

EC-Declaration of Conformity

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

Manufacturer: nal von minden GmbH, Carl-Zeiss Str.12, 47445 Moers
 Classification: Other Products

We herewith declare on our sole responsibility that all batches of below mentioned In-vitro-diagnostic devices are 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 products are suitable for the intended application (only professional users).

Relevant standards and guidelines are applied.

141000	NADAL® EARLY hCG Pregnancy dipstick
141000_SSL	NADAL® EARLY hCG Pregnancy dipstick
141002	NADAL® hCG Pregnancy Test 25 mIU/ml dipstick
142000	NADAL® EARLY hCG 10 mIU/ml cassette
142002	NADAL® hCG Pregnancy Cassette Test 25 mIU/ml
143003	NADAL® hCG Pregnancy Tests 10 mIU/ml dipstick
143004	NADAL® hCG t 25 mIU/ml dipstick
143004_SSL	NADAL® hCG t 25 mIU/ml dipstick
144001N-10	NADAL® hCG Pregnancy Test, Midstream 20 mIU/ml cassette
151002	NADAL® hCG Pregnancy
151002SE	NADAL® hCG Pregnancy rapid test
151003	NADAL® hCG Test 10mIU/ml Urin/Serum Dipstick
152000	NADAL® hCG Pregnancy 10 mIU/ml cassette
152002	NADAL® hCG Pregnancy 25 mIU/ml cassette
152003	NADAL® hCG Pregnancy Test 20 mIU/ml cassette S/P/W

153002	NADAL® hCG Pregnancy TEST 10 mIU/ml – Urin/Serum
153003	NADAL® hCG 25 mIU/mln Dipstick
153003_SSL	NADAL® hCG 25 mIU/mln Dipstick
161001	NADAL® hLH Ovulation rapid test
161001_SSL	NADAL® hLH Ovulation rapid test
162001	NADAL® hLH Ovulation rapid test
162001_SSL	NADAL® hLH Ovulation rapid test
164001	NADAL® hLH Ovulation 30 mIU/ml Midstream
165001	NADAL® hLH Ovulation 30 mIU/ml dipstick
165001_SSL	NADAL® hLH Ovulation 30 mIU/ml dipstick
165002	NADAL® hLH Ovulation rapid tests (2,5mm)
165003	NADAL® hLH Ovulation rapid test
165003_SSL	NADAL® hLH Ovulation rapid test
166001	NADAL® hLH Ovulation 30 mIU/ml cassette
172001	NADAL® FSH cassette
172001_SSL	NADAL® FSH cassette
172003N-10	NADAL® FSH cassette
194002	NADAL® pH-Test

201001	NADAL® Syphilis dipstick
201001_SSL	NADAL® Syphilis dipstick
202001	NADAL® Syphilis cassette
202001_SSL	NADAL® Syphilis cassette
203001	NADAL® Syphilis rapid tests
203002	NADAL® Syphilis rapid tests
203002_SSL	NADAL® Syphilis rapid tests
221001A	NADAL® Strep A dipstick
221005	NADAL® Strep A reagent 1
221006	NADAL® Strep A reagent 2
221050N-50	NADAL® Strep A plus rapid tests
222001A	NADAL® Strep A cassette
222007	NADAL® Strep A plus cassette
222008	NADAL® Strep A plus cassette
222011	NADAL® Strep A plus cassette
222049BUL	NADAL® Strep A Scan cassette
222049BUL-20	NADAL® Strep A Scan cassette
232001	NADAL® Strep B cassette
232001_SSL	NADAL® Strep B cassette
232005	NADAL® Strep B reagent 1
232006	NADAL® Strep B reagent 2
241005N-10	NADAL® Influenza A+B dipstick
241006N-25	NADAL® Influenza A+B dipstick
242001	NADAL® Influenza A+B cassette
242006N-10	NADAL® Influenza A/B cassette
252001	NADAL® Mononucleosis cassette
252002	NADAL® Mononucleosis dipstick
252003	NADAL® Mononucleosis cassette
252003N-20	NADAL® Mononucleosis cassette
252005	NADAL® Mononucleosis positive control
252006	NADAL® Mononucleosis negative control
252017N-05	NADAL® Mononucleosis cassette
262001	NADAL® H.Pylori Antikörper cassette
262001_SSL	NADAL® H.Pylori Antikörper

