

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 13485:2012
EN ISO 13485:2012/AC:2012

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

Effective Date: 2017-05-29
Certificate Registration No.: SX 60119808 0001
An audit was performed. Report No.: 21265422 001
This Certificate is valid until: 2019-03-30

Certification Body



Dieses Dokument wurde von einer
in Deutschland zuständigen Stelle/
Institution/Behörde ausgestellt.
Industrie- und Handelskammer Aachen
Bescheinigungsstelle Düren, den



24. NOV. 2017

Schmitz



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60119808 0001
Report No.: 21265422 001

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:

- Valenciener 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: 2017-05-29



Dipl.-Ing. Sven Hoffmann



**CHỨNG NHẬN/ HỢP PHÁP HÓA LÃNH SỰ
KONSULARISCHE BEGLAUBIGUNG/LEGALISIERUNG**

1. Quốc gia/Staat: **Việt Nam/Vietnam**

Giấy tờ, tài liệu này/Dieses Dokument

2. Với chữ ký của/U. von Herrn (Frau): **Schmitz**

3. Với chức danh/Funktion: **Nhân viên hành chính**

4. Và con dấu của/Dienstsiegel von: **Phòng Thương mại và Công nghiệp Aachen**

**được chứng nhận/hợp pháp hóa lãnh sự/
wird hiermit konsularisch beglaubigt/legalisiert**

5. Tại/in: **Berlin**

6. Ngày/Datum: **05/12/2017**

7. Cơ quan cấp/Ausgestellt von: **Đại sứ quán nước CHXHCN Việt Nam tại CHLB Đức Botschaft der SR Vietnam in der BR Deutschland**

8. Số/Nr.: **12a-LS-HPH/2017**

Vi. Đại sứ/i. A. des Botschafters
Bí thư thứ nhất/I. Sekretär



Đinh Anh Tuấn