

## 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  
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**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**

