

Anexa 3 Analizator automat, de urină

Analizator automat, de urină		
Descriere	Analizator automat de urină pentru efectuarea analizelor chimice ale urinei, care determină prezența anumitor substanțe și estimează concentrațiile lor într-o probă de urină.	Analizator automat de urină pentru efectuarea analizelor chimice ale urinei, care determină prezența anumitor substanțe și estimează concentrațiile lor într-o probă de urină
Parametrul	Specificația solicitată	Specificația oferită, model URIXXON500
Productivitate în regim normal	≥ 60 teste/ora	400 teste/ora
Productivitate în regim rapid	≥120 teste/ora	400 teste/ora
Teste chimice	Bilirubin	Bilirubin
Sînge (hematii)	da	da
Glucoză	da	da
Corpi cetoni	da	da
Esterază leucocitară	da	da
Nitrați	da	da
pH	da	da
Proteine	da	da
Greutatea specifică	da	da
Urobilinogen	da	da
Acid ascorbic	da	da
Data management	Memorie internă - da, ≥5000 de teste	Memorie internă – 500 pacienti
Monitor	LCD -da	Touchscreen display, alphanumeric input, password protection
Imprimantă	da	da
Alimentarea	220 V, 50 Hz	220 V, 50 Hz

Certificate

Standard **ISO 9001:2015**

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

Certificate Holder: **MACHEREY-NAGEL GmbH & Co. KG**
Valenciennner 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

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



TÜVRheinland®

Certificate

**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)

TÜVRheinland

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



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



Certificate



**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



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



EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1038121-1

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

Products: Products for self-testing
- Single and multi-parameter disposable test strips for urine analysis
- Indicator test strips and papers for measurement of pH in urine

Replaces Certificate, Registration No.: HL 60119814 0001

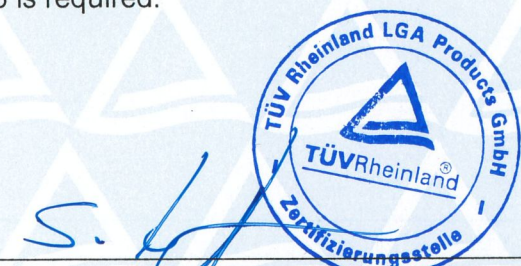
The Notified Body hereby declares that the requirements of Annex IV, excluding sections 4 and 6 of the directive 98/79/EC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex IV, section 5 of the aforementioned directive. For placing on the market of List A devices covered by this certificate an EC design-examination certificate according to Annex IV, section 4 and a verification of manufactured products according to section 6 is required.

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16



Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices,
Annex IV excluding (4, 6)

Registration No.: HL 1038121-1

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

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	MACHEREY-NAGEL GmbH & Co. KG Valenciennner Str. 11 52355 Düren Germany	Design and development, manufacture and quality control
/02	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16




Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 98/79/EC concerning in vitro diagnostic medical devices with the identification number 0197.

MACHEREY-NAGEL

Urine analysis



URYXXON® 500

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

Medi-Test

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

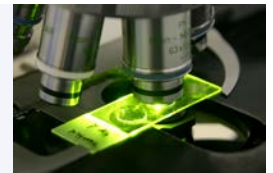
Easy and intuitive

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.



Medi-Test ordering information

REF	REF	Type	with test fields for determination of												
50 strips per pack	100 strips per pack		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



MACHEREY-NAGEL GmbH & Co. KG · Neumann-Neander-Str. 6–8 · 52355 Düren · Deutschland

DE / International:

Tel.: +49 24 21 969-0

Fax: +49 24 21 969-199

E-Mail: info@mn-net.com

CH:

Tel.: +41 62 388 55 00

Fax: +41 62 388 55 05

E-Mail: sales-ch@mn-net.com

FR:

Tel.: +33 388 68 22 68

Fax: +33 388 51 76 88

E-Mail: sales-fr@mn-net.com

