

# Certificate

## Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 ISO 13485:2016

Registration No.: SX 1038121-1

Certificate Holder: MACHEREY-NAGEL GmbH & Co. KG  
Valenciener 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.

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.: 1207720-100

Effective date: 2026-05-29

Expiry date: 2029-05-28

Issue date: 2026-05-18

Replaces certificate SX 1038121-1 issued 2025-12-09



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Germany

The scope of certification also 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. Warehousing and logistics.
/02	c/o MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Str. 6-8 52355 Düren Germany	Design and development of in vitro diagnostic products for bioanalytical sample preparation.
/04	c/o MACHEREY-NAGEL GmbH & Co. KG Nickepütz 8 52349 Düren Germany	Manufacture of in vitro diagnostic products for bioanalytical sample preparation. Warehousing.

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