EU Certificate

Technical Documentation Assessment
REGULATION (EU) 2017/746 on In Vitro Diagnostic Medical Devices
Annex IX Chapter II

Registration No.:	IX 1038121-2
Manufacturer:	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany
EUDAMED Single Registration No.:	DE-MF-000005636
Classification:	Product of class B, near-patient testing
General product group name:	CLINICAL CHEMISTRY - RAPID TESTS & POC IVR 0608 Devices intended to be used for screening, determination or monitoring of physiological markers W01010602 - URINE TESTING (CC) - RT & POC
Product name:	Medi-Test Urine Test Strips professional use
Models and types:	Medi-Test Glucose (93001, 93024, 93001.202255) Medi-Test Glucose/Keton (93025, 93020, 93020.205567) Medi-Test Protein 2 (93004, 93027, 93004.203880) Medi-Test Keton (93005, 93028) Medi-Test Nitrit (93006, 93029) Medi-Test Combi 2 (93015, 93015.004, 93037, 93037.204483, 93015.203880) Medi-Test Combi 3 (93050.205567) Medi-Test Combi 3A (93007, 93030) Medi-Test Combi 5 (93009, 93032)

The Notified Body hereby declares that the requirements of Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the REGULATION (EU) 2017/746 have been met for the listed products. The above named manufacturer has established and maintains a technical documentation defined by Annex IX, Chapter II, Section 4 and 5.1 / 5.2 of the aforementioned regulation. In addition to this certificate an EU quality management system certificate and for class D devices a batch verification is required before placing the listed products on the market.

Report No.:	1165873-20
Effective date:	2024-11-21
Expiry date:	2028-05-15
Issue date:	2024-11-21

Katja Mierisch
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
www.zlg.de
BS-MDR-091

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Medi-Test Combi 5N (93035, 93036, 93035.203880)
Medi-Test Combi 5S (93055, 93055.203880)
Medi-Test Combi 5L (93008.143993)
Medi-Test Combi 6A (93034)
Medi-Test Combi 7 (93022)
Medi-Test Combi 7L (93031, 93031.143993)
Medi-Test Combi 8 (93016.203880)
Medi-Test Combi 8L (93021)
Medi-Test Combi 9 (93023, 930879, 93023.204483)
Medi-Test Combi 10L (93058, 93079)
Medi-Test Combi 11 (93060, 930871, 93060.004, 93060.005)
Medi-Test Combi 10 SGL (93067, 93067.004, 93067.005, 93067.203880, 93067.205567, 93067.204910, 93067.2)

UriSTIX 10 GLS (93067.134408)
Medi-Test URYXXON Stick 10 (93068, 930872, 93068.004, 93068.005)
UriSTIX 6 (93078.134408)
UriSTIX 10 (93058.134408)
Urispec PLUS 3 PLUS (93030.114379.2)
Urispec PLUS 5+ Leuco PLUS (93078.114379.2)
Urispec PLUS 9+ LEUKO PLUS (93058.114379.2)
Urispec PLUS 10 SL PLUS (93067.114379.2)
Urispec PLUS 11 SYS PLUs (93060.114379.2)
Urine test strip 5+Leuko (93078.114379.3)

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EUDAMED Single Registration No.:	DE-MF-000005636
	Urine test strip 9+ Leuko (93058.114379.3) hoyer-6 (930943)
Basic UDI-DI:	4046681151040VR
Intended use:	Medi Test urine test strips are used as a diagnostic aid or screening test for the analysis of human urine. The semiquantitative test strips can be evaluated manually by visually comparing the respective test paper color reaction with the color scale. Test strip variants for the automatic reflectometric analysis with the devices URYXXON® 500 and URYXXON® Relax are labelled accordingly. The test strips can analyse up to 11 different parameters: blood, urobilinogen, bilirubin, protein, nitrite, ketone, ascorbic acid, glucose, pH, density and leukocytes.
Authorized representative(s):	N/A

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2023-05-16
1	New model added and formal changes in the scope	2024-11-21

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