

# 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<br>Valencienner Str. 11<br>52355 Düren<br>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<br>Neumann-Neander-Str. 6-8<br>52355 Düren<br>Germany | Design, development and production of products for bioanalysis and chromatography   |
| /04 | c/o MACHEREY-NAGEL GmbH & Co. KG<br>Bahnstr. 120<br>52355 Düren<br>Germany             | Storage   |

2023-04-18



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln



**TÜVRheinland**<sup>®</sup>

# 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**<sup>®</sup>

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



Deutsche  
Akkreditierungsstelle  
D-ZM-14169-01-02



# Certificate



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

Registration No.: SX 1038121-1

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

The scope of certification covers the following sites:

| No. | Facility   | Scope  |
|-----|--|--|
| /01 | c/o MACHEREY-NAGEL GmbH & Co. KG<br>Valenciennner Str. 11<br>52355 Düren<br>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<br>Neumann-Neander-Str. 6-8<br>52355 Düren<br>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<br>Bahnstr. 120<br>52355 Düren<br>Germany             | Warehousing and logistics  |

Report No.: 1127255-40  
Effective date: 2023-05-29  
Expiry date: 2026-05-28  
Issue date: 2023-04-12



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# 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

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  
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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<br>Valenciennner Str. 11<br>52355 Düren<br>Germany | Design and development, manufacture and<br>quality control |
| /02 | MACHEREY-NAGEL GmbH & Co. KG<br>Bahnstr. 120<br>52355 Düren<br>Germany          | Warehousing and logistics                                  |

Report No.: 1106581-20

Effective date: 2022-02-16

Expiry date: 2025-05-26

Issue date: 2022-02-16



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