

## 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.**

1010002N-20	NADAL® Cholera O1/O139 Test
1010002N-20_SSL	NADAL® Cholera O1/O139 Test
1120003N-20	NADAL® Candida albicans Test
1130002N-30	NADAL® HSV 1 IgG/IgM Test
1130002N-30_SSL	NADAL® HSV 1 IgG/IgM Test
1130003N-30	NADAL® HSV 2 IgG/IgM Test
1130003N-30_SSL	NADAL® HSV 2 IgG/IgM Test
1130004N-10	NADAL® HSV 1 IgG/IgM Test
1130005N-10	NADAL® HSV 2 IgG/IgM Test
1200001	NADAL® Lactoferrin Test
1201004N-10	NADAL® Ferritin Test
1201004N-10_SSL	NADAL® Ferritin Test
1212001	NADAL® Calprotectin Test
1212001_SSL	NADAL® Calprotectin Test
1212002	NADAL® Calprotectin/Lactoferrin Test
1212004N-10	NADAL® Calprotectin Test
1212004N-	NADAL® Calprotectin Test

10_SSL	
1222001	NADAL® Enterovirus Test
1222001_SSL	NADAL® Enterovirus Test
1232001	NADAL® Campylobacter Test
1232003N-10	NADAL® Campylobacter Test
1232003N-10_SSL	NADAL® Campylobacter Test
1242001	NADAL® Salmonella spp. Test
1042001_SSL	NADAL® Salmonella spp. Test
1242002	NADAL® Salmonella typhi Test
1242002_SSL	NADAL® Salmonella typhi Test
1252001	NADAL® Listeria Test
1252001_SSL	NADAL® Listeria Test
1262001	NADAL® Shigella Test
1262001_SSL	NADAL® Shigella Test
1262002	NADAL® Shigella dysenteriae Test
1062002_SSL	NADAL® Shigella dysenteriae Test
1262004N-10	NADAL® Shigella Test
1262004N-10_SSL	NADAL® Shigella Test

1320100	NADAL® Hb/Hct plus Analyser
1320101	NADAL® Hb/Hct plus Mikroküvette
1320103	NADAL® Hb/Hct plus Kontrollen
1320104	NADAL® Hb/Hct plus Kalibrator
141000	NADAL® hCG Pregnancy Test
141000_SSL	NADAL® hCG Pregnancy Test
141000N-10	NADAL® hCG Pregnancy Test
141002	NADAL® hCG Pregnancy Test
141002_SSL	NADAL® hCG Pregnancy Test
141002N-10	NADAL® hCG Pregnancy Test
141002N-10_SSL	NADAL® hCG Pregnancy Test
141002N-25	NADAL® hCG Pregnancy Test
142000	NADAL® hCG Preganacy Test
142000N-10	NADAL® hCG Preganacy Test
142002	NADAL® hCG Pregnancy Test
143003	NADAL® hCG Pregnancy Test
143004	NADAL® hCG Pregnancy Test
143004_SSL	NADAL® hCG Pregnancy Test
144001N-10	NADAL® hCG Pregnancy Test
151002	NADAL® hCG Pregnancy Test
151002SE	NADAL® hCG Pregnancy rapid test
151003	NADAL® hCG Pregnancy Test
152000	NADAL® hCG Pregnancy Test
152002	NADAL® hCG Pregnancy Test
152002BA	NADAL® hCG Pregnancy Test Barcoded
152003	NADAL® hCG Pregnancy Test
153003	NADAL® hCG Pregnancy Test
153003_SSL	NADAL® hCG Pregnancy Test
161001	NADAL® hLH Ovulation Test
161001_SSL	NADAL® hLH Ovulation Test
162001_SSL	NADAL® hLH Ovulation Test
165001	NADAL® hLH Ovulation Test
165001_SSL	NADAL® hLH Ovulation Test
166001	NADAL® hLH Ovulation Test

166001_SSL	NADAL® hLH Ovulation Test
172003N-10	NADAL® FSH Menopause Test
1770001	NADAL® Mycoplasma Test
194002	NADAL® pH-Test
1941950	NADAL® Influenza A/B Puffer
203001	NADAL® Syphilis Test
203002	NADAL® Syphilis Test
203002_SSL	NADAL® Syphilis Test
203003	NADAL® Syphilis Test
2090001	NADAL® Entamoeba Test
2090001_SSL	NADAL® Entamoeba Test
2190009	NADAL® Procalcitonin Quant RFID Chip
2190010BUL	NADAL® Procalcitonin Quant Test
2190010NBUL-20	NADAL® Procalcitonin Quant Test
2200001N-30	NADAL® IgG Test
2201001N-10	NADAL® IgE Test
2210001N-20	NADAL® Ebola Test
2210001N-20_SSL	NADAL® Ebola Test
2210002	NADAL® Ebola Zubehör
221001A	NADAL® Strep A Test
221005	NADAL® Strep A reagenz 1
221006	NADAL® Strep A reagenz 2
221050N-50	NADAL® Strep A plus Test
221050N-50_SSL	NADAL® Strep A plus Test
222001A	NADAL® Strep A Test
222007	NADAL® Strep A plus Test
222008	NADAL® Strep A plus Test
222008_SSL	NADAL® Strep A plus Test
222015N-20	NADAL® Strep A Scan Test
222049NBUL-20	NADAL® Strep A Scan Test
222049NBUL-20_SSL	NADAL® Strep A Scan Test
232001	NADAL® Strep B Test
232001_SSL	NADAL® Strep B Test

232005	NADAL® Strep B reagenz 1
232005_SSL	NADAL® Strep B reagenz 1
232006	NADAL® Strep B reagenz 2
232006_SSL	NADAL® Strep B reagenz 2
241005N-10	NADAL® Influenza A/B Test
241006N-25	NADAL® Influenza A/B Test
241006N-25_SSL	NADAL® Influenza A/B Test
241013	NADAL® Influenza A/B Test
241013N-10	NADAL® Influenza A/B Test
241014N-10	NADAL® Influenza A/B plus Test
241015N-10	NADAL® Influenza A/B Test
241015	NADAL® Influenza A/B Test
242001	NADAL® Influenza A/B Test
242006N-10	NADAL® Influenza A/B Test
242006NBUL-10	NADAL® Influenza A/B Scan Test
242006NBUL-10_SSL	NADAL® Influenza A/B Scan Test
242011N-10	NADAL® Influenza A/B Test
242014N-10	NADAL® Influenza A/B plus Test
242015	NADAL® Influenza A/B Test
242015N-10	NADAL® Influenza A/B Test
243001N-10	NADAL® COVID-19 IgG/IgM Test
243003N-25	NADAL® COVID-19 IgG/IgM Test
243004N-25	NADAL® COVID-19 IgG/IgM plus Test
243103N-20	NADAL® COVID-19 Ag Test
243104N-01	NADAL® COVID-19 Ag plus Test
243104N-20	NADAL® COVID-19 Ag plus Test
243203N-20	NADAL® COVID-19 Ag+Influenza A/B Test
243204N-20	NADAL® COVID-19 Ag+Influenza A/B plus Test
252001	NADAL® Mononucleosis Test
252003	NADAL® Mononucleosis Test
252003N-20	NADAL® Mononucleosis Test
252003N-20_SSL	NADAL® Mononucleosis Test
252017	NADAL® Mononucleosis Test

252017N-05	NADAL® Mononucleosis Test
252017N-05_SSL	NADAL® Mononucleosis Test
252019	NADAL® Mononucleosis Test
252019N-10	NADAL® Mononucleosis Test
262001	NADAL® H. pylori Ab Test
262001_SSL	NADAL® H. pylori Ab Test
262002	NADAL® H. pylori Ag Test
262004NBUL-10	NADAL® H. pylori Ag Scan Test
262004NBUL-10_SSL	NADAL® H. pylori Ag Scan Test
272001	NADAL® FOB Test
272001_SSL	NADAL® FOB Test
272007	NADAL® FOB & Hb/Hp Extraktionsröhrchen
272007_SSL	NADAL® FOB & Hb/Hp Extraktionsröhrchen
272011N-25	NADAL® Hb/Hp Complex plus Test
272015	NADAL® Hb/Hp Complex Test
272015_SSL	NADAL® Hb/Hp Complex Test
272016N-25	NADAL® FOB plus Test
272031RU	NADAL® Hb/Hp Complex Test
272031RU_SSL	NADAL® Hb/Hp Complex Test
272035N-25	NADAL® FOB60 plus Test
272035N-25_SSL	NADAL® FOB60 plus Test
272037	NADAL® FOB & Hb/Hp Patientenset
272037_SSL	NADAL® FOB & Hb/Hp Patientenset
272038	NADAL® FOB/Transferrin Test
272039	NADAL® FOB10 Test
272039N-20	NADAL® FOB10 Test
272040	NADAL® FOB II Test
272041	NADAL® FOB60 Test
272041_SSL	NADAL® FOB60 Test
272042	NADAL® FOB75 Test
272043	NADAL® FOB75 II Test
272055	NADAL® FOB Test

282000	NADAL® Troponin I Test
282000_SSL	NADAL® Troponin I Test
282001	NADAL® Troponin I Test
282001_SSL	NADAL® Troponin I Test
282003	NADAL® Cardiac Combo Test
282015	NADAL® Troponin I Test
282015_SSL	NADAL® Troponin I Test
282018	Vollblutbuffer
282018_SSL	Vollblutbuffer
282041	NADAL® Troponin I Test
282041N-05	NADAL® Troponin I Test
282041N-10	NADAL® Troponin I Test
282041N-20	NADAL® Troponin I Test
292001N-05	NADAL® Myoglobin Test
302001	NADAL® CK-MB Test
302001_SSL	NADAL® CK-MB Test
311003N-10	NADAL® CrP Test
311003N-20	NADAL® CrP Test
311004	NADAL® CRP plus Test
311006	NADAL® CRP plus Test
311804N-20	NADAL® CRP plus Test
312001	NADAL® CrP Test
312001_SSL	NADAL® CrP Test
312002	NADAL® High Sensitivity CrP Test
312021NBUL-20	NADAL® CRP Quant Test
312021NBUL-20_SSL	NADAL® CRP Quant Test
312021NBUL-40	NADAL® CRP Quant Test
312021NBUL-40_SSL	NADAL® CRP Quant Test
312023BUL	NADAL® CRP Quant Test
312023NBUL-20	NADAL® CRP Quant Test
312023NBUL-40	NADAL® CRP Quant Test
322003N-30	NADAL® Tuberkulose IgG/IgM Test
322003N-30_SSL	NADAL® Tuberkulose IgG/IgM Test

331001	NADAL® Microalbumin Test
331004N-50	NADAL® Microalbumin Test
351006	NADAL® D-Dimer Test
351006_SSL	NADAL® D-Dimer Test
351006N-05	NADAL® D-Dimer Test
351006N-10	NADAL® D-Dimer Test
351006N-25	NADAL® D-Dimer Test
351007	NADAL® D-Dimer Test
351007_SSL	NADAL® D-Dimer Test
431001N-20	NADAL® PROM Amniotic fluid Test
431006N-01	NADAL® PROM Amniotic fluid Test
431006N-03	NADAL® PROM Amniotic fluid Test
431006N-03_SSL	NADAL® PROM Amniotic fluid Test
431006N-10	NADAL® PROM Amniotic fluid Test
431006N-10_SSL	NADAL® PROM Amniotic fluid Test
431006N-20	NADAL® PROM Amniotic fluid Test
431006N-20_SSL	NADAL® PROM Amniotic fluid Test
432000N-03	NADAL® fFN Test
432000N-03_SSL	NADAL® fFN Test
432000N-10	NADAL® fFN Test
432000N-20	NADAL® fFN Test
432000N-20_SSL	NADAL® fFN Test
472003N-10	NADAL® Malaria 4 species Test
472003N-25	NADAL® Malaria 4 species Test
472003N-25_SSL	NADAL® Malaria 4 species Test
472008	NADAL® Malaria 4 species Test
472030N-01	NADAL® Malaria Pf/Pan Ag 4 Species Test
472030N-10	NADAL® Malaria Pf/Pan Ag 4 Species Test
472030N-25	NADAL® Malaria Pf/Pan Ag 4 Species Test
472036N-25	NADAL® Malaria Pf Ag Test
472036N-25_SSL	NADAL® Malaria Pf Ag Test

