

# Certificate

Certificate No.: MD 3314728-150

Manufacturer: **Sysmex Partec GmbH**  
Arndtstr. 11 a-b  
02826 Görlitz  
Germany

D-U-N-S No.: 329750942

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. 16/2013, RDC ANVISA n. 23/2012, 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 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.: 3314728-150

Issue Date: 2020-11-17

Effective Date: 2020-11-17

Expiry Date: 2023-11-16



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Certification officer: Dipl.-Ing. (FH) D. Wiedemuth  
TUV Rheinland of North America, Inc.

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