

Certificate

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

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 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, 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.

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.: 1214223-20

Effective date: 2026-06-30

Expiry date: 2029-05-18

Issue date: 2026-06-30

Replaces certificate SX 1483000-1 issued 2026-05-08

Irene Carraretto

Irene Carraretto

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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	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. User training.
/02	c/o EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany	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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23560 Lübeck
Germany

The scope of certification also covers the following sites:

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| /03 c/o EUROIMMUN
Medizinische
Labordiagnostika AG
An der Trave 1
23923 Selmsdorf
Germany | 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 and pre-natal screening. Manufacture of invitro 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 and neurologic syndromes and diseases.

Manufacture, distribution and service of in-vitro diagnostic analyzers and design and development and manufacture of invitro 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 c/o EUROIMMUN
Medizinische
Labordiagnostika AG
Im Kreppel 1
02747 Herrnhut
Germany | 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. |
| /07 c/o EUROIMMUN
Medizinische
Labordiagnostika AG
Am Pließnitztal 1
02748 Bernstadt
Germany | 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. |

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Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

The scope of certification also covers the following sites:

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| /09 | c/o EUROIMMUN
Medizinische
Labordiagnostika AG
Am Flugplatz 4
23560 Lübeck
Germany | 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. |
| /10 | c/o EUROIMMUN
Medizinische
Labordiagnostika AG
Gewerbestr. 19
23942 Dassow
Germany | 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, neurologics yndromes and diseases and kidney diseases. |
| /11 | c/o EUROIMMUN
Medizinische
Labordiagnostika AG
Am Berzdorfer See 7
02829 Markersdorf
Germany | Warehousing of components. |
| /12 | c/o EUROIMMUN
Medizinische
Labordiagnostika AG
Holmer Berg 19
23942 Dassow
Germany | 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. |

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Seekamp 31
23560 Lübeck
Germany

The scope of certification also covers the following sites:

/13	c/o EUROIMMUN Medizinische Labordiagnostika AG Reepschlägerstr. 10 23556 Lübeck Germany	Warehousing of components.
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