Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.:	SX 1192275-1
Certificate Holder:	DiaSys Diagnostic Systems GmbH Alte Str. 9 65558 Holzheim Germany
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.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	1173482-100
Effective date:	2025-02-18
Expiry date:	2028-02-17
Issue date:	2025-02-17

Replaces certificate SX 1192275-1 issued 2022-11-04

This certificate can be validated on https://www.certipedia.com

Matthias Fischer
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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland® Precisely Right.

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EN ISO 13485:2016
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Registration No.: SX 1192275-1

Certificate Holder: DiaSys Diagnostic Systems GmbH
Alte Str. 9
65558 Holzheim
Germany

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o DiaSys Diagnostic Systems GmbH Alte Str. 9 65558 Holzheim Germany	Design, development, manufacturing and distribution
/02	c/o DiaSys Deutschland Vertriebs-GmbH Bahnhofstr. 32 65558 Flacht Germany	Distribution
/05	c/o DiaSys Diagnostic Systems GmbH Bahnhofstr. 32 65558 Flacht Germany	Installation and service

This certificate can be validated on https://www.certipedia.com

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