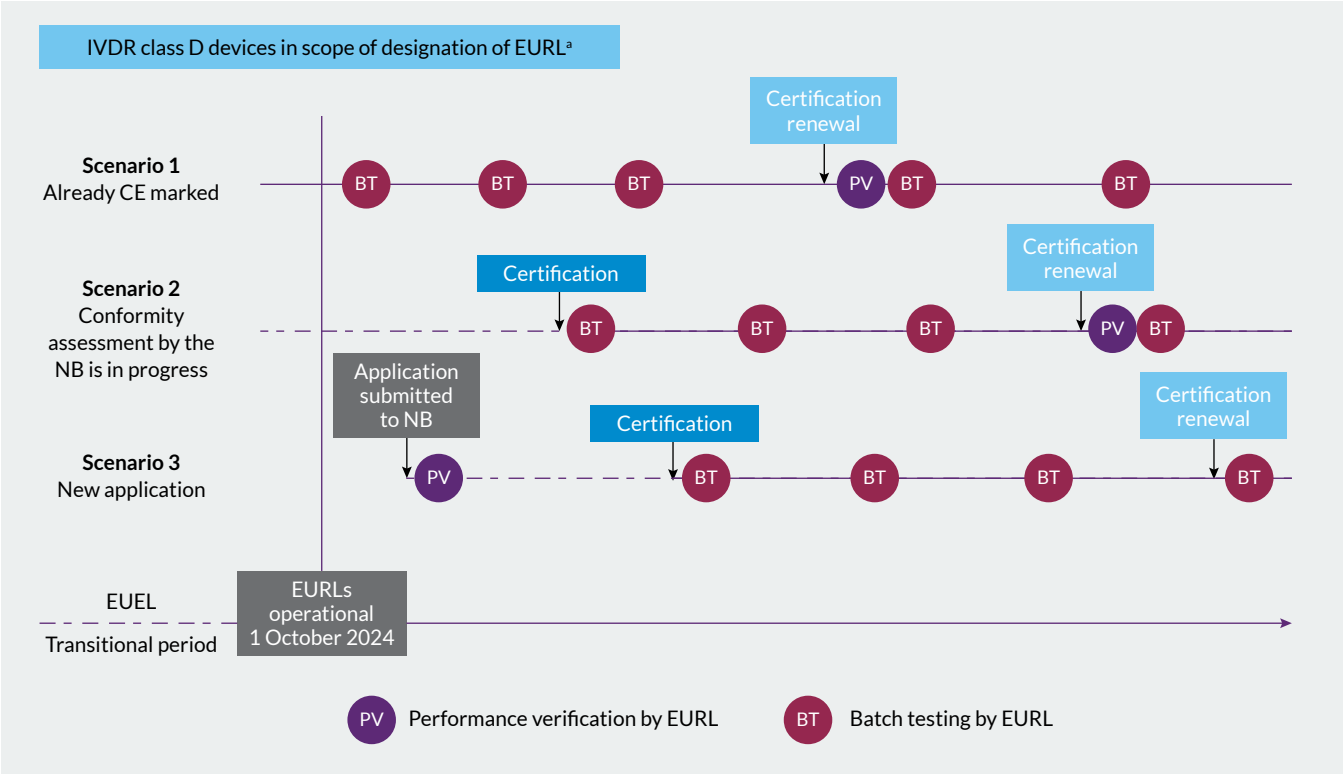
Testing sequence

The sequencing of EURL performance verification depends on when the manufacturer submits the application for conformity assessment to the NB (**Figure 1,** p. 8):

- For devices that were CE-marked before 1 October 2024, performance verification must occur prior to certificate renewal. Performance verification is also required for changes to an approved device (Annex IX, Section 4.11);
- For applications submitted before 1 October 2024, performance verification must occur prior to certificate renewal (Annex IX) and as part of type examination (Annex X, Section 3); and
- For applications submitted after 1 October 2024, performance verification must occur as part of the initial technical documentation assessment (Annex IX, Section 4.9).

