

# 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

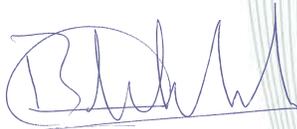
Brazil: RDC ANVISA n. 665/2022, 551/2021 and 67/2009  
Canada: Medical Devices Regulations - Part 1- SOR 98/282  
Japan: MHLW Ministerial Ordinance 169, Article 4 to Article 68 and PMD Act  
United States: 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D and 21 CFR 820

### 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

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