

Certificate

Certificate No.: MD 1483000-1-3

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
Procedure

Brazil RDC ANVISA n. 665/2022, RDC ANVISA n. 551/2021,
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

TÜV Rheinland[®]

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.: 1206149-690

Issue Date: 2026-05-11

Effective Date: 2026-05-19

Expiry Date: 2029-05-18



Certification officer: Irene Carraretto
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on <https://www.certipedia.com>
or calling 1-888-743-4652.

Certificate

Certificate No.: MD 1483000-1-3

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

Scope: Design and development, manufacture and distribution of in-vitro diagnostic test kits, design and development, manufacture, installation, service and distribution of in-vitro diagnostic analyzers and design and development, manufacture, installation and distribution of in-vitro diagnostic software used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases, pre-natal screening, allergies and intolerances, genetic testing, genetic diseases/disorders and predispositions, endocrine disorders and diseases, neurologic syndromes and diseases and kidney diseases.

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Certificate

Certificate No.: MD 1483000-1-3
 Manufacturer: **EUROIMMUN
 Medizinische Labordiagnostika AG**
 Seekamp 31
 23560 Lübeck
 Germany

The scope of certification also covers the following sites:

No.	Location	Scope
/01	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany	Design and development and manufacture of in-vitro diagnostic test kits used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases, pre-natal screening, allergies and intolerances, genetic testing, genetic diseases/disorders and predispositions, endocrine disorders and diseases, neurologic syndromes and diseases and kidney diseases. Design and development, manufacture and distribution of in-vitro diagnostic software used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases, pre-natal screening, allergies and intolerances and neurologic syndromes and diseases.
	REPs Facility ID: F001097	



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

The scope of certification also covers the following sites:

/02 EUROIMMUN
Medizinische Labordiagnostika AG
Werkstr. 1
23942 Dassow
Germany

REPs Facility ID: F002020

Design and development, manufacture and distribution of in-vitro diagnostic test kits, design and development and manufacture of in-vitro diagnostic analyzers and design and development, manufacture and distribution of in-vitro diagnostic software used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases, pre-natal screening, allergies and intolerances, genetic testing, genetic diseases/disorders and predispositions, endocrine disorders and diseases, neurologic syndromes and diseases and kidney diseases.

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

The scope of certification also covers the following sites:

/03 EUROIMMUN
Medizinische Labordiagnostika AG
An der Trave 1
23923 Selmsdorf
Germany

REPs Facility ID: F002017

Manufacture of in-vitro diagnostic test kits used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases, prenatal screening, allergies and intolerances, genetic testing, genetic diseases/disorders and predispositions and neurologic syndromes and diseases. Manufacture, distribution and service of in-vitro diagnostic analyzers and design and development and manufacture of in-vitro diagnostic software used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases, pre-natal screening, allergies and intolerances, genetic testing, genetic diseases/disorders and predispositions, endocrine disorders and diseases, neurologic syndromes and diseases and kidney diseases.



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

The scope of certification also covers the following sites:

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| /05 | EUROIMMUN
Medizinische Labordiagnostika AG
Am Born 24
23627 Groß Grönau
Germany

REPs Facility ID: F001097 | Design and development and manufacture of in-vitro diagnostic software used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases, pre-natal screening, allergies and intolerances, genetic testing, genetic diseases/disorders and predispositions, endocrine disorders and diseases, neurologic syndromes and diseases and kidney diseases. |
| /06 | EUROIMMUN
Medizinische Labordiagnostika AG
Im Kreppel 1
02747 Herrnhut
Germany

REPs Facility ID: F002019 | Manufacture of in-vitro diagnostic test kits used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases, prenatal screening and neurologic syndromes and diseases. |



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Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

The scope of certification also covers the following sites:

- /07 **EUROIMMUN**
Medizinische Labordiagnostika AG
Am Pließnitztal 1
02748 Bernstadt
Germany
REPs Facility ID: F002021
- Design and development of in-vitro diagnostic test kits used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases, pre-natal screening and neurologic syndromes and diseases. Manufacture of in-vitro diagnostic test kits used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases, prenatal screening, allergies and intolerances and neurologic syndromes and diseases.
- /08 **EUROIMMUN**
Medizinische Labordiagnostika AG
Schloßstr. 11
91257 Pegnitz
Germany
REPs Facility ID: F002018
- Manufacture of in-vitro diagnostic test kits used in the diagnosis, management and detection of markers for autoimmune diseases.



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

The scope of certification also covers the following sites:

- /09 **EUROIMMUN**
Medizinische Labordiagnostika AG
Am Flugplatz 4
23560 Lübeck
Germany
REPs Facility ID: F001097
- Distribution of in-vitro diagnostic test kits and distribution, installation and service of in-vitro diagnostic analyzers and design and development, manufacture, distribution and installation of in-vitro diagnostic software used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases, prenatal screening, allergies and intolerances, genetic testing, genetic diseases/disorders and predispositions, endocrine disorders and diseases, neurologic syndromes and diseases and kidney diseases.
- /10 **EUROIMMUN**
Medizinische Labordiagnostika AG
Gewerbestr. 19
23942 Dassow
Germany
REPs Facility ID: F002020
- Manufacture of in-vitro diagnostic analyzers used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases, pre-natal screening, allergies and intolerances, genetic testing, genetic diseases/disorders and predispositions, endocrine disorders and diseases, neurologic syndromes and diseases and kidney diseases.



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Seekamp 31
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Germany

The scope of certification also covers the following sites:

- /11 EUROIMMUN Medizinische Labordiagnostika AG Warehousing of components.
Am Berzdorfer See 7
02829 Markersdorf
Germany
REPs Facility ID: F002021
- /12 EUROIMMUN Medizinische Labordiagnostika AG Manufacture of in-vitro diagnostic test kits used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases, prenatal screening, allergies and intolerances, endocrine disorders and diseases, neurologic syndromes and diseases and kidney diseases. Design and development and manufacture of in-vitro diagnostic software used in the diagnosis, management and detection of infectious diseases including sexually transmitted diseases, genetic testing, genetic diseases/disorders and predispositions.
Holmer Berg 19
23942 Dassow
Germany
REPs Facility ID: F002020
- /13 EUROIMMUN Medizinische Labordiagnostika AG Warehousing of components.
Reepschlägerstr. 10
23556 Lübeck
Germany
REPs Facility ID: F001097



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or calling 1-888-743-4652.