As of 1 October 2024, batch testing by an EURL is compulsory for devices falling within its designated scope. Therefore, contractual and logistical arrangements among EURLs, NBs, and manufacturers needed to be established. Until these arrangements were fully in place, NBs could temporarily continue to use alternative means established in the absence of the EURL contract. NBs may still also use alternative means for device scopes that are not yet covered, per the Medical Device Coordination Group (MDCG) guidance.[9] For parasites and blood grouping devices, the same principles apply from 1 May 2026, in line with the phased implementation.

Figure 1. EURL performance verification sequencing for high-risk IVDs[8]



EURL, EU reference laboratory; **IVD,** vitro diagnostic [medical device]; **IVDR,** [EU] In Vitro Diagnostic Medical Devices Regulation; **NB,** notified body.

[a]**NB** legacy devices are not subject to **EURL** testing

Adapted from **MDCG** in vitro diagnostic working group meeting[8]

Contractual arrangements

As per Regulation (EU) 2022/944, NBs and EURLs must establish contractual and logistical arrangements that allow testing activities to be established and implemented. To ensure consistent implementation of their respective responsibilities and roles, NBs and EURLs have jointly developed a general framework agreement template comprising a master service agreement and a statement of work template. These two documents together will form the contractual agreement between an EURL and an NB.

Following agreement and approval of these templates, each NB must execute contracts with the EURLs whose designated device categories fall within its scope. Using standardized templates will also support smoother future collaborations between newly designated NBs and the EURLs. Additionally, to further harmonize the testing workflow, NBs and EURLs have agreed to use and develop common templates for performance verification and batch testing activities, promoting a unified approach to these critical processes. This joint effort contributes directly to the development of a harmonized workflow, as described below.

Harmonized workflow

Creating a common and harmonized workflow between EURLs and NB working groups was a particularly ambitious challenge. The work had to be completed under a tight deadline, and the teams were tasked with developing a new process in an area with no prior process. This joint work took place during the first transition period, which ended on 1 October 2024. The initial contact between the NB and the EURLs took place in April 2024, followed by intensive work to establish both the workflow and the necessary procedural documents (e.g., general framework agreement).

After several iterations and reviews, a unified workflow was agreed upon, outlining the key steps for performance

verification and batch testing. In **Figure 2**, rectangles indicate a process, ovals indicate a document, and the cylinder indicates a batch of Class D devices. The criteria-setting step will only apply if the IVDR certification was initiated before 1 October 2024 and performance verification had not occurred. Batch criteria setting will occur before performance verification is conducted, as per MDCG 2021-4 Rev. 1.

