

## Anexa 31, Analizator semiautomat de urina cu masurare continuă

### Urixon 500, Macherey Nagel, Germania

| Parametri ceruti                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Parametri ofertati                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>"Analizator semi-automat, de urină cu masurare continue<br/>Cod 150120<br/>Descriere Analizator semiautomat de urină pentru efectuarea analizelor chimice ale urinei, care determină prezența anumitor substanțe și estimează concentrațiile lor într-o probă de urină.<br/>Parametrul Specificația<br/>Analize chimice Productivitate <math>\geq 500</math> teste /ora<br/>Bilirubin da<br/>Sînge da<br/>Glucoză da<br/>Corpi cetonici da<br/>Esterază leucocitară da<br/>Nitrați da<br/>pH da<br/>Proteine da<br/>Greutatea specifică da<br/>Urobilinogen da<br/>Data management Interfață LIS bidirecțională<br/>Cititor bar cod da<br/>Memorie internă da<br/>Monitor LCD sau LED da<br/>Imprimantă da<br/>Alimentarea 220 V, 50 Hz<br/>Consumabile<br/>""Să fie inclus benzi pentru teste cu toți parametrii<br/>solicitați mai sus"" <math>\geq 5000</math> analize<br/>Termenul de valabilitate din ziua livrării <math>\geq 6</math> luni<br/>"</p> | <p>"Analizator semi-automat, de urină cu masurare continue<br/>Cod 150120<br/>Descriere Analizator semiautomat de urină pentru efectuarea analizelor chimice ale urinei, care determină prezența anumitor substanțe și estimează concentrațiile lor într-o probă de urină. <b>DA</b><br/>Parametrul Specificația<br/>Analize chimice Productivitate 400 teste /ora pag 2 broșura<br/>Bilirubin <b>DA</b> pag 4 broșura<br/>Sînge <b>DA</b> pag 4 broșura<br/>Glucoză <b>DA</b> pag 4 broșura<br/>Corpi cetonici <b>DA</b> pag 4 broșura<br/>Esterază leucocitară <b>DA</b> pag 4 broșura<br/>Nitrați <b>DA</b> pag 4 broșura<br/>pH <b>DA</b> pag 4 broșura<br/>Proteine <b>DA</b> pag 4 broșura<br/>Greutatea specifică <b>DA</b> pag 4 broșura<br/>Urobilinogen <b>DA</b> pag 4 broșura<br/>Data management Interfață LIS bidirecțională <b>DA</b> pag 4 broșura<br/>Cititor bar cod <b>DA</b> pag 4 broșura<br/>Memorie internă <b>DA</b> pag 4 broșura<br/>Monitor LCD sau LED <b>DA</b> pag 4 broșura<br/>Imprimantă <b>DA</b> pag 4 broșura<br/>Alimentarea 220 V, 50 Hz <b>DA</b> pag 2 broșura<br/>Consumabile <b>DA</b><br/>""Să fie inclus benzi pentru teste cu toți parametrii<br/>solicitați mai sus"" <math>\geq 5000</math> analize <b>DA PN 93068</b> pag 4 broșura<br/>Termenul de valabilitate din ziua livrării <math>\geq 6</math> luni <b>DA</b></p> |

# Urine analysis



## URYXXON® 500

**Quick** – Reads 400 strips per hour

**Easy** – Touch screen operation

**Hygienic** – Automatic strip detection

## 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 with 5 levels each
- Optional external sediment keyboard

### Interface

- User: Touch screen display, alphanumeric input, password protection
- Computer: 1 x USB (type B) and 2 x RS232 interfaces for connection to PC, PS/2 interface for connection of keyboard and/or barcode reader

### Power requirements

- 110-240 V AC, automatic

### Dimensions / Weight

- Depth: 24 cm (9.5 inches)
- Width: 28 cm (11 inches)
- Height: 15 cm (5.9 inches)
- Weight: 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

## Intended use

The URYXXON® 500 is 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/EG.

## 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 terminal. Powerful user defined sieve 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 28x24 cm (11x9,4 in) the URYXXON® 500 fits onto every bench. The clear design allows access to all parts and makes cleaning easy.

