

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 13485:2016

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

Effective Date: 2018-06-08
Certificate Registration No.: SX 60129534 0001
An audit was performed. Report No.: 21264033 005
This Certificate is valid until: 2020-05-18

Certification Body



Date 2018-06-08



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 60129534 0001
Report No.: 21264033 013

Organization: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Scope:

Design and development, manufacture, installation, service and distribution of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic/genetic test systems, test systems for the determination of infectious agents and instruments/software for in vitro diagnostics

Sites included:

EUROIMMUN Medizinische Labordiagnostika AG
Werkstraße 1, 23942 Dassow, Germany

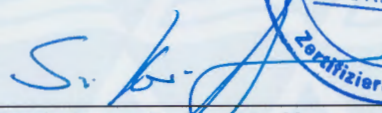
Activities: Design and development, manufacture and distribution

Certification Body



Date: 2019-07-17




Dipl.-Ing. Sven Hoffmann

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60129534 0001
Report No.: 21264033 013

Organization: **EUROIMMUN**
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Scope:

Sites included:

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

Activities: Design and development, manufacture

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

Activities: Design and development, distribution,
installation, service

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

Activity: Manufacture

Certification Body



Date: 2019-07-17




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Registration No.: SX 60129534 0001
Report No.: 21264033 013

Organization: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Scope:

Sites included:

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

Activity: Manufacture

EUROIMMUN Medizinische Labordiagnostika AG
Schloßstraße 11, 91257 Pegnitz, Germany

Activities: Manufacture, installation and service

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

Activities: Design and development, manufacture and service

Certification Body



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Report No.: 21264033 013

Organization: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Scope:

Sites included:

EUROIMMUN Medizinische Labordiagnostika AG
Am Flugplatz 4, 23560 Lübeck, Germany

Activity: Distribution

EUROIMMUN Medizinische Labordiagnostika AG
Gewerbestr. 19, 23942 Dassow, Germany

Activities: Manufacture

Certification Body



Date: 2019-07-17

