

Certificate



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 and Development, Manufacture and Distribution of In vitro
Diagnostic Products

Product groups included:

- Reagents for clinical chemistry, immunoturbidimetric and hematology tests
- analyzers for the determination of glucose and lactate in the blood
- photometric analyzers
- point-of-care analyzers
- analyzers for 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.: 3338617-50
Effective date: 2021-02-05
Expiry date: 2022-11-21
Issue date: 2021-02-05



A blue ink signature is written over a circular blue seal. The seal contains the TÜV Rheinland logo and the text 'TÜV Rheinland LGA Products GmbH', 'TÜVRheinland', and 'Zertifizierungsstelle'.
Dipl.-Ing. S. Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

No.	Facility	Scope
/01	c/o DiaSys Diagnostic Systems GmbH Alte Str. 9 65558 Holzheim Germany	Design and Development, Manufacture and Distribution of In vitro Diagnostic Products
/02	c/o DiaSys Deutschland Vertriebs-GmbH Bahnhofstr. 32 65558 Flacht Germany	Manufacturing of immunoassays, rapid tests and related instruments in the field of clinical chemistry and coagulation. Distribution of reagents and instruments for in-vitro diagnostic use.
/03	c/o pes Gesellschaft für medizinische Diagnosesysteme mbH Hauptstr. 103 04416 Markkleeberg Germany	Design and development of in-vitro diagnostic reagents used in the detection of different markers and point-of-care in-vitro diagnostic

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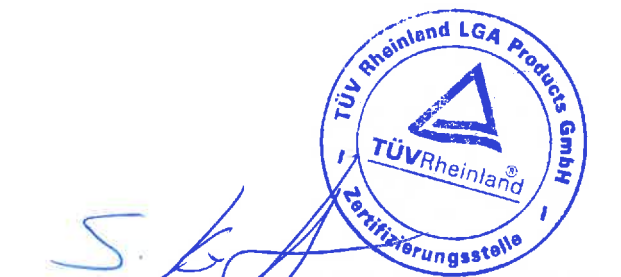
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65558 Holzheim
Germany

/04 c/o DiaSys Technologies S.a.r.l.
Cap Gamma
1682 RUE DE LA VALSIERE
34790 GRABELS
France

Design and development of IVD analyzers

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