Certificate

Certificate No.:	MD 1743284-1-1
Manufacturer:	**Sysmex Partec GmbH** Arndtstr. 11 a-b 02826 Görlitz Germany
REPs Facility ID:	F004842
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 Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope:	Design and development, manufacturing and distribution of in-vitro diagnostic analyzers, in-vitro diagnostic reagents, in-vitro diagnostic test kits, single monoclonal antibodies and lysing solutions used in the detection of disease status and immune status.

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.:	1133792-40
Issue Date:	2023-07-18
Effective Date:	2023-08-15
Expiry Date:	2026-08-14

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: M.Sc. Irene Carraretto
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000008896?locale=en or calling 1-888-743-4652.

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