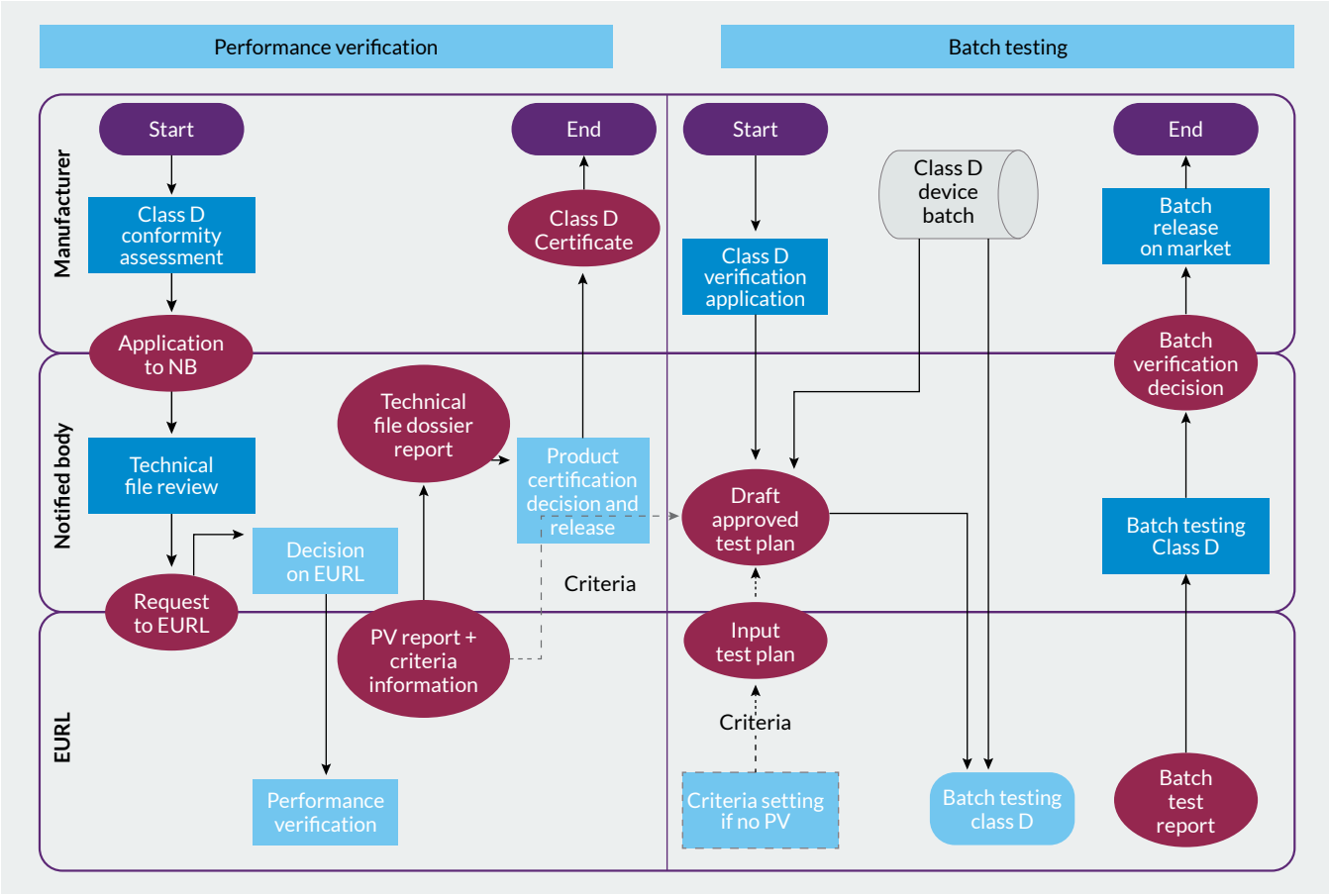
Performance verification

As illustrated in Figure 2, performance verification begins with the manufacturer's submission of a Class D conformity assessment application to the NB during contract review. Once the NB accepts the application, it collaborates with the relevant EURL during the technical documentation assessment to organize and initiate the performance verification process. An application is considered accepted by the NB once the NB has completed its contract review and confirmed that the submission is complete, eligible, and ready to enter the conformity assessment process.

The NB provides the EURL with all documentation related to the device and other relevant information in its possession that is necessary to fulfill the task (i.e., the performance verification). The NB ensures that the manufacturer provides the EURL with the necessary equipment and reference materials for testing the device. This includes the necessary device samples for testing. Within 60 days of receiving the required documentation and device samples, the EURL issues a written scientific opinion (i.e., a written testing report) to the NB.

The EURL's scientific opinion is based on the testing results

Figure 2. Harmonized workflow between manufacturer, notified body, and EURL



BT, batch testing; **EURL,** EU reference laboratory; **PV,** performance verification.
Created by Carnielli et al

and plays a crucial role in determining the certification outcome. When the scientific opinion is negative, the NB will halt the device's certification process. On the other hand, if the scientific opinion is positive and all related conformity assessment review activities are successfully completed, the NB can proceed with a positive decision on the device's certification.

The results of the performance verification testing activity are used to establish the batch testing criteria that will be applied to verify the performance of individual batches post-certification.

