Certificate

TÜV Rheinland®

Certificate No.:	MD 1192275-1
Manufacturer:	**DiaSys Diagnostic Systems GmbH** Alte Str. 9 65558 Holzheim Germany
REPs Facility ID:	F006229
Certification criteria:	ISO 13485:2016 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, development, manufacturing and distribution of in-vitro diagnostic reagents for clinical chemistry, immunoturbidimetry and hematology. Design, development, manufacturing, distribution, installation and service of in-vitro diagnostic analyzers for clinical chemistry, immunoturbidimetry and hematology.

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.:	1098938-150
Issue Date:	2022-09-19
Effective Date:	2022-09-19
Expiry Date:	2025-02-17

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dipl.-Ing. S. Pane
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000011289?locale=en or calling 1-888-743-4652.

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