

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.

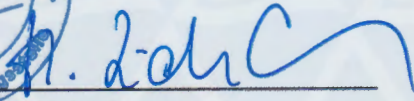
Effective Date: 2014-10-13
Certificate Registration No.: SX 60096220 0001
An audit was performed. Report No.: 21179583 008
This Certificate is valid until: 2017-05-28

Certification Body



Date 2014-10-13




Dr. H. Lüdemann

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
Registration No.: SX 60096220 0001
Report No.: 21179583 010

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

Additional 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: 2015-05-29


Dr. H. Lüdemann

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: SX 60096220 0001
Report No.: 21179583 010

Organization: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Scope: Additional 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: 2015-05-29


Dr. H. Lüdemann

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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Registration No.: SX 60096220 0001
Report No.: 21179583 010

Organization: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Deutschland

Scope: Additional sites included:


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

Activities: Production

Certification Body



Date: 2015-05-29


Dr. H. Lüdemann