EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

Products:
- Immuno-biochemical test systems
- Immunofluorescence test systems
- Molecular diagnostic test systems
- Test systems for the determination of pathogens

Replaces Certificate, Registration No.: HL 60139384 0001

The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 1104471-10

Effective date: 2022-05-10

Expiry date: 2025-05-26

Issue date: 2022-05-10

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Katja Mierisch
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

Products included:

Anti-CMV ELISA (IgG, IgM, Avidity IgG, CSF IgG, p52 IgM)
Anti-Chlamydia ELISA (IgA, IgG, IgM)
Anti-Chlamydia trachomatis ELISA (IgA, IgG, IgM)
Anti-Chlamydia pneumoniae ELISA (IgA, IgG, IgM)
Anti-Toxoplasma gondii ELISA (IgG, IgM, Avidity IgG, CSF IgG, IgA)
Anti-Rubella Virus ELISA (IgG, Avidity IgG, CSF IgG, Glycoprotein IgM)

Anti-Toxoplasma gondii IIFT (IgG, IgM)
Anti-Toxoplasma gondii IIFT EUROPattern (IgG, IgM)

Anti-Chlamydia MIF (IgA, IgG, IgM)
Anti-Chlamydia trachomatis MIF (IgA, IgG, IgM)
Anti-Chlamydia pneumoniae MIF (IgA, IgG, IgM)
Anti-Chlamydia MIF EUROPattern (IgA, IgG, IgM)
Anti-Chlamydia pneumoniae MIF EUROPattern (IgA, IgG, IgM)

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Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

Products included:

Anti-Rubella Virus WESTERNBLOT (IgG)
Anti-Chlamydia HP EUROLINE-WB (IgA, IgG)

Multimarker Controls for Euroimmun ELISA

EUROLINE Anti-TO.R.C.H. Profile (IgG, IgM)
EUROLINE Anti-TO.R.C.H. 10-Profile (IgG)
EUROLINE Anti-CMV (IgG, IgM)

EUROArray STI

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Registration No.: HL 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

The scope of certification includes the following manufacturing sites:

No.	Location	Scope
/01	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany	Design and Development, Manufacture
/02	EUROIMMUN Medizinische Labordiagnostika AG Am Sonnenberg 9 23627 Groß Grönau Germany	Design and Development, Manufacture
/03	EUROIMMUN Medizinische Labordiagnostika AG Im Kreppel 1 02747 Herrnhut Germany	Manufacture

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Registration No.: HL 1483000-1

Manufacturer:
EUROIMMUN
Medizinische Labordiagnostika AG
Seekamp 31
23560 Lübeck
Germany

No.	Location	Scope
/04	EUROIMMUN Medizinische Labordiagnostika AG Werkstr. 1 23942 Dassow Germany	Design and Development, Manufacture, final Quality Control
/05	EUROIMMUN Medizinische Labordiagnostika AG An der Trave 1 23923 Selmsdorf Germany	Manufacture
/06	EUROIMMUN Medizinische Labordiagnostika AG Am Pließnitztal 1 02748 Bernstadt Germany	Manufacture

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