

# Certificate

Certificate No.: MD 1192275-1-1

Manufacturer: **DiaSys Diagnostic Systems GmbH**  
Alte Str. 9  
65558 Holzheim  
Germany

REPs Facility ID: F006229

Certification criteria: ISO 13485:2016  
Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,  
RDC ANVISA n. 67/2009  
United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –  
Subparts A to D

Scope: Design, development, manufacturing, distribution, installation, and service of in-vitro diagnostic analyzers, in-vitro diagnostic reagents incl. in-vitro diagnostic test kits used in the diagnosis, management, and detection of atherosclerosis, bone metabolism, metabolic parameters, stool diagnostics, renal markers, electrolytes, thrombotic markers, inflammatory markers, iron status markers, lipid markers, cardiac markers, nutrition markers, markers of the immune status, diabetes markers, pancreatic markers, liver markers including point of care in-vitro diagnostic medical devices.

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.: 1173482-690  
Issue Date: 2025-02-17  
Effective Date: 2025-02-18  
Expiry Date: 2028-02-17



Certification officer: 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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The scope of certification also covers the following sites:

No.	Location	Scope
/01	DiaSys Diagnostic Systems GmbH Alte Str. 9 65558 Holzheim Germany	Design, development, manufacturing and distribution  REPs Facility ID: F006229
/02	DiaSys Diagnostic Systems GmbH Bahnhofstr. 32 65558 Flacht Germany	Installation and Service  REPs Facility ID: F006229



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