

# 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



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

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The scope of certification also covers the following sites:

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

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