Batch testing

Batch testing is initiated post-certification when the manufacturer informs the NB when the batches will be produced. The NB provides the necessary documentation to the EURL and ensures that the manufacturer provides equipment, reference materials, and device samples. The NB prepares the testing plan based on the criteria resulting from performance verification.

IVD manufacturers should contact their NB in a timely manner to clarify which IVDR requirements apply to their device and to determine the appropriate timing for installing instrumentation at the EURL.

The frequency of batch testing is based on MDCG 2022-3 Rev. 1.[10] For Class D IVDs, where performance verification is conducted only at certificate renewal, the EURL must establish the batch testing criteria for the device. To establish the criteria for future batches, the EURL tests three batches of the device. These criteria must be in place before the first batch is tested, irrespective of the performance verification. MDCG 2022-3 also provides additional guidance on the detailed arrangements that must be put in place for performance and batch testing to take place. The requirement to provide all necessary materials to the EURL can be formalized in the contract between the manufacturer and the NB and, where applicable, through separate loan agreements between the manufacturer and the EURL for equipment provision.

During routine batch testing, the EURL tests the IVD against the predetermined batch testing criteria and provides a summary of the results to the NB within 30 days of receipt of the device. When the scientific opinion resulting from the batch testing is positive, the NB releases the device batch. NBs must ensure that all equipment and materials required to perform the testing are provided to the EURLs free of charge. The costs of the actual EURL testing are included in the NB's quotation to the manufacturer, usually during the preapplication phase.

Considerations for IVD manufacturers

When enrolling in the conformity assessment process, it is important for IVD manufacturers to have a clear dialogue with NBs to develop a solid understanding of the entire workflow, as this helps predict the certification process. IVD manufacturers should contact their NB in a timely manner to clarify which IVDR requirements apply to their device and to determine the appropriate timing for installing instrumentation at the EURL. These discussions may take place through *structured dialogue* – a formal, preassessment exchange in which the NB and manufacturer address scope, expectations, and procedural requirements – or as part of the application process itself.

If communication is not initiated early, this can lead to delays in scheduling EURL activities and ultimately a longer overall conformity assessment timeline. For Class D IVDs falling under testing categories for which EURLs have not yet been designated, alternative batch testing methods may currently be used.

Conclusion

EURLs are a new type of scientific body established by the IVDR, tasked with confirming the performance of high-risk IVDs through laboratory testing. As of early 2026, five EURLs have been designated in the EU, and another call is expected to be completed by the second half of 2026. Since 1 October 2024, EURLs have been active in the areas of Class D devices for the detection of hepatitis and retroviruses, herpesviruses, respiratory viruses, and bacterial pathogens. As of 1 May 2026, they also cover Class D parasites and blood grouping IVDs.

NBs and EURLs have closely collaborated to establish a harmonized contract template, testing workflows, and standardized testing templates for Class D IVDs. These significant achievements streamline interactions between

EURLs and NBs, ultimately improving consistency, clarity, and efficiency throughout the testing process.

The establishment of EURL testing is a major milestone in implementing the IVDR, contributing to the availability of safe and performant IVDs in the EU. Devices subject to EURL testing are used for tissue compatibility testing and blood supply testing in Europe, as well as for the detection and monitoring of life-threatening infectious diseases. The work of EURLs is therefore highly relevant and important for public health.

Abbreviations

EU, European Union; **EURL,** EU reference laboratory; **IVD**, in vitro diagnostic [medical device]; **IVDD**, In Vitro Diagnostic Medical Devices Directive; **EU IVDR,** EU In Vitro Diagnostic Medical Devices Regulation; **MDCG,** Medical Device Coordination Group; **NB,** notified body.

