

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
Valenciener 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
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.

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The scope of certification includes the following manufacturing sites:

| No. | Location | Product groups manufactured |
|-----|---|---|
| /01 | MACHEREY-NAGEL GmbH & Co. KG Valenciener 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 |

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TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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