GMED LNE GROUP Newsletter

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IVDR CLASS C: WHY "APPLICATION SUBMITTED" IS NOT ENOUGH

A valid Class C application is necessary to maintain your transitional timeline — but it is not, by itself, sufficient to achieve certification

The May 26, 2026 deadline for Class C legacy device applications under EU IVDR - 2017/746 is not an administrative formality. It is a deadline for legacy devices that fall within Class C. Manufacturers must make an application to a Notified Body (NB) by this date to maintain transitional period protection and continued market access. Meeting this submission alone does not immediately guarantee continued market access.

Under the IVDR transitional provisions, a Notified Body (NB) application must pass administrative screening before it is considered valid. If after the May deadline a written agreement is not concluded by September 26, 2026 for Class C, the conditions of Article 110(3c)(f) are not met and the transitional period ceases. The practical consequence is potential immediate market exit for any affected device.

This article covers what constitutes a complete and acceptable NB application under IVDR, the specific documentation and QMS requirements NBs apply during administrative review, and the regulatory consequences of a non-valid submission.

> **The application and the conformity assessment are not sequential phases — they are parallel workstreams. Manufacturers who treat them as sequential may not complete certification within the transitional window.**

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A THE "VALID APPLICATION" THRESHOLD

Under Article 110(3) of Regulation (EU) 2017/746 (IVDR), as amended by Regulation (EU) 2024/1860, the extension of transitional periods for "legacy" devices is conditional. Manufacturers must implement a Quality Management System (QMS) in accordance with Article 10(9) and lodge a formal application for conformity assessment with a Notified Body. A signed, formal written agreement between the manufacturer and the Notified Body must be in place covering the devices under transition to maintain market access.

A valid application is not achieved by the transfer of technical documentation. The Notified Body will not commence a substantive technical documentation review until the application passes a formal completeness check. This administrative and technical validation ensures that all core data required by the relevant Annexes are present before the application is officially accepted for assessment.

Failure to pass this completeness check carries significant regulatory risk. The transitional period protection is lost if no qualifying application is lodged by the applicable deadline, the application is subsequently withdrawn, the written agreement is terminated without immediate transfer to another Notified Body, or the NB refuses the application on grounds of IVDR non-compliance. In such instances, the legal basis for placing the device on the Union market is terminated, necessitating the immediate removal of the device from the market.

Note: A manufacturer must also have a signed Declaration of Conformity (DoC) under Directive 98/79/EC (IVDD) dated prior to **May 26, 2022,** and must ensure no significant changes are made to the device's design or intended purpose. Manufacturers should also consider MDCG 2022-14 rev.1 and MDCG2022-6.

B CORE COMPONENTS OF A COMPLETE SUBMISSION

A complete application under Annex IX (the most common route for Class C) must ultimately include, at a minimum:

- **Evidence of an IVDR-Compliant QMS:** Documentation demonstrating that the QMS has been established and implemented in accordance with Article 10(9) IVDR. ISO 13485 is widely used as the base.
- **Technical Documentation (Annex II & III):** A substantive package covering device description, design and manufacturing information, and a comprehensive risk management file in accordance with ISO 14971:2019. For Class C devices under Annex IX, the NB must assess at least one representative technical documentation file per generic device group, reflecting the applicable sampling obligation.
- **Performance Evaluation Report (PER):** The primary evidence of conformity, encompassing Scientific Validity, Analytical Performance, and Clinical Performance in accordance with Annex XIII IVDR.
- **Post-Market Surveillance (PMS) and Post-Market Performance Follow-up (PMPF) Plans:** Proactive, device-specific strategies for ongoing safety and performance monitoring, in accordance with Articles 79–82 and Annex III IVDR.
- **Draft Labelling and Instructions for Use (IFU):** Must align with the General Safety and Performance Requirements of Annex I IVDR. UDI assignment under Article 24 IVDR is a standalone market placement requirement and must also be addressed in conjunction with EUDAMED registration obligations.

