

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810000**

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

including the locations according to annex

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.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2025-10-27 until 2026-05-18.
First certification 2018

2025-11-04



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

Annex to certificate

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No.	Location	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 invitro 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, pre-natal screening and allergies and intolerances. Aspects related to user training.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810000**

/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.

/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.

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Standard

ISO 9001:2015

Certificate Registr. No. **01 100 1810000**

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| /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, 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. |
| /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. |

Annex to certificate

Standard

ISO 9001:2015

Certificate Registr. No. **01 100 1810000**

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| /08 | <p>c/o EUROIMMUN
Medizinische Labordiagnostika AG
Schloßstr. 11
91257 Pegnitz
Germany</p> | <p>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, 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 user training.</p> |
| /09 | <p>c/o EUROIMMUN
Medizinische Labordiagnostika AG
Am Flugplatz 4
23560 Lübeck
Germany</p> | <p>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.</p> |

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810000**

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| /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, pre-natal screening, allergies and intolerance s, genetic testing, genetic diseases/disorders and predispositions, endocrine disorders and diseases, neurologic syndromes and diseases, cancer and kidney diseases. |
| /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. |

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Standard

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Certificate Registr. No. **01 100 1810000**

/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.

2025-11-04



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln