Certificate

TÜVRheinland®

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)

Digitally signed by Ceaicovschi Tudor
Date: 2023.03.15 15:44:19 EET
Reason: MoldSign Signature
Location: Moldova

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

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

Certificate

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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 Valencienner Str. 11 52355 Düren Germany	Design and development, manufacture, quality control, distribution and customer service
/03	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Warehousing and logistics

Report No.: 3309079-90

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D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

Certificate

Standard **ISO 9001:2015**

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

Certificate Holder: **MACHEREY-NAGEL GmbH & Co. KG**
Neumann-Neander-Str. 6-8
52355 Düren
Germany

including the locations according to annex

Scope: Design and development, production and distribution of products for filtration, rapid tests, water analysis, chromatography and bioanalysis

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

Validity: The certificate is valid from 2020-05-29 until 2023-05-28.

2020-05-25

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	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design, development and production of products for chromatography and bioanalysis
/02	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany	Design, development, production and distribution of products for filtration, rapid tests, water analysis. Service and administration
/03	MACHEREY-NAGEL GmbH & Co. KG Papiermühle 50 52349 Düren Germany	Waste disposal
/04	MACHEREY-NAGEL GmbH & Co. KG Bahnstr. 120 52355 Düren Germany	Storage
/05	MACHEREY-NAGEL GmbH & Co. KG Monschauer Str. 64 52355 Düren Germany	Production

2020-05-25

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

EC Certificate

TÜVRheinland®

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
Valencienner 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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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

TÜVRheinland®

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
Valencienner 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 Valencienner 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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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.

Certificate of Completion

this is to certify

Mr. Alexei Legun

has successfully completed

The technical maintenance training course

On

Urine Analysis

URYXXON 200;
URYXXON RELAX;
URYXXON 500;

Mars, 2006

President
MACHEREY-NAGEL GMBH & CO.KG

EC Declaration of Conformity

EC Declaration of Conformity for In-vitro Diagnostic Products

The procedure for EC declaration of conformity was established on the basis of a full quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012 according to the IVD directive 98/79/EC Annex IV, except chapters 4 and 6.

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 test strips for professional use

Name of product	**Reference numbers**
Medi-Test Glucose PN	93017; 930965
Medi-Test Glucose	93001; 93024
Medi-Test Glucose 3	93003; 93026
Medi-Test Glucose/Keton	93020; 93025
Medi-Test Protein 2	93004; 93027
Medi-Test Keton	93005; 93028
Medi-Test Nitrit	93006; 93029
Medi-Test Combi 2	93015; 93037
Medi-Test Urbi	93012
Medi-Test Combi 3	93050
Medi-Test Combi 3A	93007; 93030
Medi-Test Combi 5	93009; 93032
Medi-Test Combi 5N	93035; 93036
Medi-Test Combi 5S	93055
Medi-Test Combi 6	93018; 93078
Medi-Test Combi 6A	93013; 93034
Medi-Test Combi 7	93010; 93022
Medi-Test Combi 7L	93031
Medi-Test Combi 8L	93021
Medi-Test Combi 9	93011; 93023
Medi-Test Combi 10	93056
Medi-Test Combi 10L	93058; 93079
Medi-Test Combi 10 SGL	93067; 93077
Medi-Test URYXXON Stick 10	93068; 930872
Medi-Test Combi 11	93060; 930871
Medi-Test Mikroalbumin	930874

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

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Tel.: +33 388 68 22 68
Fax: +33 388 51 76 88
E-mail: sales-fr@mn-net.com

US:
Tel.: +1 484 821 0984
Fax: +1 484 821 1272
E-mail: sales-us@mn-net.com

Type:	Urine Multi-constituent Test Strips EDMS 11-70-02-02-00
Registration number:	DE/CA21/MACHEREY/2002/06/IVD/0001
Notified body:	TÜV Rheinland LGA Products GmbH Tillystr. 2, 90431 Nürnberg

are manufactured in compliance with the European Directive 98/79/EC. The manufacturer is exclusively responsibility for the declaration of conformity.

Düren, 22.09.2017

ppa. Dr. Markus Meusel (QAM, Manager Reg. Affairs)

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

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Fax: +1 484 821 1272
E-mail: sales-us@mn-net.com

EC Declaration of Conformity

The procedure for EC declaration was established according to the IVD directive 98/79/EC on the basis of a full quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012.

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 product for professional use

Name of product	Medi-Test Control
Reference number, REF	930 38
Type:	Other calibrators and standards (CC) EDMS 11-50-03-90-00
Registration number:	DE/CA21/MACHEREY/2002/11/IVD/0007

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

Dueren, 12.02.2014

i.A. Markus Meusel (QA Manager)

MACHEREY-NAGEL

EC DECLARATION OF CONFORMITY

according to Annex III of the IVD Directive 98/79/EC

EG Konformitätserklärung

gemäß Anhang III der IVD Richtlinie 98/79/EG

We hereby declare that the in vitro diagnostic medical device (IVD)

Hiermit erklären wir, dass das In-vitro-Diagnostikum (IVD)

URYXXON® 500
REF 930 080

URYXXON® 500
REF 930 080

GMDN Code: CT943 Instrument/analyser IVDs
EDMA IVD Classification: 21 05 Urine Analyser

GMDN Code: CT943 Instrumente/Analysatoren, IVD
EDMA IVD Klassifizierung: 21 05 Urin Analysegerät

is classified as ***all other IVD*** according to Annex II of the European directive 98/79/EC on in vitro diagnostic medical devices (IVDD)

gemäß Anhang II der Europäischen Richtlinie 98/79/EG über In-vitro-Diagnostika als ***sonstiges IVD*** klassifiziert ist

and complies with the essential requirements (Annex I) of the IVD Directive 98/79/EC.

und die Grundlegenden Anforderungen (Anhang I) der IVD Richtlinie 98/79/EG erfüllt.

In addition, it meets the requirements according to the following directive

Darüberhinaus erfüllt es die Anforderungen gemäß der folgenden Richtlinie

European directive 2011/65/EU on the restriction of the use of certain hazardous sub-stances in electrical and electronic equipment (RoHS 2)

Europäische Richtlinie 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (RoHS 2)

applied harmonized standards

angewandte Harmonisierte Normen

DIN EN ISO 9001:2008
DIN EN ISO 13485:2012 + AC:2012
DIN EN ISO 14971:2012

DIN EN ISO 18113-1:2010
DIN EN ISO 18113-3:2010
DIN EN 13612:2002
DIN EN 980:2008

DIN EN ISO 15223-1:2013
DIN EN 62366:2008
DIN EN 62304:2006

DIN EN 61010-1:2010

DIN EN 61010-2-101:2003-09

DIN EN 61326-1:2013

Düren, 12 September 2016

ppa.

Quality-management representative (authorized representative)

www.mn-net.com

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MACHEREY-NAGEL

EC DECLARATION OF CONFORMITY

according to Annex III of the IVD Directive 98/79/EC

EG Konformitätserklärung

gemäß Anhang III der IVD Richtlinie 98/79/EG

We hereby declare that the in vitro diagnostic medical device (IVD)

URYXXON® Relax
REF 930 88

GMDN Code: CT943 Instrument/analyser IVDs
EDMA IVD Classification: 21 05 Urine Analyser

is classified as ***all other IVD*** according to Annex II of the European directive 98/79/EC on in vitro diagnostic medical devices (IVDD)

and complies with the essential requirements (Annex I) of the IVD Directive 98/79/EC.

In addition, it meets the requirements according to the following directive

European directive 2011/65/EU on the restriction of the use of certain hazardous sub-stances in electrical and electronic equipment (RoHS 2)

Hiermit erklären wir, dass das In-vitro-Diagnostikum (IVD)

URYXXON® Relax
REF 930 88

GMDN Code: CT943 Instrumente/Analysatoren, IVD
EDMA IVD Klassifizierung: 21 05 Urin Analysegerät

gemäß Anhang II der Europäischen Richtlinie 98/79/EG über In-vitro-Diagnostika als ***sonstiges IVD*** klassifiziert ist

und die Grundlegenden Anforderungen (Anhang I) der IVD Richtlinie 98/79/EG erfüllt.

Darüberhinaus erfüllt es die Anforderungen gemäß der folgenden Richtlinie

Europäische Richtlinie 2011/65/EU zur Beschränkung der Verwendung bestimmter gefährlicher Stoffe in Elektro- und Elektronikgeräten (RoHS 2)

applied harmonized standards

angewandte Harmonisierte Normen

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DIN EN 13612:2002
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DIN EN ISO 15223-1:2013
DIN EN 62366:2008
DIN EN 62304:2006

DIN EN 61010-1:2010

DIN EN 61010-2-101:2003-09

DIN EN 61326-1:2013

Düren, 12 September 2016

Quality management representative (authorized representative)

www.mn-net.com

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