Certificate

Certificate No.:	MD 1070846-1-1
Manufacturer:	**Thermo Fisher Scientific Oy** Ratastie 2 FI-01620 Vantaa Finland
REPs Facility ID:	F007972
Certification criteria:	ISO 13485:2016 Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021, RDC ANVISA n. 67/2009 Canada Medical Devices Regulations – Part 1 – SOR 98/282, United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope:	The design and development, manufacturing, service, installation and distribution of in vitro diagnostic medical devices including clinical chemistry analysing systems, laboratory automation and diagnostic assays and reagents.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	1175400-32
Issue Date:	2025-01-20
Effective Date:	2025-01-20
Expiry Date:	2027-03-31

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dr. Matthias Fischer
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com
or calling 1-888-743-4652.

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