

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

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

see attachment

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: 2017-05-19
Certificate Registration No.: SX 60118882 0001
An audit was performed. Report No.: 21264033 001
This Certificate is valid until: 2019-03-30

Certification Body



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2017-05-19



Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60118882 0001
Report No.: 21264033 001

Organization: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Scope: Design and development, production, service and sales of immunobiochemical systems, immunofluorescence test systems, molecular diagnostic/genetic test systems and test systems for the determination of pathogens and analysers/software for in vitro diagnosis

Sites included:

- EUROIMMUN Medizinische Labordiagnostika AG
Am Sonnenberg 9, 23627 Groß Grönau, Germany

Activities: Production and quality control

- EUROIMMUN Medizinische Labordiagnostika AG
Am Born 24, 23627 Groß Grönau, Germany

Activities: Production and service for software solutions for IVD applications

Certification Body



Date: 2017-05-19



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Report No.: 21264033 001

Organization: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Scope:

Sites included:

- EUROIMMUN Medizinische Labordiagnostika AG
Schloßstraße 11, 91257 Pegnitz, Germany

Activities: Production and service

- EUROIMMUN Medizinische Labordiagnostika AG
Werkstraße 2-22, 23942 Dassow, Germany

Activities: Production, quality control, warehousing and distribution

- EUROIMMUN Medizinische Labordiagnostika AG
Im Kreppel 1, 02747 Herrnhut, Germany

Activities: Production

Certification Body



Date: 2017-05-19



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Organization: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Scope:

Sites included:

- EUROIMMUN Medizinische Labordiagnostika AG
Am Pließnitztal 1, 02748 Bernstadt, Germany

Activities: Production

- EUROIMMUN Medizinische Labordiagnostika AG
An der Trave 1, 23923 Selmsdorf, Germany

Activities: Design and development and production

Certification Body



Date: 2017-05-19


Dipl.-Ing. Sven Hoffmann

