

Certificate

Certificate No.: MD 1483000-1-1

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

Scope: Design and development, manufacture, installation, service and distribution of immuno-biochemical 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.: 1130650-140

Issue Date: 2023-05-11

Effective Date: 2023-05-19

Expiry Date: 2026-05-18



Daniela Wiedemuth

Certification officer: Dip.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

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

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Germany

The scope of certification includes the following additional sites:

No.	Location	Scope
/01	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany REPs Facility ID: 001097	Design and development, manufacture, installation, service and distribution of immuno-biochemical 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
/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	Manufacture of immunofluorescence test systems for in vitro diagnostics

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Germany

The scope of certification includes the following additional sites:

- | | | |
|-----|-----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------|
| /04 | EUROIMMUN
Medizinische Labordiagnostika AG
Am Pließnitztal 1
02748 Bernstadt
Germany

REPs Facility ID: F002021 | Manufacture of immuno-biochemical test systems and instruments for in vitro diagnostics |
| /05 | EUROIMMUN
Medizinische Labordiagnostika AG
Im Kreppel 1
02747 Herrnhut
Germany

REPs Facility ID: F002019 | Manufacture of immuno-biochemical test systems and immunofluorescence test systems for in vitro diagnostics |
| /06 | EUROIMMUN
Medizinische Labordiagnostika AG
Schloßstr. 11
91257 Pegnitz
Germany

REPs Facility ID: F002018 | Manufacture of immunofluorescence test systems, installation and service of instruments / software for in vitro diagnostic |

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Seekamp 31
23560 Lübeck
Germany

The scope of certification includes the following additional sites:

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|-----|----------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| /07 | EUROIMMUN
Medizinische Labordiagnostika AG
An der Trave 1
23923 Selmsdorf
Germany
REPs Facility ID: F002017 | Design and development, manufacture, service and distribution of immuno-biochemical 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 and development, manufacture and distribution of immuno-biochemical 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 |
| /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 |

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- | | | |
|-----|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| /10 | EUROIMMUN
Medizinische Labordiagnostika AG
Am Flugplatz 4
23560 Lübeck
Germany
REPs Facility ID: F001097 | Design and development, installation, service and distribution of immuno-biochemical 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 |
| /11 | EUROIMMUN
Medizinische Labordiagnostika AG
Am Berzdorfer See 7
02829 Markersdorf
Germany
REPs Facility ID: F002021 | Warehousing and manufacture of immuno-biochemical test systems and instruments for in vitro diagnostics |

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