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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







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Standard ISO 9001:2015

Certificate Registr. No. 01 100 1810000

No. Location

/01 c/o EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany

Scope

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.





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Certificate Registr. No. 01 100 1810000

/02 c/o EUROIMMUN Werkstr. 1 23942 Dassow Germany

Aspects related to design and development, Medizinische Labordiagnostika AG 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 invitro 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.

/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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Certificate Registr. No. 01 100 1810000

/05 c/o EUROIMMUN Am Born 24 23627 Groß Grönau Germany

Aspects related to design and development and Medizinische Labordiagnostika AG 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.





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Certificate Registr. No. 01 100 1810000

/08 c/o EUROIMMUN Schloßstr. 11 91257 Pegnitz Germany

Aspects related to manufacture of in-vitro Medizinische Labordiagnostika AG 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 invitro 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.

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Standard ISO 9001:2015

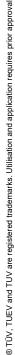
01 100 1810000 Certificate Registr. No.

/10 c/o EUROIMMUN Gewerbestr. 19 23942 Dassow Germany

Aspects related to manufacture of in-vitro Medizinische Labordiagnostika AG diagnostic analyzers used in the diagnosis, management and detection of markers for autoimmune diseases, infectious diseases including sexually transmitted diseases, prenatal 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 vitro diagnostic reagents and in-Am Berzdorfer See 7 02829 Markersdorf Germany

Aspects related to warehousing of invitro diagnostic test kits.





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/12 c/o EUROIMMUN Holmer Berg 19 23942 Dassow Germany

Aspects related to distribution and manufacture Medizinische Labordiagnostika AG 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, prenatal 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

Am Grauen Stein · 51105 Köln

