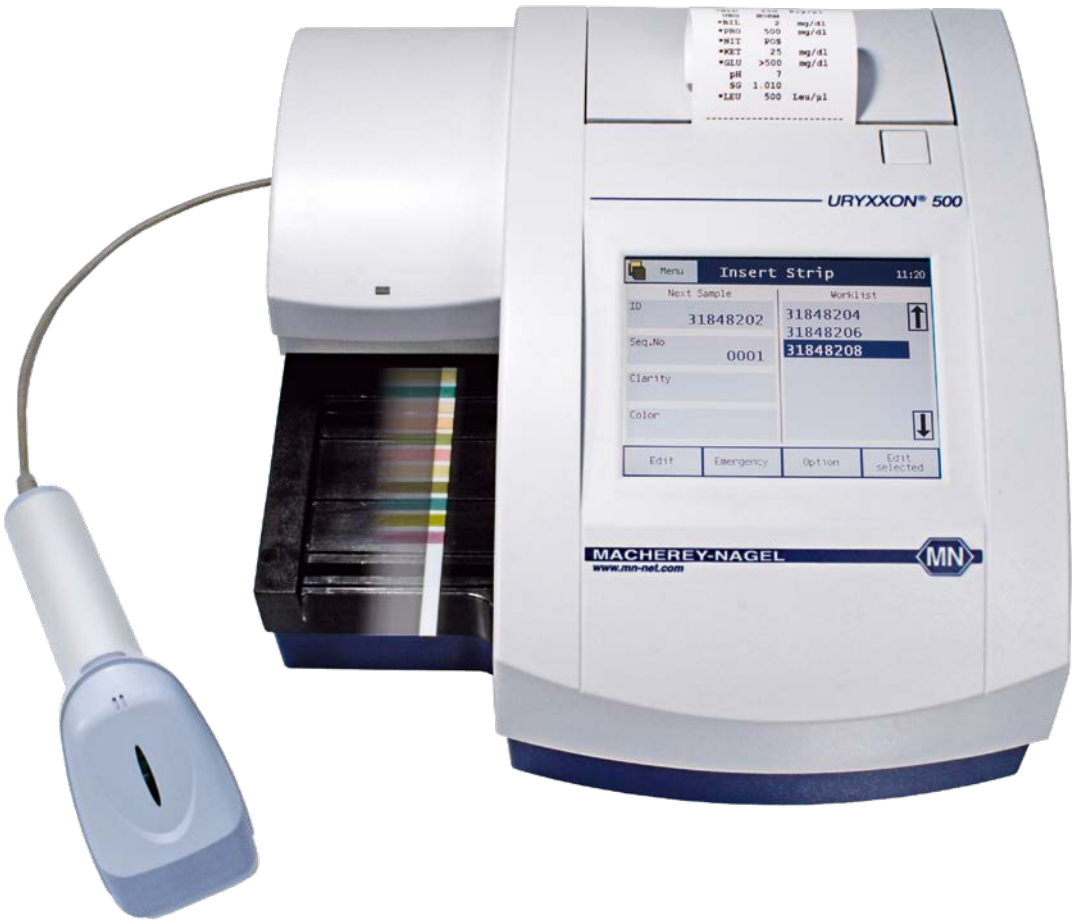
MACHEREY-NAGEL

Urine analysis

Medi-Test



URYXXON® 500

- Quick – Reads 400 strips per hour
- Easy – Touch screen operation
- Hygienic – Automatic strip detection

URYXXON® 500

High performance urine analysis

The URYXXON® 500 is an automatic reader for URYXXON® Stick 10 urine test strips. With a capacity of 400 strips per hour, it is ideal for use in hospitals and practices. The “easy-to-use-features” allow hygienic operation with hardly any training.

The URYXXON® 500 provides dependable urine status results to detect early stages of many diseases such as urinary tract infections, kidney diseases or diabetes. The device eliminates the subjectivity of visual strip evaluation and minimizes risks associated with manual result transcription.

The URYXXON® 500 makes urine analysis quicker, easier and more reliable.