About the authors

Karin Agrenius, MSc, is the head of the unit for diagnostics and pandemic preparedness at RISE. She also serves as co-coordinator of the EURLs network for IVD. She holds a master's degree in chemical engineering from Chalmers University of Technology, Sweden, and has more than 10 years of experience working primarily in microbiology and molecular biology research and development projects. She can be reached atkarin.agrenius@ri.se

Marta Carnielli, PharmD, is the head of certification IVD at TÜV SÜD. With more than 30 years of experience in IVD medical devices, Carnielli represents TÜV SÜD on regulatory committees and at conferences, supporting management and technical experts in interpreting regulatory requirements. She holds a master's degree in pharmaceutical chemistry and pharmacy from the University of Trieste, Italy. She chairs the IVD Notified Bodies Working Group within NBCG-MED. Carnielli is a RAPS member and can be reached at marta.carnielli@tuvsud.com

Alex Laan, BSc, BASc, Dipl-Ing, is head of the notified body BSI. He previously worked as a product specialist in immunohematologic and plasma products at Sanquin blood bank, a quality assurance and regulatory affairs manager at Meddens Diagnostics, an audit team leader, dossier reviewer, and project manager at the notified body KEMA, and a principal certification manager at DEKRA Certification. He worked as a regulatory consultant immediately before assuming his current position. Laan has a Bachelor of Science in Technical Management from Saxion University of Applied Sciences in the Netherlands and a degree in applied science from Teesside University in England. Laan is a RAPS member and can be reached at Alex.Laan@bsigroup.com

Tom Patten, MSc, is the international IVDR manager at GMED, with a diverse role encompassing notified body and client-focused responsibilities and collaboration with GMED international sites. He represents the wider notified body group as secretary of the NBCG-Med executive committee. Before joining GMED, Patten worked in the notified body space for five years and before that, in the IVD industry for 15 years. He has an honors degree in biology from Maynooth University, Ireland, and a master's degree in microbiology and parasitology from University College Dublin. Patten can be reached at tom.patten@lne-gmed.com

Jennifer Rosendahl, MSc, PhD, is the coordinator of the EURL IVD network for IVDs and deputy director at RISE EURL. She is also currently a project manager at RISE. Rosendahl has a doctorate in biomedicine from the University of Gothenburg, Sweden, with a multidisciplinary background in diagnostics, genetics, quality control, cancer research, and biomaterials. She can be reached at jennifer.a.rosendahl@gmail.com

Aisha V. Sauer, MSc, PhD, is team leader at the European Commission's Joint Research Centre (Unit F2, technologies for health), where her team supports the EC's Directorate-General for Health and Food Safety in the implementation of the EU regulations on medical devices and in vitro diagnostic medical devices. This includes running the selection procedure for EURLs for high-risk in vitro diagnostics and supporting EURLs toward designation and operationalization. Sauer holds an MSc from the University of Tübingen, Germany, and a PhD from the San Raffaele University, Milan. Sauer can be reached at aisha.sauer@ec.europa.eu

Olga Tkachenko, MSci, PhD, is a policy officer in the Medical Devices Unit (SANTE D.3) of the European Commission's Directorate General for Health and Food Safety. She holds an MSci and BA in natural sciences from the University of Cambridge, England, and a PhD in Physical and Theoretical Chemistry from the University of Oxford, England. She joined the Commission in 2017 and works on IVDs, borderline products, and cooperation with the JRC on EURLs. She also serves as chair of the MDCG IVD Subgroup, supporting implementation of Regulation (EU) 2017/746. Tkachenko can be reached at olga.tkachenko@ec.europa.eu

Panna Vass, MSc, PhD, is a scientific project officer at the European Commission, Joint Research Centre. Her work focuses

on the implementation of the medical devices and in vitro diagnostic medical devices regulations. She contributed to the selection procedure for the newly established European Union Reference Laboratories (EURLs) for high-risk in vitro diagnostics. Her regulatory expertise is complemented by experience at the European Medicines Agency and prior work developing high-risk IVD genotyping software. Vass holds a PhD from the Budapest University of Technology and Economics. She can be reached at panna.vass@ec.europa.eu

Disclaimer The information and views set out in this article by Aisha V. Sauer, Olga Tkachenko, Jennifer Rosendhal, and Panna Vass are those of those four individuals and do not necessarily reflect the official opinion of the European Commission.

Acknowledgment This article was adapted from a presentation at the 2025 RAPS Convergence in Pittsburgh, PA, from 7-9 October. The original presenters at the meeting were: Marta Carnielli, Alex Laan, Jennifer Rosendahl, and Guillaime Berger, who substituted for Tom Patten. Karin Agrenius, Aisha V. Sauer, Olga Tkachenko, and Panna Vass contributed to the writing of the article.

Citation Rosendahl J, et al. From IVDD to IVDR: Interplay between EU reference laboratories and notified bodies. RAPS Journal of Regulatory Affairs. 2026;1(3):4-12. Published online 4 May 2026. https://www.raps.org/resource/from-ivdd-to-ivdr-the-interplay-between-notified-bodies-and-eu-reference-laboratories.html

References

All references were last checked and verified on 13 April 2026.

1. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU. Accessed 13 February 2026. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0746
2. Commission Implementing Regulation (EU) 2022/944 of 17 June 2022 laying down rules for the application of Regulation (EU) 2017/746 of the European Parliament and of the Council as regards the tasks of and criteria for European Union reference laboratories in the field of in vitro diagnostic medical devices. Accessed 13 February 2026. https://eur-lex.europa.eu/eli/reg_impl/2022/944/oj/eng
3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. Accessed 13 February 2026. https://eur-lex.europa.eu/eli/dir/1998/79/oj/eng
4. Co-ordination of Notified Bodies Medical Devices. Verification of manufactured products for the IVD Directive [recommendation]. Revised 11 April 2000. Accessed 13 February 2026. https://www.team-nb.org/wp-content/uploads/2015/05/nbmeddocuments/Recommendation-NB-MED-2_5_4-2_rev3_Verification_of_Manufactured_Products_for_the_IVD_Directive.pdf
5. The European Association of Medical Devices Notified Bodies. Class D measures in the absence of EU reference laboratories – Points to consider for notified body approach [position paper]. Adopted 5 October 2022. Accessed 13 February 2026 https://www.team-nb.org/wp-content/uploads/members/M2022/Team-NB-PositionPaper-Inter-Verif-classD-V1-20221005.pdf
6. Commission Implementing Regulation (EU) 2023/2713 of 5 December 2023 designating European Union reference laboratories in the field of in vitro diagnostic medical devices. Accessed 13 February 2026. https://eur-lex.europa.eu/eli/reg_impl/2023/2713/oj/eng
7. Commission Implementing Regulation (EU) 2025/2526 of 16 December 2025 amending Implementing Regulation (EU) 2023/2713 to correct the designation of an EU reference laboratory and to designate European Union reference laboratories for in vitro diagnostic medical devices intended for detection or quantification of markers of parasite infection and detection of blood grouping markers. Accessed 13 February 2026. https://eur-lex.europa.eu/eli/reg_impl/2025/2526/oj/eng
8. Medical Devices Coordination Group. EU reference laboratories – Medical Devices Coordination Group meeting [presentation]. Dated 10 October 2023. Accessed 13 February 2026. https://ec.europa.eu/transparency/expert-groups-register/core/api/front/document/100695/download
9. European Commission. MDCG 2021-4 rev.1 – Application of transitional provisions for certification of Class D in vitro diagnostic medical devices under Reg (EU) 2017/746. Dated 25 September 2024. Accessed 13 February 2026. https://health.ec.europa.eu/latest-updates/mdcg-2021-4-rev1-application-transitional-provisions-certification-class-d-vitro-diagnostic-medical-2024-09-25_en
10. Medical Device Coordination Group Document. MDCG 2022-3 Rev. 1 Verification of manufactured Class D IVDs by notified bodies. Dated December 2024. Accessed 13 February 2026. https://health.ec.europa.eu/document/download/ebbc4f6a-4945-4d5d-9c22-9bc1aafc5532_en