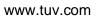
Certificate			
Standard Certificate Registr. No.	ISO 9001:2015 01 100 1810008		
Certificate Holder:	MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany including the locations according to annex		
Scope:	Design, development, production and distribution of products for filtration, rapid 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		







Annex to certificate

Standard

/02

ISO 9001:2015

Certificate Registr. No. 01 100 1810008

Location No.

52355 Düren

Germany

/01 c/o MACHEREY-NAGEL GmbH & Co. KG Valencienner Str. 11 52355 Düren Germany

Scope

Design, development, production and distribution of products for filtration, rapid tests, and water analysis, as well as service and administration

c/o MACHEREY-NAGEL GmbH & Co. KG Design, development and production Neumann-Neander-Str. 6-8 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

Page 1 of 1



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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)

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.

1127255-40

2023-05-29

2026-05-28

2023-04-12

Report No.: Effective date: Expiry date: Issue date:



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> 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
		LEA Provense

Report No.: Effective date: Expiry date: Issue date:

OAkkS

Deutsche

1127255-40 2023-05-29 2026-05-28 2023-04-12



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

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Akkreditierungsstelle D-ZM-14169-01-02



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 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

aland LGA TÜVRheinland Zierungsst 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 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	aneithend LGA Prope
Effective date:	2022-02-16	
Expiry date:	2025-05-26	TÜVRheinland
Issue date:	2022-02-16	S. C. Hornizierungsstalle
		Dipl-Ing Sven Hoffmann

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.