## Test strips for urine analysis

| REF                                                    | REF                 | Medi-Test type                             | with test fields for determination of |         |               |         |       |            |         |                  |          |           |              |            |                |          |
|--------------------------------------------------------|---------------------|--------------------------------------------|---------------------------------------|---------|---------------|---------|-------|------------|---------|------------------|----------|-----------|--------------|------------|----------------|----------|
| 50 strips per pack                                     | 100 strips per pack |                                            | Glucose                               | Ketones | Ascorbic acid | Protein | Blood | Leukocytes | Nitrite | Specific Gravity | pH value | Bilirubin | Urobilinogen | Creatinine | Glutaraldehyde | Oxidants |
| 930 01                                                 | 930 24              | Glucose <sup>1)</sup>                      | •                                     |         |               |         |       |            |         |                  |          |           |              |            |                |          |
| 930 03                                                 | 930 26              | Glucose 3 <sup>1)</sup>                    | •                                     | •       | •             |         |       |            |         |                  |          |           |              |            |                |          |
| 930 04                                                 | 930 27              | Protein 2 <sup>1)</sup>                    |                                       |         |               | •       |       |            |         |                  | •        |           |              |            |                |          |
| 930 05                                                 | 930 28              | Keton <sup>1)</sup>                        |                                       | •       |               |         |       |            |         |                  |          |           |              |            |                |          |
| 930 06                                                 | 930 29              | Nitrit <sup>1)</sup>                       |                                       |         |               |         |       |            | •       |                  |          |           |              |            |                |          |
| 930 12                                                 | —                   | Urbi                                       |                                       |         |               |         |       |            |         |                  |          | •         | •            |            |                |          |
| 930 15                                                 | 930 37              | Combi 2 <sup>1)</sup>                      | •                                     |         |               | •       |       |            |         |                  |          |           |              |            |                |          |
| 930 07                                                 | 930 30              | Combi 3 A <sup>® 4)</sup>                  | •                                     |         | •             | •       |       |            |         |                  | •        |           |              |            |                |          |
| 930 09                                                 | 930 32              | Combi 5 <sup>4)</sup>                      | •                                     |         | •             | •       | •     |            |         |                  | •        |           |              |            |                |          |
| 930 35                                                 | 930 36              | Combi 5 N <sup>® 4)</sup>                  | •                                     |         | •             | •       | •     |            | •       |                  | •        |           |              |            |                |          |
| 930 55                                                 | —                   | Combi 5 S <sup>4)</sup>                    | •                                     | •       |               | •       | •     |            |         |                  | •        |           |              |            |                |          |
| 930 18                                                 | 930 78              | Combi 6 <sup>4)</sup>                      | •                                     |         |               | •       | •     | •          | •       |                  |          |           | •            |            |                |          |
| 930 13                                                 | 930 34              | Combi 6 A <sup>4)</sup>                    | •                                     | •       | •             | •       | •     |            |         |                  | •        | •         |              |            |                |          |
| 930 10                                                 | 930 22              | Combi 7 <sup>4)</sup>                      | •                                     | •       | •             | •       | •     |            | •       |                  | •        |           |              |            |                |          |
| —                                                      | 930 21              | Combi 8 L <sup>4)</sup>                    | •                                     |         | •             | •       | •     | •          | •       | •                | •        |           |              |            |                |          |
| 930 11                                                 | 930 23              | Combi 9 <sup>® 4)</sup>                    | •                                     | •       | •             | •       | •     |            | •       |                  | •        | •         | •            |            |                |          |
| —                                                      | 930 56              | Combi 10 <sup>® 4)</sup>                   | •                                     | •       | •             | •       | •     |            | •       | •                | •        | •         | •            |            |                |          |
| 930 79                                                 | 930 58              | Combi 10 <sup>® L 4)</sup>                 | •                                     | •       | •             | •       | •     | •          | •       |                  | •        | •         | •            |            |                |          |
| —                                                      | 930 60              | Combi 11                                   | •                                     | •       | •             | •       | •     | •          | •       | •                | •        | •         | •            |            |                |          |
| 930 77                                                 | 930 67              | Combi 10 <sup>® SGL 4)</sup>               | •                                     | •       |               | •       | •     | •          | •       | •                | •        | •         | •            |            |                |          |
| —                                                      | 930 68              | URYXXON® Stick 10 <sup>2/4)</sup>          | •                                     | •       |               | •       | •     | •          | •       | •                | •        | •         | •            |            |                |          |
| <b>Test strips for veterinary applications</b>         |                     |                                            |                                       |         |               |         |       |            |         |                  |          |           |              |            |                |          |
| —                                                      | 930 870             | Combi 10 <sup>® VET 3/4)</sup>             | •                                     | •       |               | •       | •     | •          | •       | •                | •        | •         | •            |            |                |          |
| <b>Test strips for detection of urine adulteration</b> |                     |                                            |                                       |         |               |         |       |            |         |                  |          |           |              |            |                |          |
| 930 19                                                 | —                   | Medi-Test Adulteration Stick <sup>3)</sup> |                                       |         |               |         |       |            | •       | •                | •        |           |              | •          | •              | •        |

All products are CE-marked according to the directive 98/79/EC

<sup>1)</sup> suitable for patient self-testing    <sup>2)</sup> for evaluation with URYXXON® reflectometers    <sup>3)</sup> not an IVD product

<sup>4)</sup> optimal protection of the blood and/or glucose test against ascorbic acid

### Instruments for evaluation of urine test strips URYXXON® Stick 10

|         |                                                               |
|---------|---------------------------------------------------------------|
| 930 88  | URYXXON® Relax, automated urine analysis at the point of care |
| 930 080 | URYXXON® 500, high performance automated urine analysis       |

### Accessories and spare parts

|         |                                                                                               |
|---------|-----------------------------------------------------------------------------------------------|
| 930 38  | Medi-Test Control, Solution for check of Medi-Test urine test strips and URYXXON® instruments |
| 930 65  | Printer paper for URYXXON® Relax, Pack of 5 rolls                                             |
| 930 890 | Strip adaptor for URYXXON® Relax                                                              |
| 930 891 | PC-software pack for URYXXON® Relax                                                           |
| 930 71  | Printer paper for URYXXON® 500, Pack of 5 rolls                                               |
| 930 74  | Barcode scanner for URYXXON® 500 and URYXXON® Relax                                           |

## Test strips for semi-quantitative determination of glucose in blood (capillary blood)

### Blood-glucose test strips

|        |                                                                                                    |
|--------|----------------------------------------------------------------------------------------------------|
| 928 07 | Test strips Glycaemie C (bicolored) for visual determination, pack of 50 test strips <sup>1)</sup> |
| 928 12 | Test strips Glycaemie V for visual determination, pack of 50 test strips <sup>1)</sup>             |

Distributed by:



# MACHEREY-NAGEL



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## 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.



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**  
URYXXON<sup>®</sup> 500

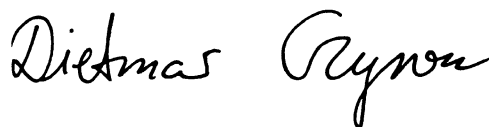
**Reference numbers**  
930 080

**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



i.A. D. Czyron (QA Manager)

# Certificate

**Quality Management System  
EN ISO 13485:2016**

Registration No.: SX 1038121-1

Organization: MACHEREY-NAGEL GmbH & Co. KG  
Neumann-Neander-Str. 6-8  
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, gastric and vaginal 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.: 3309079-90

Effective date: 2020-05-29

Expiry date: 2023-05-28

Issue date: 2020-05-28



Dipl.-Ing. S. Hoffmann  
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  
Neumann-Neander-Str. 6-8  
52355 Düren  
Germany

| No. | Facility                                                                       | Scope                                                                                         |
|-----|--------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|
| /02 | MACHEREY-NAGEL GmbH & Co. KG<br>Valencienner Str. 11<br>52355 Düren<br>Germany | Design and development, manufacture,<br>quality control, distribution and customer<br>service |
| /03 | MACHEREY-NAGEL GmbH & Co. KG<br>Bahnstr. 120<br>52355 Düren<br>Germany         | Warehousing and logistics                                                                     |

Report No.: 3309079-90

Effective date: 2020-05-29

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TÜV Rheinland LGA Products GmbH  
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| Nr          | Denumire                    | Den.comerc. | Model                          | Nr. catalog | Tara     | Producatorul                | Reprezentant   | Ordin              | Data       | Cod vamal |
|-------------|-----------------------------|-------------|--------------------------------|-------------|----------|-----------------------------|----------------|--------------------|------------|-----------|
|             |                             |             |                                |             |          |                             |                |                    |            |           |
| DM000030992 | ANALIZATOR DE URINĂ AUTOMAT |             | URYXXON RELAX                  | 93088       | Germania | MACHEREY-NAGEL GMBH & CO.KG | GBG-MLD S.R.L. | A07.PS-01.Rg04-247 | 01-12-2017 |           |
| DM000030984 | ANALIZATOR DE URINĂ AUTOMAT |             | URYXXON 500                    | 930080      | Germania | MACHEREY-NAGEL GMBH & CO.KG | GBG-MLD S.R.L. | A07.PS-01.Rg04-247 | 01-12-2017 |           |
| DM000030636 | STRIP TEST PENTRU URINĂ     |             | MEDI-TEST URYXXON STICK 10/125 | 930872      | Germania | MACHEREY-NAGEL GMBH & CO.KG | GBG-MLD S.R.L. | A07.PS-01.Rg04-239 | 27-11-2017 |           |
| DM000030628 | STRIP TEST PENTRU URINĂ     |             | MEDI-TEST URYXXON STICK 10/100 | 93068       | Germania | MACHEREY-NAGEL GMBH & CO.KG | GBG-MLD S.R.L. | A07.PS-01.Rg04-239 | 27-11-2017 |           |