

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

DiaSys
Diagnostic Systems GmbH
Alte Str. 9
65558 Holzheim
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and Distribution
of In vitro Diagnostic Products**
(see attachment for included product groups and
additional sites)

Proof has been furnished that the requirements specified in

EN ISO 13485:2012
EN ISO 13485:2012/AC:2012

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2016-11-18
Certificate Registration No.: SX 60115260 0001
An audit was performed. Report No.: 21256841 001
This Certificate is valid until: 2019-03-30

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2016-11-18



Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60115260 0001
Report No.: 21256841 001

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


Scope: Product groups included:

- Reagents for clinical chemistry and for immunoturbidimetric tests
- analyzers for the determination of glucose and lactate in the blood
- photometric analyzers
- point-of-care analyzers

Certification Body



Date: 2016-11-16



Dipl.-Ing. Syen Hoffmann

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60115260 0001
Report No.: 21256841 001

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

Scope:

Additional sites included:

DiaSys Deutschland Vertriebs-GmbH,
Bahnhofstr. 32, 65558 Flacht, Germany

- Manufacturing of immunoassays, rapid tests, staining solutions and related instruments in the field of clinical chemistry and coagulation. Distribution of reagents and instruments for in-vitro diagnostic use.

DiaSys Technologies S.a.r.l.,
Cap Gamma, 1682 rue de la Valsière, Parc Euromedecine II,
34790 Grabels, France

- Design and development of IVD analyzers

pes diagnosesysteme GmbH


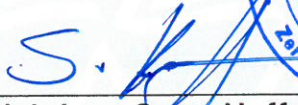
Hauptstraße 10, 304416 Leipzig-Markkleeberg, Deutschland

- Design and development of in-vitro diagnostic reagents used in the diagnosis and detection of different markers and point-of-care in-vitro diagnostic

Certification Body



Date: 2016-11-16



Dipl.-Ing. Sven Hoffmann