EU Certificate

Quality Management System
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HX 1483000-1
Manufacturer:	EUROIMMUN Medizinische Labordiagnostika AG Seekamp 31 23560 Lübeck Germany
EUDAMED Single Registration No.:	DE-MF-000005296
Products:	Products of class B: IMMUNOCHEMISTRY (IMMUNOLOGY) IVR 0602: Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease W01021001 - AUTOIMMUNE CONNECTIVE TISSUE DISEASES W01021002 - NEURO-AUTO-IMMUNE DISEASE W01021090 - VARIOUS AUTO-IMMUNE DISEASE W01021112 - ANTI-CYCLIC CITRULLINATED PEPTIDE W01021520 - CONTROLS – IMMUNOCHEMISTRY W01021199 - RHEUMATOID / INFLAMMATORY DISEASE MARKERS – OTHER

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class D devices are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4 is required before placing them on the market.
If class B, C or D devices for self-testing or near-patient testing are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.1 is required before placing them on the market.
If companion diagnostics are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 5.2 is required before placing them on the market.

Report No.:	1189960-20
Effective date:	2025-06-13
Expiry date:	2028-05-09
Issue date:	2025-06-13

Dr. Volker Schlueter
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/746 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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IVR 0603: Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances
W01020201 - IMMUNOGLOBULIN E – TOTAL
W01020204 - IMMUNOGLOBULIN E – MONOTEST/PLURIRESULT-MULTI AG

IVR 0608: Devices intended to be used for screening, determination or monitoring of physiological markers
W01020190 - OTHER SPECIFIC PROTEINS
W01020702 - VITAMINES
W01021520 - CONTROLS – IMMUNOCHEMISTRY
W01029099 - IMMUNOCHEMISTRY REAGENTS - OTHER

INFECTIOUS DISEASES
IVR 0503: Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
W01050106 - LYME BORRELIOSIS
W01050117 - OTHER BACTERIOLOGY IMMUNOASSAYS
W01050404 - EPSTEIN BARR VIRUS

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	W01050405 - OTHER VIROLOGY - NA REAGENTS W01050406 - OTHER VIROLOGY ANTIGEN/ANTIBODY DETECTION W01050407 - MEASLES VIRUS W01050502 - MISCELLANEOUS PARASITOLOGY W01050808 - CONTROLS - INFECT. IMMUNOLOGY IVR 0504: Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging W01050117 - OTHER BACTERIOLOGY IMMUNOASSAYS CHEMISTRY / IMMUNOCHEMISTRY INSTRUMENTS IVR 0503: Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents W0201020192 - AUTOMATED IMMUNOCHEMISTRY ANALYSERS – IVD MEDICAL DEVICE SOFTWARE
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Products of class C:

IMMUNOCHEMISTRY (IMMUNOLOGY)
IVR 0602: Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease
W01021001 - AUTOIMMUNE CONNECTIVE TISSUE DISEASES
W01021090 - VARIOUS AUTO-IMMUNE DISEASE
W01050501 - TOXOPLASMA

INFECTIOUS DISEASES
IVR 0501: Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents
W01050101 - CHLAMYDIA
W01050401 - RUBELLA VIRUS
W01050402 - CYTOMEGALOVIRUS
W01050501 - TOXOPLASMA

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IVR 0503: Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents
W01050405 - OTHER VIROLOGY - NA REAGENTS
W01050107 - MYCOBACTERIA GENUS + SPECIES GENETIC TESTING

IVR 0402: Devices intended to be used to predict genetic disease/disorder risk and prognosis
W01060101 - MONOGENETIC DISORDERS
W01060104 - POLYMORPHISMS

NUCLEIC ACID TESTING INSTRUMENTS
IVR 0402: Devices intended to be used to predict genetic disease/disorder risk and prognosis
W02050292 - MICRO-ARRAY INSTRUMENTS – IVD
MEDICAL DEVICE SOFTWARE

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	CHEMISTRY / IMMUNOCHEMISTRY INSTRUMENTS IVR 0501: Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents W0201020192 - AUTOMATED IMMUNOCHEMISTRY ANALYSERS – IVD MEDICAL DEVICE SOFTWARE
Authorized representative(s):	N/A

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Germany

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-05-10
1	Scope extension, EUROI_PDQ2_HX_2023-07-12_2_20230822_extsigned.pdf	2023-08-22
2	Scope extension: Products of class B (W01050405, W01021199, W01020204, W01020190, W01021520) Scope reduction: Products of class B (W01020299) and class C (W01050403, W01050705) EUROI_PDQ2_HX_2023-12-15_2024-03-26_extsigned.pdf	2024-03-26
3	Scope extension: Products of class B (W01050117, W01021001), Products of class C (W01021001), EUROI_PDQ2_HX_2024-03-06_exsigned.pdf	2024-05-17
4	Scope extension: Product of class D (W01050406) and class C and B EUROI_PDQ2_HX_2024-08-07	2024-08-19
5	Scope extension: Products of class B (W01050407, W01029099), EUROI_PDQ2_HX_2024-12-18.pdf	2024-12-18
6	Scope extension: Products of class C (W01050501) Scope reduction: Products of class B (W01050106) EUROI_PDQ2_HXIX_2025-03-26.pdf	2025-03-31
7	Scope extension: Products of class B (W01050106, W01021002) and class C (W01050101, W01050401) Scope reduction: Products of class D (W01050406)	2025-06-13

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