

# Certificate



## Quality Management System EN ISO 13485:2016

Registration No.: SX 1034230-1

Organization: nal von minden GmbH  
Carl-Zeiss-Str. 12  
47445 Moers  
Germany

Scope: Design and development, manufacture and distribution of in vitro diagnostic test kits and reagents for the detection or determination of cardiac markers, tumor markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing as well as associated in vitro diagnostic devices for sampling and analysis systems for rapid tests.

Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs and lancets.

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.: 1089325-40  
Effective date: 2021-12-02  
Expiry date: 2024-12-01  
Issue date: 2021-11-29

  
  
Dipl.-Ing. Sven Hoffmann  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany



# Certificate



## Quality Management System EN ISO 13485:2016

Registration No.: SX 1034230-1

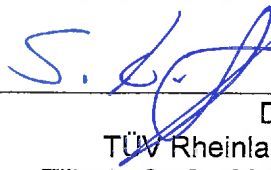

Organization: nal von minden GmbH  
Carl-Zeiss-Str. 12  
47445 Moers  
Germany

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o nal von minden GmbH Carl-Zeiss-Str. 12 47445 Moers Germany	Manufacture and distribution
/02	c/o nal von minden GmbH Friedenstr. 32 93053 Regensburg Germany	Design and development and distribution
/03	c/o nal von minden GmbH Robert-Bosch-Breite 34 37079 Göttingen Germany	Design and development and manufacture
/04	c/o nal von minden GmbH Raseweg 4 37124 Rosdorf Germany	Administration and distribution

Report No.: 1089325-40  
Effective date: 2021-12-02  
Expiry date: 2024-12-01  
Issue date: 2021-11-29



  
  
Dipl.-Ing. Sven Hoffmann  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

# Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

Certificate Holder: **nal von minden GmbH**  
Carl-Zeiss-Str. 12  
47445 Moers  
Germany

including the locations according to annex

Scope: Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances.  
Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2021-09-10 until 2024-09-09.  
First certification 2018

2021-09-10



TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln

# Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

No.	Location	Scope
/01	c/o nal von minden GmbH Carl-Zeiss-Str. 12 47445 Moers Germany	Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances. Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

# Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

/02 c/o nal von minden GmbH  
Friedenstr. 32  
93053 Regensburg  
Germany

Design and development, distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances. Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

# Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1810016**

/03 c/o nal von minden GmbH  
Robert-Bosch-Breite 34  
37079 Göttingen  
Germany

Design and development, manufacture and distribution of in-vitro diagnostic test kits and reagents for the detection of cardiac markers, tumour markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, drug misuse, immune status, vaginal pH levels, pregnancy, kidney function, for urine analysis, performance diagnostics, sperm testing, coagulation management systems, for use in clinical laboratories, as near-patient tests and for self-testing and associated in-vitro diagnostic devices for sampling and analysis systems, as well as veterinary diagnostic devices and testing for narcotics and substances. Distribution of control materials and tests for blood group determination, medical masks, medical gloves, blood pressure monitoring devices, medical thermometers, swabs, lancets and laboratory analyses.

2021-09-10

  
TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln