

# Certificate

Certificate No.: MD 1102316-60

Manufacturer: **EUROIMMUN**  
**Medizinische Labordiagnostika AG**  
Seekamp 31  
23560 Lübeck  
Germany

REPs Facility ID: F001097

Certification criteria: ISO 13485:2016

Australia Therapeutic Goods (Medical Devices) Regulations, 2002,  
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance

Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC  
ANVISA n. 67/2009

Canada Medical Devices Regulations – Part 1 – SOR 98/282

Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD  
Act

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –  
Subparts A to D

Scope: Design, 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.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 3350288-160

Issue Date: 2021-11-30

Effective Date: 2021-11-30

Expiry Date: 2023-05-18



Certification officer: M. Sc. Irene Carraretto

TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on [https://www.certipedia.com/quality\\_marks/9105087979?locale=en](https://www.certipedia.com/quality_marks/9105087979?locale=en)  
or calling 1-888-743-4652.

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Manufacturer: **EUROIMMUN**  
**Medizinische Labordiagnostika AG**  
Seekamp 31  
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Germany

The scope of certification includes the following sites:

No.	Location	Scope
/01	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany  REPs Facility ID: F001097	Design, development and manufacture of immunobiochemical test systems, immunofluorescence test systems, molecular diagnostic / genetic test systems, test systems for the determination of infectious agents, and instruments / software, including manufacture of sheet metal and other components for instruments for in vitro diagnostics
/02	EUROIMMUN Medizinische Labordiagnostika AG Am Born 24 23627 Groß Grönau Germany  REPs Facility ID: F001097	Design and development of software for in vitro diagnostics
/03	EUROIMMUN Medizinische Labordiagnostika AG Am Sonnenberg 9 23627 Groß Grönau Germany  REPs Facility ID: F001097	Design, development and manufacture of immunofluorescence test systems for in vitro diagnostics

Project No.: 3350288-160  
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Certification officer: M. Sc. Irene Carraretto  
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Seekamp 31  
23560 Lübeck  
Germany

The scope of certification includes the following sites:

- /04 **EUROIMMUN  
Medizinische Labordiagnostika AG  
Am Pließnitztal 1  
02748 Bernstadt  
Germany** Manufacture of immunobiochemical test systems, test systems for the determination of infectious agents and instruments for in vitro diagnostics  
REPs Facility ID: F002021
- /05 **EUROIMMUN  
Medizinische Labordiagnostika AG  
Im Kreppel 1  
02747 Herrnhut  
Germany** Manufacture of immunobiochemical test systems and immunofluorescence test systems for in vitro diagnostics  
REPs Facility ID: F002019
- /06 **EUROIMMUN  
Medizinische Labordiagnostika AG  
Schloßstr. 11  
91257 Pegnitz  
Germany** Manufacture of immunofluorescence test systems, installation and service of instruments / software for in vitro diagnostic  
REPs Facility ID: F002018

Project No.: 3350288-160  
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Manufacturer: **EUROIMMUN**  
**Medizinische Labordiagnostika AG**  
Seekamp 31  
23560 Lübeck  
Germany

The scope of certification includes the following sites:

- /07 **EUROIMMUN**  
Medizinische Labordiagnostika AG  
An der Trave 1  
23923 Selmsdorf  
Germany  
REPs Facility ID: F002017  
Design, development, manufacture, service and distribution of immunobiochemical test systems, immunofluorescence test systems and instruments / software for in vitro diagnostics
- /08 **EUROIMMUN**  
Medizinische Labordiagnostika AG  
Werkstr. 1  
23942 Dassow  
Germany  
REPs Facility ID: F002020  
Design, development, manufacture 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, including manufacture of sheet metal and other components for instruments for in vitro diagnostics
- /09 **EUROIMMUN**  
Medizinische Labordiagnostika AG  
Gewerbestr. 19  
23942 Dassow  
Germany  
REPs Facility ID: F002020  
Manufacture of sheet metal and other components for instruments for in vitro diagnostics

Project No.: 3350288-160  
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Seekamp 31  
23560 Lübeck  
Germany

The scope of certification includes the following sites:

/10 EUROIMMUN  
Medizinische Labordiagnostika AG  
Am Flugplatz 4  
23560 Lübeck  
Germany

REPs Facility ID: F001097

Design, development, 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



**TÜV Rheinland**<sup>®</sup>

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