Technical specifications

Instrument memory	500 patient test results including name or patient ID	
Sediment	30 user defined sediment parameters	
Interface	User:	Touchscreen display, alphanumeric input, password protection
	Computer:	1 x USB (type B) and 2 x RS232 interfaces for connection to PC
		PS/2 interface for keyboard / barcode reader
Power requirements	110–240 V AC, automatic	
Dimensions / Weight	240 x 280 mm x 150 mm (D x W x H)	
	3.9 kg (10.5 lb)	
Operation	Temperature range:	5–40 °C (41–104 °F)
	Humidity range:	20–80 % relative humidity, non condensing
	Calibration:	automatic, self calibrating
Capacity	400 strips per hour	
CE	CE labeling according to IVDD 98/79/EC	

URYXXON® 500

Field of application

The URYXXON® 500 is intended for the automatic evaluation of URYXXON® Stick 10 urine test strips. It provides reliable results for the semi-quantitative detection of the following parameters in urine: blood, urobilinogen, bilirubin, protein, nitrite, ketones, glucose, pH, specific gravity and leukocytes. URYXXON® 500 and URYXXON® Stick 10 are CE marked according to the IVD-directive 98/79/EC.

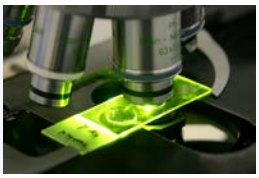
Improvements for your lab

Easy and intuitive

Operating the URYXXON® 500 is easy. Access all functions using the easy-to-follow menu on the touch screen. It nearly eliminates the need for training and makes urine analysis more reliable.

Informative and unique

Add microscopic evidence to the urine chemistry results using the sediment options. Powerful user defined filter functions only admit those samples to sediment analysis that need further diagnostic.



Clean and hygienic

Start the measurement without touching the instrument. Simply place the strip on the transport tray, the detector will recognize it and automatically start the measurement.

Fast and efficient

Once turned on, the URYXXON® 500 is immediately ready for use. It reads up to 400 strips per hour ensuring fast urine chemistry results.

Accurate and convenient

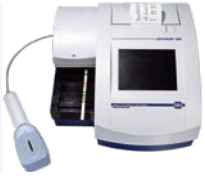
Use a barcode reader to enter patient IDs. Set up lists of samples with ease and convenience and quickly add urine chemistry results to the patient file in your laboratory information system.

Reliable and safe

Use the QC menu to maintain clinical reporting standards with ease and convenience. Medi-Test Control solutions are ideal to ensure correct results at any time.

Small and practical

Free up space with the smallest instrument in its class. With a size of only 28 x 24 cm (11 x 9,4 in) the URYXXON® 500 fits onto every bench. The clear design allows access to all parts and makes cleaning easy.



URYXXON® 500

Medi-Test ordering information

REF 50 strips per pack	REF 100 strips per pack	Type	with test fields for determination of											
			Glucose	Ketones	Ascorbic acid	Protein/ Albumin	Blood	Leukozytes	Nitrite	Density	pH value	Bilirubin	Urobilinogen	Creatinine
93001	930 24	Glucose [1]	■											
93025	930 20	Glucose / Ketone [1]	■	■										
93004	930 27	Protein 2 [1]				■					■			
93005	93028	Ketone [1]		■										
93006	93029	Nitrite [1]							■					
93012	–	Urbi										■	■	
93015	93037	Combi 2 [1]	■			■								
93007	93030	Combi 3 A®	■		■	■					■			
93009	93032	Combi 5	■		■	■	■				■			
93035	93036	Combi 5 N®	■		■	■	■		■		■			
93055	–	Combi 5 S	■	■		■	■				■			
93018	93078	Combi 6	■			■	■	■	■				■	
93013	93034	Combi 6 A	■	■	■	■	■				■	■		
93010	93022	Combi 7	■	■	■	■	■		■		■			
–	93021	Combi 8 L	■		■	■	■	■	■	■	■			
93011	93023	Combi 9®	■	■	■	■	■		■		■	■	■	
–	93056	Combi 10®	■	■	■	■	■		■	■	■	■	■	
93079	93058	Combi 10® L	■	■	■	■	■	■	■		■	■	■	
–	93060	Combi 11	■	■	■	■	■	■	■	■	■	■	■	
93077	93067	Combi 10® SGL	■	■		■	■	■	■	■	■	■	■	
–	93068	URYXXON® Stick 10 [2] [3]	■	■		■	■	■	■	■	■	■	■	
930874	–	Microalbumin [3] [5]				■								■