	cassette
262002	NADAL® H.Pylori Antigen cassette
262003	NADAL® H. pylori Ab cassette
262004BUL	NADAL® H. pylori Scan Ab cassette
262004BUL N-10	NADAL® H. pylori Scan Ab cassette
272001	NADAL® FOB cassette
272001_SSL	NADAL® FOB cassette
272008	NADAL® FOB cassette
272009	NADAL® Hb/Hp Complex cassette
272010	NADAL® FOB cassette
272011	NADAL® Hb/Hp cassette
272011N-25	NADAL® Hb/Hp cassette
272015	NADAL® Hb/Hp Complex cassette
272015_SSL	NADAL® Hb/Hp Complex cassette
272016	NADAL® FOB plus cassette
272031RU	NADAL® Hb/Hp Complex cassette
272031RU-01	NADAL® Hb/Hp Complex cassette
272031RU_SSL	NADAL® Hb/Hp Complex cassette
272035	NADAL® FOB60 plus cassette
272035_SSL	NADAL® FOB60 plus cassette
272037	NADAL® FOB & Hb/Hp patient set
272040	NADAL® FOB II Cassettes
272041	NADAL® FOB60 Cassette
272041_SSL	NADAL® FOB60 Cassette
272042	NADAL® FOB75 Cassette
272043	NADAL® FOB75 II Cassette
282000	NADAL® Troponin I cassette
282001	NADAL® Troponin I cassette
282001_SSL	NADAL® Troponin I cassette
282003	NADAL® Trop I, CK-MB, Myoglobin Combi- cassette
282015	NADAL® Troponin I cassette
292001	NADAL® Myoglobin cassette
292001N-05	NADAL® Myoglobin cassette

302001	NADAL® CK-MB cassette
302001_SSL	NADAL® CK-MB cassette
311003	NADAL® CrP Dipstick
311004	NADAL® CRP plus Dipstick
311006	NADAL® CRP plus Dipstick
312001	NADAL® CrP cassette
312002	NADAL® high sensitive CrP cassette
312017	NADAL® CRP Quant RFID chip
312021BUL	NADAL® CRP Quant cassette
312021NBU L-20	NADAL® CRP Quant cassette
322003N-30	NADAL® Tuberkulose IgG/IgM cassette
322003N-30_SSL	NADAL® Tuberkulose IgG/IgM cassette
331001	NADAL® Mikroalbumin Dipstick
331004N-50	NADAL® Mikroalbumin Dipstick
333001	NADAL® Mikroalbumin Dipstick
351006	NADAL® D-Dimer cassette
351006_SSL	NADAL® D-Dimer cassette
351007	NADAL® D-Dimer cassette
374018	qLabs aPTT-INR Control
431001N-03	NADAL® PROM Test Dipstick
431001N-03_SSL	NADAL® PROM Test Dipstick
431001N-10	NADAL® PROM Test Dipstick
431001N-10_SSL	NADAL® PROM Test Dipstick
431001N-20	NADAL® PROM Test Dipstick
431006N-03	NADAL® PROM Amniotic fluid Dipstick
431006N-10	NADAL® PROM Amniotic fluid Dipstick
431006N-20	NADAL® PROM Amniotic fluid Dipstick
472001N-25	NADAL® Malaria Pf Ag test cassette
472001N-25_SSL	NADAL® Malaria Pf Ag test cassette
472003N-25	NADAL® Malaria 4 species cassette

472003N-10	NADAL® Malaria 4 species cassette
472003_SSL	NADAL® Malaria 4 species cassette
472008	NADAL® Malaria 4 species cassette
472009	NADAL® Malaria Pf/Pv Ab cassette
472030N-25	NADAL® Malaria Pf/Pan Ag 4Species cassette
472030N-10	NADAL® Malaria Pf/Pan Ag 4Species cassette
472036N-25	NADAL® Malaria Pf/Pan Ag 4Species cassette
481002	NADAL® Adenovirus rapid tests
481003	NADAL® Adenovirus rapid tests
481004	NADAL® Rotavirus rapid tests
481005	NADAL® Rotavirus rapid tests
481006	NADAL® Adenovirus 40/41 strips
481007	NADAL® Adenovirus 40/41 strips
481008	NADAL® Adenovirus Respiratory rapid tests
481013	Adenovirus Positive Control
481015	NADAL® Rota-Adenovirus cassette
481015_SSL	NADAL® Rota-Adenovirus cassette
481015N-20	NADAL® Rota-Adenovirus cassette
481016	NADAL® Adenovirus cassette
481016_SSL	NADAL® Adenovirus cassette
481017	NADAL® Rotavirus cassette
481049BUL	NADAL® Rota-Adenovirus Scan cassette
481049BUL-10	NADAL® Rota-Adenovirus Scan cassette
491000N-10	NADAL® RSV plus Dipstick
491000N-10_SSL	NADAL® RSV plus Dipstick
491003N-25	NADAL® RSV Dipstick
491005	NADAL® RSV cassette
491008BUL	NADAL® RSV Scan cassette
491009	NADAL® RSV-Adeno Resp cassette
491015	NADAL® RSV Dipstick
495001	NADAL® MRSA Screen Latex-Agglutinationstest

