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

TÜVRheinland®

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

IVR 0603: Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances
W01020299 - ALLERGY TESTS - OTHER
W01020201 - IMMUNOGLOBULIN E - TOTAL

IVR 0608: Devices intended to be used for screening, determination or monitoring of physiological markers
W01020702 - VITAMINES

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. 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. If class D devices are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.10 is required before placing them on the market.

Report No.: 1144466-20

Effective date: 2023-08-22

Expiry date: 2028-05-09

Issue date: 2023-08-22

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierstelle

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-097

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

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

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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
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

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

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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
W01050403 - HERPES SIMPLEX VIRUS
W01050405 - OTHER VIROLOGY - NA REAGENTS
W01050705 - MULTIPLE PANELS FOR INFECTIONS - VARIOUS
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

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

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Authorised 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

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