Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1192275-1

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

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

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.: 1098938-40
Effective date: 2022-11-22
Expiry date: 2025-11-21
Issue date: 2022-11-04

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1192275-1

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

The scope of certification also covers the following:

No.	Facility	Scope
/01	DiaSys Diagnostic Systems GmbH Alte Str. 9 65558 Holzheim Germany	Design, development, manufacturing, distribution, service and installation of in-vitro diagnostic reagents for clinical chemistry, immunoturbidimetry, hematology and in-vitro diagnostic analyzers
/02	DiaSys Deutschland Vertriebs-GmbH Bahnhofstr. 32 65558 Flacht Germany	Distribution of in-vitro diagnostic reagents for clinical chemistry, immunoturbidimetry and hematology.
/03	peS Diagnosesysteme mbH Hauptstr. 10 304416 Leipzig-Markkleeberg Germany	Design and development of in-vitro diagnostic reagents for clinical chemistry, immunoturbidimetry and hematology.
/04	DiaSys Technologies S.a.r.l. Cap Gamma, Parc Euromédecine II, 1682 Rue de la Valsière 34790 Grabels France	Design and development of in-vitro diagnostic analyzers for clinical chemistry, immunoturbidimetry and hematology.

Report No.: 1098938-40
Effective date: 2022-11-22
Expiry date: 2025-11-21
Issue date: 2022-11-04

TÜV Rheinland LGA Products GmbH

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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