CERTIFICATE

Number: 2281659

The management system of:

Labsystems Diagnostics Oy

Tiilitie 3
FI-01720 Vantaa
Finland

Manufacturer Facility Identifier F006494

Conforms with the following standard and regulatory requirements:

ISO 13485:2016

Brazil:	RDC ANVISA n. 665/2022, 551/2021 and 67/2009
Canada:	Medical Devices Regulations - Part 1- SOR 98/282
Japan:	MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act
United States:	21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

Scope:
The design and development, manufacturing, installation, servicing and distribution of in vitro diagnostic test kits and in vitro diagnostic analyzers/software used in the newborn screening using FEIA. The design and development, manufacturing, installation, servicing and distribution of in vitro diagnostic test kits and in vitro diagnostic reagents used in the newborn screening using Real-Time PCR and LC-MS/MS. The design and development and manufacturing of in vitro diagnostic test kits used as an aid in the diagnosis of infectious diseases using Real-Time PCR and Enzyme Immunoassay for professional use, including point of care, and in the detection of gastroenterology affection using Enzyme Immunoassay for professional (including point of care) and home use. The design and development, manufacturing and distribution of in vitro diagnostic test kits and in vitro diagnostic reagents used for quantitative determination of various analytes/drugs levels using HPLC and LC-MS/MS methods

Certificate expiry date:	2026-07-27
Certificate effective date:	2024-01-15
Certified since:	2024-01-15

DEKRA Certification B.V.

B.T.M. Holtus
Managing Director

J.M. McKenzie
Certification Manager

Digitally signed by Olaru Victoria
Date: 2025.04.24 13:23:56 EEST
Reason: MoldSign Signature
Location: Moldova
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The validation of the validity of this certificate can be checked through DEKRA's website using the following link:
https:/www.dekra-product-safety.com/en/certified-organizations

DEKRA Certification B.V. is recognized under the Medical Devices Single Audit Program.

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM