

To: BIOgenetiX Solutions SRL,
Regulatory Department,
Republic of Moldova

Subject: Declaration of Conformity Statement

Labsystems Diagnostics Oy as a Manufacturer hereby declares that the product listed below is in compliance with the In Vitro Diagnostic Directive (IVDD) 98/79/EC. In accordance with EU Regulation 2017/746 and its amendment 2024/1860, we confirm that these products fall under Class C as per the IVDR classification. As stated in the amendment, the transition period for Class C legacy devices has been extended until 31 December 2028. Therefore, the current IVDD Declaration of Conformity remains valid until the new IVDR DoC becomes available.

Furthermore, we confirm that a formal IVDR application has been submitted in accordance with Annex VII of Regulation (EU) 2017/746 and that a written agreement has been concluded. The applicability of the IVDR transitional provisions under Regulation (EU) 2024/1860 has been confirmed, subject to continued compliance with Article 110(3c) of the IVDR.

Additionally, we confirm that the product listed below is registered in the EUDAMED database, and that Post-Market Surveillance has been implemented for this product. Any mandatory notifications related to supply interruptions of this IVD will be promptly communicated to all affected distributors and customers.

Cat No	Product Name	EUDAMED ID	EUDAMED Actor ID
6199896	Neonatal Phenylalanine	06438172085015	FI-MF-000018281



Thanks & Regards,
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