

Certificate

Certificate No.: MD 1483000-1-4

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 (as applicable)

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

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,

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.: 1214223-20

Issue Date: 2026-06-30

Effective Date: 2026-06-30

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.:

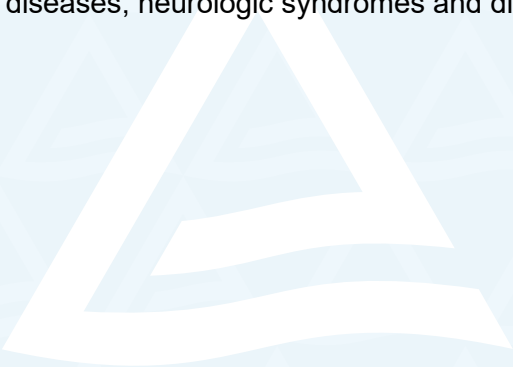
MD 1483000-1-4

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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**
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 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 REPs Facility ID: F001097	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.



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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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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.

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

The scope of certification also covers the following sites:

- | | |
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| <p>/07</p> <p>EUROIMMUN
Medizinische Labordiagnostika AG
Am Pließnitztal 1
02748 Bernstadt
Germany</p> <p>REPs Facility ID: F002021</p> | <p>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.</p> |
| <p>/09</p> <p>EUROIMMUN
Medizinische Labordiagnostika AG
Am Flugplatz 4
23560 Lübeck
Germany</p> <p>REPs Facility ID: F001097</p> | <p>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.</p> |



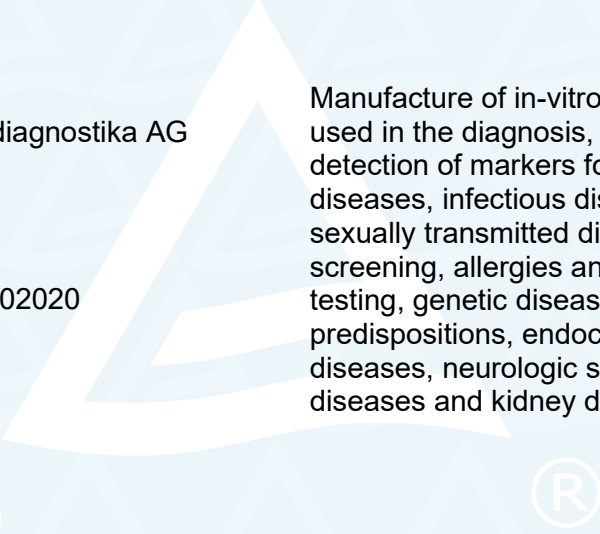
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Germany

The scope of certification also covers the following sites:

- | | | |
|---|--|--|
| /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. |
|  | | |
| /11 | EUROIMMUN
Medizinische Labordiagnostika AG
Am Berzdorfer See 7
02829 Markersdorf
Germany

REPs Facility ID: F002021 | Warehousing of components. |



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23560 Lübeck
Germany

The scope of certification also covers the following sites:

- | | | |
|-----|--|--|
| /12 | EUROIMMUN
Medizinische Labordiagnostika AG
Holmer Berg 19
23942 Dassow
Germany

REPs Facility ID: F002020 | 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. |
| /13 | EUROIMMUN Medizinische
Labordiagnostika AG
Reepschlägerstr. 10
23556 Lübeck
Germany

REPs Facility ID: F001097 | Warehousing of components. |



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