Further Medi-Test urine test strips

Test strips for veterinary applications			
–	930870	Combi 10® VET [4]	■ ■ ■ ■ ■ ■ ■ ■ ■ ■
Test strips for detection of urine adulteration			
93019	–	Medi-Test Adulteration Stick [4]	for the detection of urine adulteration prior to drugs-of-abuse tests with test fields for Creatinine, Glutaraldehyde, Nitrite, pH, Oxidants and Density

All products (except 4) are CE-marked according to the directive 98/79/EC
[1] suitable for patient self-testing [2] for evaluation with reflectometer URYXXON® 500 [3] for evaluation with reflectometer URYXXON® Relax [4] not an IVD product (no CE-mark) [5] pack of 24 test strips

Instruments for evaluation of urine test strips URYXXON® Stick 10	
93088	URYXXON® Relax, suitable for the evaluation of MT URYXXON® Stick 10
930080	URYXXON® 500, suitable for the evaluation of MT URYXXON® Stick 10
Accessories and spare parts	
93038	Medi-Test Control, solution to check Medi-Test urine test strips and URYXXON® instruments
93071	Printer paper for URYXXON® 300 and URYXXON® 500, pack of 5 rolls
93074	Barcode scanner for URYXXON® instruments

www.mn-net.com

MACHEREY-NAGEL

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Fax: +33 388 51 76 88
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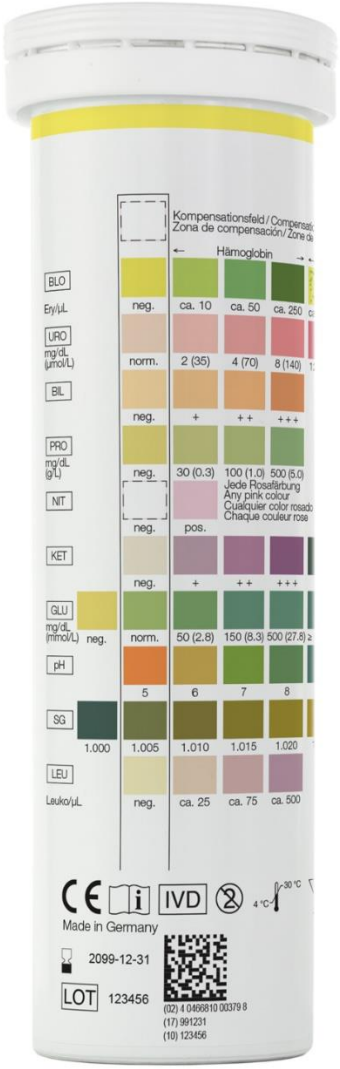
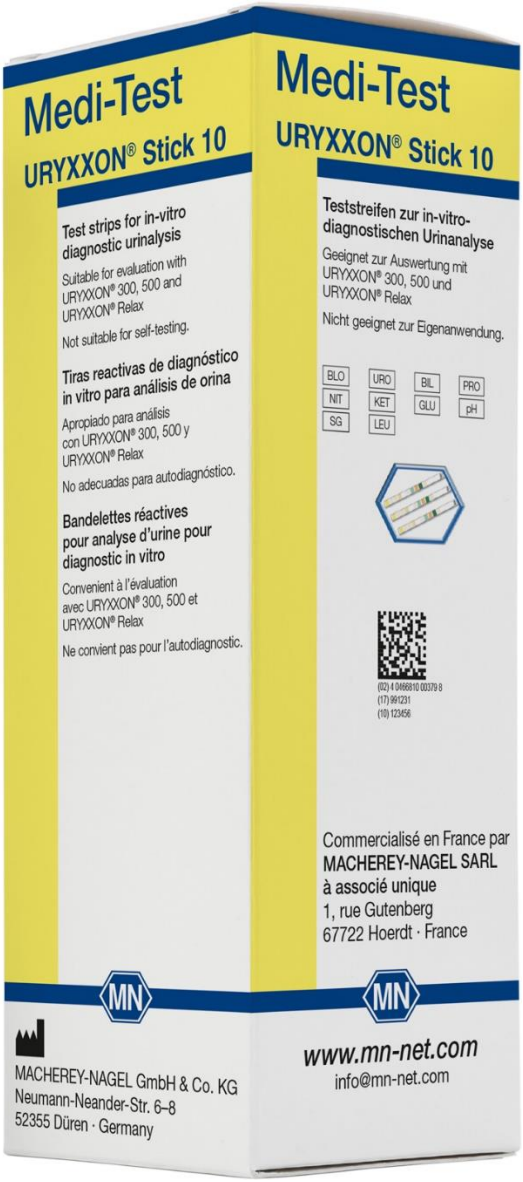
Urine test strips, Medi-Test URYXXON Stick 10





The use of urine test strips is acknowledged as modern screening method in medical practice. Within minutes important information on the health status of the patient is obtained. This simplifies the decision about further diagnostic and therapeutic action.

