Digitally signed by Ceaicovschi Tudor
Date: 2020.11.23 09:49:01 EET
Reason: MoldSign Signature
Location: Moldova

EC-Declaration of Conformity

According to Directive 98/79/EC on in-vitro-diagnostic devices, Annex III

product number:	243103N-20
product name:	**NADAL® COVID-19 Ag Test**
classification:	Other Products
manufacturer:	nal von minden GmbH Carl-Zeiss-Str. 12 47445 Moers

We herewith declare on our sole responsibility that all batches of above In-vitro-diagnostic device is conform with the Essential Requirements Annex I of the directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. The product is suitable for the intended application (only professional users). Relevant standards and guidelines are applied.

This document is valid until 2022-08-30.

Moers, 31.08.2020

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BIC/SWIFT: BYLADEM1RBG
Commercial register::
Kleve, HRB 5679
VAT-ID: DE189 016086
Tax-No: 244/133/00130

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 laboratory diagnostic, clinical diagnostic and rapid tests

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

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

2018-09-17

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

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Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. 01 100 1810016

No.	Location	Scope
01	nal von minden GmbH Carl-Zeiss-Str. 12 47445 Moers Germany	Design and development, manufacture and distribution of laboratory diagnostic, clinical diagnostic and rapid tests
02	nal von minden GmbH Friedensstr. 32 93053 Regensburg Germany	Design and development, manufacture and distribution of laboratory diagnostic, clinical diagnostic and rapid tests
/03	nal von minden GmbH Robert-Bosch-Breite 23 37079 Göttingen Germany	Design and development, manufacture and distribution of laboratory diagnostic, clinical diagnostic and rapid tests

2018-09-17

TÜV Rheinland Cert GmbH
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Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Deutschland

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

Design and development, manufacture and distribution of laboratory diagnostic, clinical diagnostic and rapid tests (see attachment for sites included)

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:	2018-12-02
Certificate Registration No.:	SX 60131401 0001
An audit was performed. Report No.:	21200072 015
This Certificate is valid until:	2021-12-01

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-11-27

Dipl.-Ing. Sven Hoffmann

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 60131401 0001
Report No.: 21200072 015

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

Scope:

Sites included:

nal von minden GmbH
Friedenstr. 32
93053 Regensburg, Germany

Activities: Design, development and distribution

nal von minden GmbH
Robert-Bosch-Breite 23
37079 Göttingen, Germany

Activities:
Design, development, manufacture and distribution

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date: 2018-11-27

Dipl.-Ing. Sven Hoffmann

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