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 1038121-1

Manufacturer: **MACHEREY-NAGEL GmbH & Co. KG**
Valencienner Str. 11
52355 Düren
Germany

EUDAMED Single Registration No.: DE-MF-000005636

Products: Products of class B:

CLINICAL CHEMISTRY
IVR 608: Devices intended to be used for screening, determination or monitoring of physiological markers
W01010602 URINE TESTING (CC) - RT & POC

Products of class B, for near-patient testing:

CLINICAL CHEMISTRY
IVR 608: Devices intended to be used for screening, determination or monitoring of physiological markers
W01010602 URINE TESTING (CC) - RT & POC
W01010699 CLIN. CHEM. RT & POC - 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. 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.: 1085166-80

Effective date: 2023-05-16

Expiry date: 2028-05-15

Issue date: 2023-05-16

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

Katja Mierisch
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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.

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 1038121-1

Manufacturer: **MACHEREY-NAGEL GmbH & Co. KG**
Valencienner Str. 11
52355 Düren
Germany

Products of class B, for self-testing:

CLINICAL CHEMISTRY
IVR 608: Devices intended to be used for screening, determination or monitoring of physiological markers
W01010602 URINE TESTING (CC) - RT & POC

Products of class C, for self-testing:

CLINICAL CHEMISTRY
IVR 608: Devices intended to be used for screening, determination or monitoring of physiological markers
W01010602 URINE TESTING (CC) - RT & POC

Authorised representative(s): N/A

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-05-16

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