Platform	Urine test strips
Brand	Medi-Test URYXXON
Parameter	**Bilirubin, Blood, Density, Glucose, Ketones, Leukocytes, Nitrite, pH, Protein, Urobilinogen**
Bilirubin	neg • + • ++ • +++
Blood	neg • ca. 5–10 • ca. 50 • ca. 250 Ery/µL
Density	1.000 • 1.005 • 1.010 • 1.015 • 1.020 • 1.025 • 1.030
Glucose	neg • norm • 50 • 150 • 500 • ≥1000 mg/dL
Ketones	neg • + • ++ • +++
Leukocytes	neg • ca. 25 • ca. 75 • ca. 500 Leuco/µL
Nitrite	neg • pos
pH	5 • 6 • 7 • 8 • 9
Protein	neg. • 30 • 100 • 500 mg/dL
Urobilinogen	norm • 2 • 4 • 8 • 12 mg/dL
Evaluable on reflectometer	URYXXON 500, URYXXON Relax
Shelf life (from production)	2 Years
FDA 510(k)	K991927, Complexity Waived
Hazardous material	No
CE certified	CE-certified according to IVD Directive 98/79/EC, for professional use.
Remark	Optimal protection of the blood test against ascorbic acid, optimal protection of the glucose test against ascorbic acid
Storage temperature	4−30 °C
Scope of delivery	100 test strips in a tube, instructions for use

EC Declaration of Conformity for In-vitro-diagnostics

according to directive 98/79/EC

The procedure for EC declaration established a quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2003+AC:2009.

CE

We

Name of manufacturer:	MACHEREY-NAGEL GmbH & Co. KG
Address:	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Strasse 6-8 D - 52355 Dueren Germany

confirm that the following reflectometer for professional use

Name of product	**Reference numbers**
URYXXON® 500	930 080

Type:	URINE MULTI-CONSTITUENT TEST STRIPS EDMS 11-70-02-02-00
Registration number:	DE/CA21/MACHEREY/2003/11/IVD/0005

is manufactured in compliance with the European Directive 98/79/EC.

Dueren, 2013-07-30

Dietmas Czyron

i.A. D. Czyron (QA Manager)

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

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

including the locations according to annex

Scope: Design, development, production and distribution of products for filtration, rapid tests, water analysis, bioanalysis and chromatography, as well as service and administration.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2023-05-29 until 2026-05-28.

2023-04-18

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810008**

No.	Location	Scope
/01	c/o MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design, development, production and distribution of products for filtration, rapid tests, and water analysis, as well as service and administration
/02	c/o MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design, development and production of products for bioanalysis and chromatography
/04	c/o MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Storage

2023-04-18

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

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Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

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

Scope: Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine and gastric fluid analysis, as well as in vitro diagnostic products for bioanalytical sample preparation.

(see attachment for sites included)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1127255-40
Effective date: 2023-05-29
Expiry date: 2026-05-28
Issue date: 2023-04-12

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Irene Carraretto
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 1038121-1

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

The scope of certification covers the following sites:

No.	Facility	Scope
/01	c/o MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design and development, manufacture and distribution of in vitro diagnostic test strips including self-testing devices and reflectometers used in the field of urine and gastric fluid analysis, as well as in vitro diagnostic products for bioanalytical sample preparation.
/02	c/o MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design and development, manufacture and quality control of in vitro diagnostic products for bioanalytical sample preparation.
/03	c/o MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 1127255-40
Effective date: 2023-05-29
Expiry date: 2026-05-28
Issue date: 2023-04-12

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Irene Carraretto
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

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
TÜV Rheinland LGA Products GmbH
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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

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 TÜVRheinland®

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

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