Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.:	SX 1483000-1
Certificate Holder:	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany
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 in-vitro 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.

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.:	1185447-100
Effective date:	2025-10-29
Expiry date:	2026-05-18
Issue date:	2025-10-29

Replaces certificate SX 1483000-1 issued 2023-05-11

This certificate can be validated on https://www.certipedia.com

Irene Carraretto
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜVRheinland®
Precisely Right.

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Certificate Holder: EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany	Aspects related to design and development and manufacture of in-vitro diagnostic reagents and in-vitro diagnostic test kits, and 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. Aspects related to 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, prenatal screening and allergies and intolerances. Aspects related to user training.
/02	c/o EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany	Aspects related to 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, 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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Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

The scope of certification also covers the following sites:

/03	c/o EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany	Aspects related to 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, 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.
/05	c/o EUROIMMUN Medizinische Labordiagnostika AG Am Born 24 23627 Groß Grönau Germany	Aspects related to 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, prenatal screening, allergies and intolerances, genetic testing, genetic diseases/disorders and predispositions, endocrine disorders and diseases, neurologic syndromes and diseases, cancer and kidney diseases.
/06	c/o EUROIMMUN Medizinische Labordiagnostika AG Im Kreppel 1 02747 Herrnhut Germany	Aspects related to 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	c/o EUROIMMUN Medizinische Labordiagnostika AG Am Pließnitztal 1 02748 Bernstadt Germany	Aspects related to 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, pre-natal screening and allergies and intolerances.

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Seekamp 31
23560 Lübeck
Germany

The scope of certification also covers the following sites:

/08	c/o EUROIMMUN Medizinische Labordiagnostika AG Schloßstr. 11 91257 Pegnitz Germany	Aspects related to manufacture of in-vitro diagnostic reagents used in the diagnosis, management and detection of markers for autoimmune diseases and the 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, prenatal screening, allergies and intolerances, genetic testing, genetic diseases/disorders and predispositions, endocrine disorders and diseases, neurologic syndromes and diseases, cancer and kidney diseases. Aspects related to user training.
/09	c/o EUROIMMUN Medizinische Labordiagnostika AG Am Flugplatz 4 23560 Lübeck Germany	Aspects related to 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	c/o EUROIMMUN Medizinische Labordiagnostika AG Gewerbestr. 19 23942 Dassow Germany	Aspects related to manufacture of in-vitro diagnostic analyzers 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:

/11	c/o EUROIMMUN Medizinische Labordiagnostika AG Am Berzdorfer See 7 02829 Markersdorf Germany	Aspects related to warehousing of in-vitro diagnostic reagents and in-vitro diagnostic test kits.
/12	c/o EUROIMMUN Medizinische Labordiagnostika AG Holmer Berg 19 23942 Dassow Germany	Aspects related to 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, endocrine disorders and diseases, neurologic syndromes and diseases, cancer and kidney diseases and the 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.

This certificate can be validated on https://www.certipedia.com

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