Certificate

TÜVRheinland®

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.

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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

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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

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DAkkS
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