

## EC Certificate

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

Registration No.: HL 60119814 0001

Report No.: 21265422 001

**Manufacturer:** Macherey-Nagel GmbH & Co. KG  
Neumann-Neander-Str. 6-8  
52355 Düren  
Deutschland

**Products:** Products for self-testing  
(see attachment for products and sites included)  
Replaces Certificate, Registration No.: HL 60076687 0001

**Expiry Date:** 2022-05-28

The Notified Body hereby declares that the requirements of Annex IV, excluding section 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.

**Effective Date:** 2017-05-29

**Date:** 2017-05-29

Notified Body

  
Dipl.-Ing. Sven Hoffmann



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**

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.

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HL 60119814 0001  
**Report No.:** 21265422 001

**Manufacturer:** Macheray-Nagel GmbH & Co. KG  
Neumann-Neander-Str. 6-8  
52355 Düren  
Deutschland

**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

**Additional site for warehousing and logistics:**

Bahnstr. 120  
52355 Düren, Germany

**Date:** 2017-05-29

**Notified Body**

  
**Dipl.-Ing. Sven Hoffmann**



# 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 Valenciener 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  
Effective date: 2020-05-29  
Expiry date: 2023-05-28  
Issue date: 2020-05-28



*S. Hoffmann*  
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

# 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 Valenciennener 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