

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
Macherey-Nagel GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

has established and applies a quality management system for medical devices
for the following scope:

Discription see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-08-21
Certificate Registration No.: SX 60129407 0001
An audit was performed. Report No.: 21265422 003
This Certificate is valid until: 2020-05-28

Certification Body



Date 2018-08-21



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60129407 0001
Report No.: 21265422 003

Organization: Macherey-Nagel GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

Scope:

Design and development, production and distribution of medical test strips and reflectometers for evaluation and products for bioanalytical sample preparation.

Sites included:

- Valencienner Str. 11
52355 Düren, Germany

Activities: Distribution, warehousing, manufacturing and quality control of reflectometers, customer service

- Bahnstr. 120
52355 Düren, Deutschland

Activities: Storage of raw materials and intermediate products

Certification Body



Date: 2018-08-21


Dipl.-Ing. Sven Hoffmann