495001_SSL	NADAL® MRSA Screen Latex-Agglutinationstest
501006	NADAL® <i>E.coli</i> O157 Cassette
501006_SSL	NADAL® <i>E.coli</i> O157 Cassette
501012	NADAL® EHEC Verotoxin 1-2, feces - cassette á 10
501012_SSL	NADAL® EHEC Verotoxin 1-2, feces - cassette á 10
511002	NADAL® Cryptosporidium Dipstick
511006	NADAL® Cryptosporidium cassette
511006_SSL	NADAL® Cryptosporidium cassette
521001	NADAL® Giardia Dipstick
521004	NADAL® Crypto/Giardia Test strips
521006	NADAL® Giardia cassette
521009	NADAL® Giardia cassette
521010	NADAL® Giardia-Crypto-Combo cassette
521010_SSL	NADAL® Giardia-Crypto-Combo cassette
532001_SSL	NADAL® Dengue cassette
532001N-25	NADAL® Dengue cassette
532002N-25	NADAL® Dengue cassette
532003N-25	NADAL® Dengue cassette
532004N-25	NADAL® Dengue cassette
532004N-25_SSL	NADAL® Dengue cassette
532011	NADAL® Dengue IgG/IgM cassette
532011N-25	NADAL® Dengue IgG/IgM cassette
532012N-25	NADAL® Dengue NS1 Ag Cassette
532016N-25	NADAL® Dengue NS1 Ag+IgG/IgM Cassette
542001N-25	NADAL® Tetanus cassette
552005	NADAL® Legionella Urin Antigen cassette
552005_SSL	NADAL® Legionella Urin Antigen cassette
552006	NADAL® Legionella Urin Antigen cassette
552006_SSL	NADAL® Legionella Urin Antigen cassette

552020	NADAL® Legionella Urine Antigen test
562003N-10	NADAL® BCA/HB inkl.
562003RU	NADAL® BCA/HB inkl.
572004N-10	NADAL® Streptococcus pneumoniae cassette
572005	NADAL® Legionella/S. pneumonia cassette
580005N-25	NADAL® TSH cassette
582003	NADAL® C. difficile Toxin A/B cassette
582003_SSL	NADAL® C. difficile Toxin A/B cassette
582004	NADAL® Clostridium Difficile GDH
582008	NADAL® Clostridium Difficile Toxins A&B cassette
582009	NADAL® C. perfringens Ag cassette
582009_SSL	NADAL® C. perfringens Ag cassette
582016N-10	NADAL® Clostridium Difficile Toxin A+B/GDH Cassette
600002N-30	NADAL® Rheumatoid Factor test cassette
611003N-10	NADAL® Gonorrhea cassette
611003N-10_SSL	NADAL® Gonorrhea cassette
611005N-10	NADAL® Gonorrhea cassette
612004N-25	NADAL® CCA (Bilharzia) cassette
622001N-30	NADAL® HAV IgM test cassette
622040N-30	NADAL® HEV IgM cassette
622070N-30	NADAL® HAV IgG/IgM cassette
622070N-30_SSL	NADAL® HAV IgG/IgM cassette
652001N-30	NADAL® Chagas IgG cassette
652001N-30_SSL	NADAL® Chagas IgG cassette
662001N-30	NADAL® Leishmania cassette
672001N-30	NADAL® Filariasis cassette
672001N-30_SSL	NADAL® Filariasis cassette
682002N-20	NADAL® Chikungunya IgM Cassette

