Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1483000-1

Organization:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

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

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1130650-10
Effective date: 2023-05-19
Expiry date: 2026-05-18
Issue date: 2023-05-11

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Location: Moldova
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TÜV Rheinland LGA Products GmbH

Dipl.-Ing. (FH) Daniela Schuhmuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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Seekamp 31
23560 Lübeck
Germany

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany	Design and development and manufacture 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 instruments for in vitro diagnostics
/02	c/o EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany	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
/03	c/o EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany	Design and development, manufacture, service and distribution of immuno-biochemical test systems, immunofluorescence test systems and instruments / software for in vitro diagnostics

Report No.: 1130650-10
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Issue date: 2023-05-11

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Dipl.-Ing. (FH) Daniele Wiedemuth
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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Seekamp 31
23560 Lübeck
Germany

The scope of certification also covers the following:

/04	c/o EUROIMMUN Medizinische Labordiagnostika AG Am Sonnenberg 9 23627 Groß Grönau Germany	Manufacture of immunofluorescence test systems for in vitro diagnostics
/05	c/o EUROIMMUN Medizinische Labordiagnostika AG Am Born 24 23627 Groß Grönau Germany	Design and development of software for in vitro diagnostics
/06	c/o EUROIMMUN Medizinische Labordiagnostika AG Im Kreppel 1 02747 Herrnhut Germany	Manufacture of immuno-biochemical test systems and immunofluorescence test systems for in vitro diagnostics
/07	c/o EUROIMMUN Medizinische Labordiagnostika AG Am Pließnitztal 1 02748 Bernstadt Germany	Manufacture of immuno-biochemical test systems and instruments for in vitro diagnostics

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TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

D. Wiedemuth

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Organization:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

The scope of certification also covers the following:

/08	c/o EUROIMMUN Medizinische Labordiagnostika AG Schloßstr. 11 91257 Pegnitz Germany	Manufacture of immunofluorescence test systems, installation and service of instruments / software for in vitro diagnostic
/09	c/o EUROIMMUN Medizinische Labordiagnostika AG Am Flugplatz 4 23560 Lübeck Germany	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
/10	c/o EUROIMMUN Medizinische Labordiagnostika AG Gewerbestr. 19 23942 Dassow Germany	Manufacture of sheet metal and other components for instruments for in vitro diagnostics

Report No.: 1130650-10
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Expiry date: 2026-05-18
Issue date: 2023-05-11

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

D. Wiedemuth

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Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

The scope of certification also covers the following:

/11	c/o EUROIMMUN Medizinische Labordiagnostika AG Am Berzdorfer See 7 02829 Markersdorf Germany	Warehousing of immuno-biochemical test systems and instruments for in vitro diagnostics

Report No.: 1130650-10
Effective date: 2023-05-19
Expiry date: 2026-05-18
Issue date: 2023-05-11

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

D. Wiedemuth

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CE

Declaration of Conformity

EUROIMMUN Medizinische Labordiagnostika AG
Seekamp 31, 23560 Lübeck, Germany

declares under its sole responsibility as manufacturer that the ELISA product

Anti-Treponema pallidum ELISA (IgM) *EI 2111-9601 M*
(product name, order number)

meets the following demands of:

Directive 98/79/EC on in vitro diagnostic medical devices of 27 October 1998 and its transpositions in national laws which apply to it.

Conformity assessment procedure: Annex III

This Declaration of Conformity is valid based on the respective currently valid version of technical documentation.

Lübeck, May 17, 2022
(Place and date of issue)

ppa
Dr. Ewald Müller-Kunert
- Head of Quality Management -

Susanne Aleksandrowicz
- Member of the Executive Board -

CE

Declaration of Conformity

EUROIMMUN Medizinische Labordiagnostika AG
Seekamp 31, 23560 Lübeck, Germany

declares under its sole responsibility as manufacturer that the ELISA product

Anti-Treponema pallidum ELISA (IgG) *EI 2111-9601 G*
(product name, order number)

meets the following demands of:

Directive 98/79/EC on in vitro diagnostic medical devices of 27 October 1998 and its transpositions in national laws which apply to it.

Conformity assessment procedure: Annex III

This Declaration of Conformity is valid based on the respective currently valid version of technical documentation.

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ppc
Dr. Ewald Müller-Kunert
- Head of Quality Management -

Susanne Aleksandrowicz
- Member of the Executive Board -

EUROIMMUN
a PerkinElmer company

Medizinische
Labordiagnostika
AG

CE

Declaration of Conformity

EUROIMMUN Medizinische Labordiagnostika AG
Seekamp 31, 23560 Lübeck, Germany

declares under its sole responsibility as manufacturer that the Blot product:

Anti-Treponema pallidum EUROLINE-WB (IgM) *DY 2111-####-1 M*

(product name, order number)

meet the following demands of:

Directive 98/79/EC on in vitro diagnostic medical devices of 27 October 1998 and its transpositions in national laws which apply to it.

Conformity assessment procedure: Annex III

This Declaration of Conformity is valid based on the respective currently valid version of technical documentation.

Lübeck, 25.04.2022
(Place and date of issue)

ppa.

Dr. Ewald Müller-Kunert
- Head of Quality Management and Regulatory Affairs -

Susanne Aleksandrowicz
- Member of the Executive Board -

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Medizinische
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