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 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.:	1155411-20
Effective date:	2023-03-26
Expiry date:	2028-05-09
Issue date:	2024-03-26

Dr. Volker Schlüter
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

W01020702 – VITAMINES
W01020190 – OTHER SPECIFIC PROTEINS
W01021520 – CONTROLS – IMMUNOCHEMISTRY

INFECTIOUS DISEASES

IVR 0503: Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

W01050808 - CONTROLS - INFECT. IMMUNOLOGY
W01050404 - EPSTEIN BARR VIRUS
W01050405 - OTHER VIROLOGY - NA REAGENTS

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W01050502 - MISCELLANEOUS PARASITOLOGY
W01050117 - OTHER BACTERIOLOGY IMMUNOASSAYS
W01050406 - OTHER VIROLOGY ANTIGEN/ANTIBODY DETECTION

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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EUDAMED Single Registration No.:	DE-MF-000005296

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

W01021090 - VARIOUS AUTO-IMMUNE DISEASE

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

W01050501 - TOXOPLASMA

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

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EUDAMED Single Registration No.:	DE-MF-000005296
	W01050107 - MYCOBACTERIA GENUS + SPECIES GENETIC TESTING IVR 0402: Devices intended to be used to predict genetic disease/disorder risk and prognosis W01060101 - MONOGENETIC DISORDERS 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

Certificate history		
Revision:	Description:	Issue date:
0	Initial issuing	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

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