While these items are not all required at the point of application, manufacturers who are not actively preparing them in parallel risk missing the September 2026 written agreement window.

Note that complete technical documentation is not required at the point of lodging the transitional period application — it may be submitted per an agreed timeline ahead of actual assessment.

C RISKS OF LATE OR INCOMPLETE SUBMISSIONS

1. **Loss of Transitional Protection:** If a manufacturer fails to lodge a qualifying application by the May 2026 deadline, withdraws the application thereafter, or allows the written agreement to be terminated without immediate transfer to another Notified Body, the device loses its "legacy" status. It cannot be legally placed on the market until a full IVDR certificate is issued, typically a 12-to-18-month process.
2. **NB Queue Displacement:** Notified Bodies prioritize complete, high-quality dossiers. Incomplete submissions often require multiple rounds of clarification, which can result in the loss of a scheduled review slot and significant project delays.
3. **Contractual Termination:** The transitional protection also requires a signed written agreement with an NB by September 26, 2026. If an initial application is incomplete, the resulting delays may prevent the finalization of this agreement by the deadline, independently triggering the loss of transitional period protection.

D IVDR CLASS C SUBMISSION READINESS CHECKLIST

The following table outlines the technical documentation required for a valid submission. Note that GMED has a well-established checklist we can share, but here is a simplified version.

Topic	Required	Requirement	Example of evidence	Am I ready?
Needed for formal application				
Administrative	Formal NB Application Form	IVDR Annex IX / XI	NB-specific application forms	
QMS	Valid Quality Management System (QMS)	Article 10(9)	Updated Quality Manual; SOPs for Vigilance, PMS, and Trend Reporting	
ADMIN	Device list, including IVD qualification	IVDR Article 2 / Article 110	Comprehensive device list with IVDR classification (IVP/IVR/IVS codes); confirmation of IVD status	
ADMIN	DoC for legacy devices and Change Status Confirmation	Directive 98/79/EC & MDCG 2022-14 rev.1	Signed DoC prior to May 26, 2022; statement confirming no significant changes to design or intended purpose	
Needed for a successful conformity assessment				
GSPR	GSPR Checklist & Evidence Map	IVDR Annex I	Matrix mapping Annex I requirements to specific internal test reports or design files	
Risk Mgmt	Risk Management File	EN ISO 14971:2019	Risk Management Plan; Hazard Analysis; Benefit-Risk Analysis Report	
Performance Overall	Performance Evaluation Report (PER)	IVDR Annex XIII	Overarching report synthesizing Scientific Validity, Analytical, and Clinical data	
Performance Scientific Validity	Scientific Validity Report	IVDR Annex XIII, Part A	Peer-reviewed literature search; clinical guidelines; consensus statements	
Performance Analytical	Analytical Performance Report	IVDR Annex XIII, Part A	Reports on Accuracy, Precision, LOD/LOQ, Interference, and Cross-reactivity	
Performance Clinical	Clinical Performance Report	IVDR Annex XIII, Part A	Diagnostic Sensitivity/Specificity data; Method Comparison study results	
Stability	Stability Study Data	IVDR Annex II, Section 6.3	Real-time stability protocols; Shelf-life reports; Open-vial and Transport stability	
Labelling	IVDR-Compliant IFU and Labels	IVDR Annex I, Section 20	Artwork drafts featuring UDI-DI, IVDR symbols, and required safety warnings	
PMS	Post-Market Surveillance (PMS) Plan	IVDR Annex III	Schedule for PSUR (Periodic Safety Update Report) and complaint data analysis	
PMPF	PMPF Plan	IVDR Annex XIII, Part B	Post-market study protocols or rationale for exclusion	
EUDAMED	Actor (SRN) and Device Registration	IVDR Article 28 & 29	Proof of Single Registration Number (SRN); Basic UDI-DI registration status	

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E RECOMMENDED ACTIONS

For manufacturers who have not yet submitted a valid application:

1. **Contact GMED —** Our scope covers your device type!
2. **Conduct a gap analysis against Annexes II and III** — identify missing or incomplete documentation elements - Cf. IVDR readiness checklist soon available
3. **Assess QMS compliance specifically against IVDR Article 10(8)** do not assume ISO 13485 certification is sufficient – also covered in our checklist - Cf. IVDR readiness checklist soon available
4. **Initiate or verify EUDAMED registration** — the SRN must be in place before or at the time of submission
5. **Submit a review-ready dossier** — Once ready submit, using the checklists above will help unsure your submission will successfully pass the completeness check allowing you to maintain market access for your legacy device.

Conclusion

The Difference Between "Submitted" and "Secured"

The IVDR Class C deadline is not simply about submitting an application; it is about ensuring that your submission is complete, compliant, and actionable by your Notified Body.

The practical risks of an incomplete or delayed submission are real. An application that causes delays preventing conclusion of the written agreement by September 26, 2026 — or one that is subsequently withdrawn — is not a minor administrative setback. It can be a decisive risk to maintaining market access in the European Union. In a constrained regulatory environment, timelines are tight, and quality and completeness at first submission are critical differentiators.

Manufacturers who succeed in this transition will be those who:
- Treat the May 2026 deadline as a readiness milestone, not a submission target
- Align early with their Notified Body on expectations
- Ensure their technical documentation and QMS are IVDR-native, not IVDD-adapted

"Application submitted" is not the goal; "application accepted and planned / under assessment" is.

Choose GMED

WHY CHOOSE GMED FOR THE CERTIFICATION OF YOUR IVD'S?

Selecting the right Notified Body is a strategic decision that directly impacts your timelines, risk exposure, and long-term market access. GMED offers a combination of regulatory depth, operational efficiency, and partnership-driven support tailored to the realities of IVDR.

GMED is fully designated across all IVDR scopes, covering with **100% IVDR Designations,** the entire range of IVD technologies. This ensures continuity and scalability for your product portfolio, today and as it evolves.

With decades of **experience since the origins** of the early European directives, GMED combines historical regulatory insight with current IVDR expectations. Our teams understand not just the requirements, but how they are interpreted and applied in practice.

Each manufacturer is supported by **a single point of contact,** a Dedicated Certification Project Managers (CPMs), ensuring clarity, responsiveness, and continuity throughout the certification process.

Our secure digital platform, GMED Connect, streamlines interactions, document exchange, and project tracking, enhancing transparency and efficiency at every stage of your certification journey, providing a **seamless digital experience.**

Beyond conformity assessment, GMED acts as a **trusted regulatory partner,** helping you anticipate expectations, reduce submission risks, and navigate IVDR with confidence.

To go further

SCHEDULED TRAINING SESSIONS IN NORTH AMERICA TIME ZONE

European In Vitro Diagnostic Device Regulation (EU) 2017/746
2-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

Technical Documentation per European In Vitro Diagnostic Device Regulation (EU) 2017/746
1.5-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

Post Market Surveillance and Vigilance
1-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

Risk management applied to Medical Devices
2-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

ON DEMAND TRAININGS

Understanding the requirements for importers and distributors under Regulations (EU) 2017/745 and 2017/746
1-day training session | On demand

Analyze the role of the PCVRR (Person Responsible for Ensuring Compliance with Regulatory Requirements)
1-day training session | On demand

Perform a performance evaluation and clinical evidence assessment for in vitro diagnostic medical devices (IVDMDs)
1.5-day training session | On demand

Implementing the requirements relating to the UDI (Unique Device Identifier)
1-day training session | On demand

Advertising of medical devices
1-day training session | On demand

Identify regulatory and legal responsibilities according to your role
2-day training session | On demand

→ CONTACT GMED TRAINING CENTER

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Disclaimer: This document reflects the regulatory position as of April 2026. Manufacturers should consult their notified body directly and refer to applicable MDCG guidance documents for device-specific requirements. This document does not constitute legal or regulatory advice.

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