

# Certificate

Certificate No.: MD 1483000-1-2

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.: 1185447-690

Issue Date: 2025-10-29

Effective Date: 2025-10-29

Expiry Date: 2026-05-18



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.

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Seekamp 31  
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Scope:

Design and development, manufacture and distribution of in-vitro diagnostic reagents and in-vitro diagnostic test kits and design and development, manufacture, installation, service and distribution of invitro diagnostic analyzers and 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, cancer and kidney diseases.



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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 reagents and in-vitro diagnostic test kits and manufacture of invitro 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, cancer 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 and allergies and intolerances.



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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 reagents and in-vitro diagnostic test kits, and design and development and manufacture of in-vitro diagnostic analyzers and design and development, 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, prenatal screening, allergies and intolerances, genetic testing, genetic diseases/disorders and predispositions, endocrine disorders and diseases, neurologic syndromes and diseases, cancer and kidney diseases.

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The scope of certification also covers the following sites:

- |  |   |
|--|---|
| <p>/03</p> <p><b>EUROIMMUN</b><br/><b>Medizinische Labordiagnostika AG</b><br/>An der Trave 1<br/>23923 Selmsdorf<br/>Germany</p> <p>REPs Facility ID: F002017</p> | <p>Design and development and manufacture of in-vitro diagnostic reagents and in-vitro diagnostic test kits and design and development, manufacture, 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, prenatal screening, allergies and intolerances, genetic testing, genetic diseases/disorders and predispositions, endocrine disorders and diseases, neurologic syndromes and diseases, cancer and kidney diseases.</p> |
| <p>/05</p> <p><b>EUROIMMUN</b><br/><b>Medizinische Labordiagnostika AG</b><br/>Am Born 24<br/>23627 Groß Grönau<br/>Germany</p> <p>REPs Facility ID: F001097</p>   | <p>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, cancer and kidney diseases.</p>   |



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| /06 | EUROIMMUN<br>Medizinische Labordiagnostika AG<br>Im Kreppel 1<br>02747 Herrnhut<br>Germany<br><br>REPs Facility ID: F002019       | Manufacture of in-vitro diagnostic reagents and in-vitro diagnostic test kits used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases and pre-natal screening.   |
| /07 | EUROIMMUN<br>Medizinische Labordiagnostika AG<br>Am Pließnitztal 1<br>02748 Bernstadt<br>Germany<br><br>REPs Facility ID: F002021 | Design and development and manufacture of in-vitro diagnostic reagents and 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 allergies and intolerances.   |
| /08 | EUROIMMUN<br>Medizinische Labordiagnostika AG<br>Schloßstr. 11<br>91257 Pegnitz<br>Germany<br><br>REPs Facility ID: F002018       | Manufacture of in-vitro diagnostic reagents used in the diagnosis, management and detection of markers for autoimmune diseases. 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, cancer and kidney diseases. |



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- |     |   |  |
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| /09 | <b>EUROIMMUN</b><br><b>Medizinische Labordiagnostika AG</b><br>Am Flugplatz 4<br>23560 Lübeck<br>Germany<br><br>REPs Facility ID: F001097 | Distribution of in-vitro diagnostic reagents and in-vitro diagnostic test kits and installation, service and distribution of in-vitro diagnostic analyzers and design and development, manufacture 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, pre-natal screening, allergies and intolerances, genetic testing, genetic diseases/disorders and predispositions, endocrine disorders and diseases, neurologic syndromes and diseases, cancer and kidney diseases. |
| /10 | <b>EUROIMMUN</b><br><b>Medizinische Labordiagnostika AG</b><br>Gewerbestr. 19<br>23942 Dassow<br>Germany<br><br>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, cancer and kidney diseases.   |



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| /11 | <b>EUROIMMUN</b><br><b>Medizinische Labordiagnostika AG</b><br>Am Berzdorfer See 7<br>02829 Markersdorf<br>Germany<br><br>REPs Facility ID: F002021 | Warehousing of in-vitro diagnostic reagents and 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 allergies and intolerances.   |
| /12 | <b>EUROIMMUN</b><br><b>Medizinische Labordiagnostika AG</b><br>Holmer Berg 19<br>23942 Dassow<br>Germany<br><br>REPs Facility ID: F002020           | Distribution and manufacture of in-vitro diagnostic reagents and 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 diseases/disorders and predispositions, endocrine disorders and diseases, neurologic syndromes and diseases, cancer and kidney diseases and design and development, manufacture and distribution of in-vitro diagnostic software used in the diagnosis, management and detection of genetic testing and genetic diseases/disorders and predispositions. |



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