692001N-30	NADAL® Typhus Cassette
692001N-30_SSL	NADAL® Typhus Cassette
712001	NADAL® AFP Cassette
712001_SSL	NADAL® AFP Cassette
722003	NADAL® CEA Cassette
722003_SSL	NADAL® CEA Cassette
790001	NADAL® Celiac Disease tTG Cassette
790001_SSL	NADAL® Celiac Disease tTG Cassette
790002	NADAL® Celiac Disease tTG & Gliadine Cassette
795002	NADAL® ASO Latex
795003	NADAL® ASO Latex
795005	NADAL® CRP Latex
795006	NADAL® CRP Latex
795008	NADAL® RF Latex
795008_SSL	NADAL® RF Latex
795009	NADAL® RF Latex
795010	NADAL® RPR Carbon Latex
795011	NADAL® RPR Latex
795015	NADAL® VDRL
795016	NADAL® VDRL
795017	NADAL® Waaler Rose Latex
795018	NADAL® Waaler Rose Latex
795024	NADAL® IM Latex
795027	NADAL® TPHA
795028	NADAL® TPHA
795030	NADAL® Rose Bengale
850003	NADAL®Astrovirus Test Cassette
850003N-10	NADAL®Astrovirus Test Cassette
860001	NADAL® Bence Jones Proteinurie Dipstick

870001	NADAL® Lyme Borreliose Cassette
920001	NADAL® Norovirus Cassette
920001_SSL	NADAL® Norovirus Cassette
920002	NADAL® Norovirus I+ II Cassette
920002_SSL	NADAL® Norovirus I+ II Cassette
1010002N-20	NADAL® Cholera O1/O139 cassette
1120003N-20	NADAL®Candida Albicans (Cassette á 20)
1130002N-30	NADAL® HSV-1 IgG/IgM - Herpes-Simplex-Virus
1130003N-30	NADAL®HSV-2 IgG/IgM - Herpes-Simplex-Virus
1200001	NADAL® Lactoferrin – Test – Feces (Cassette á 10)
1201004N-10	NADAL® Ferritin cassette
1212001	NADAL® Calprotectin – Test – Feces (TK á 10)
1212001_SS L	NADAL® Calprotectin – Test – Feces (TK á 10)
1212002	NADAL® Calprotectin +Lactoferrin Test Feces (TK á 10)
1222001	NADAL® Enterovirus – Test – Feces (TK á 10)
1222001_SS L	NADAL® Enterovirus – Test – Feces (TK á 10)
1232001	NADAL® Campylobacter – Test – Feces (TK á 10)
1242001	NADAL® Salmonella spp. – Test – Feces (TK á 10)
1242002	NADAL® Salmonella Typhi-Test – Feces (TK á 10)
1252001	NADAL® Listeria-Test – Feces (TK á 10)
1262001	NADAL® Shigella-Test - Feces (TK á 10)
1262002	NADAL® Shigella Dysenteriae-Test – Feces (TK á 10)
1320002	NADAL® HB Hämoglobin Dipstick (á 50)

1320003	NADAL® HB Kontroll Dipstick (á 2)
1320004	NADAL® HB Kapillarröhrchen 10 µl (á 50)
2090001	NADAL® Entamoeba cassette
2090001_SS L	NADAL® Entamoeba cassette
2200001	NADAL® IgG cassette
2201001N-10	NADAL® IgE cassette
2210001	NADAL® IgE cassette

2210001_SS L	NADAL® IgE cassette
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This document is valid until 23.03.2019.

Moers, 24.03.2017
nal von minden GmbH



Sandra von Minden
CEO
nal von minden GmbH

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

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

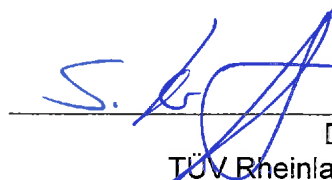
Scope: Design and development, manufacture and distribution of in vitro diagnostic test kits and reagents for the detection or determination of cardiac markers, tumor markers, infections, inflammation, allergies, endocrine disorders, diabetes, hormones, vitamins, special proteins, metabolic disorders, 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
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Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1034230-1

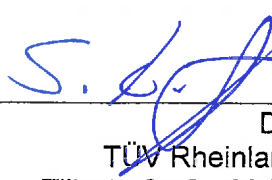
Organization: nal von minden GmbH
Carl-Zeiss-Str. 12
47445 Moers
Germany

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
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