Erba Lachema s.r.o.

ADVISORY NOTICE

38_2026_Technical documentation IVDR compliance

Dear Business Partners,

In line with the requirements of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), we are developing and compiling our Summary Technical Documentation (STED) in accordance with the new regulatory framework, to ensure compliance with the applicable IVDR requirements.
This process includes, among other aspects:

- Device classification and regulatory requirements in accordance with the IVDR.
- General Safety and Performance Requirements (GSPR) and their demonstration of compliance.
- Performance evaluation documentation, including scientific validity, analytical performance and clinical performance.
- Risk management documentation and the assessment of the overall benefit-risk profile.
- Post-market surveillance (PMS) and, where applicable, post-market performance follow-up (PMPF) documentation.
- Labelling and Instructions for Use (IFU) to ensure consistency with the applicable IVDR requirements.
- UDI and traceability-related information, where applicable.

The documentation is being developed progressively across our product portfolio, taking into account the applicable regulatory requirements and relevant conformity assessment processes. Should you require the updated technical documentation for product registration, regulatory submissions or import-related purposes in your respective markets, please contact our Regulatory Affairs Department at m.miklova@erba.com.
Our team will be pleased to assist you and provide the relevant documentation in accordance with your specific regulatory needs.

Thank you for your continued cooperation and support.

Best regards,

Regulatory Affairs Manager, PRRC
Michaela Miklová

Best regards,
Erba Lachema s.r.o.

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Brno, 12th November 2026

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