472038	NADAL® Malaria Pf/Pan Ag 4 Species Test
472038BA	NADAL® Malaria Pf/Pan Ag 4 Species Test Barcoded
472038N-25	NADAL® Malaria Pf/Pan Ag 4 Species Test
472040N-01	NADAL® Malaria Pf/Pan Ag 4 Species plus Test
472040N-25	NADAL® Malaria Pf/Pan Ag 4 Species plus Test
472040N-10	NADAL® Malaria Pf/Pan Ag 4 Species plus Test
481015	NADAL® Rota-Adenovirus Test
481015_SSL	NADAL® Rota-Adenovirus Test
481015N-20	NADAL® Rota-Adenovirus Test
481016	NADAL® Adenovirus Test
481016_SSL	NADAL® Adenovirus Test
481017	NADAL® Rotavirus Test
481017_SSL	NADAL® Rotavirus Test
481049NBUL-10	NADAL® Rota-Adenovirus Scan Test
481049NBUL-10_SSL	NADAL® Rota-Adenovirus Scan Test
491000N-10	NADAL® RSV Test
491000N-10_SSL	NADAL® RSV Test
491003N-25	NADAL® RSV Test
491003N-25_SSL	NADAL® RSV Test
491005	NADAL® RSV Test
491008NBUL-20	NADAL® RSV Scan Test
491008NBUL-20_SSL	NADAL® RSV Scan Test
491009	NADAL® RSV-Adenovirus Respiratory Test
491009_SSL	NADAL® RSV-Adenovirus Respiratory Test
495001	NADAL® MRSA Latextest
495001_SSL	NADAL® MRSA Latextest
501006	NADAL® E.coli O157 Test
501006_SSL	NADAL® E.coli O157 Test
501012	NADAL® EHEC Verotoxin 1/2 Test

501012_SSL	NADAL® EHEC Verotoxin 1/2 Test
511006	NADAL® Cryptosporidium Test
511006_SSL	NADAL® Cryptosporidium Test
521001	NADAL® Giardia Test
521001_SSL	NADAL® Giardia Test
521009	NADAL® Giardia Test
521009_SSL	NADAL® Giardia Test
521010	NADAL® Crypto/Giardia Test
521010_SSL	NADAL® Crypto/Giardia Test
532001_SSL	NADAL® Dengue IgG/IgM Test
532001N-25	NADAL® Dengue IgG/IgM Test
532002N-25	NADAL® Dengue Ag Test
532003N-25	NADAL® Dengue Ag+IgG/IgM Test
532003N-25_SSL	NADAL® Dengue Ag+IgG/IgM Test
532004N-25	NADAL® Dengue IgG/IgM Test
532004N-25_SSL	NADAL® Dengue IgG/IgM Test
532011N-25	NADAL® Dengue IgG/IgM Test
532011N-25_SSL	NADAL® Dengue IgG/IgM Test
532012N-25	NADAL® Dengue NS1 Ag Test
532012N-25_SSL	NADAL® Dengue NS1 Ag Test
532016N-25	NADAL® Dengue NS1 Ag+IgG/IgM Test
532016N-25_SSL	NADAL® Dengue NS1 Ag+IgG/IgM Test
542001N-25	NADAL® Tetanus Test
542020N-25	NADAL® Tetanus Test
552005	NADAL® Legionella Test
552005_SSL	NADAL® Legionella Test
552006	NADAL® Legionella Test
552006_SSL	NADAL® Legionella Test
552020	NADAL® Legionella Test
552020_SSL	NADAL® Legionella Test
552022	NADAL® Legionella Test
552022N-10	NADAL® Legionella Test
562003	NADAL® BCA/Hb Combo Test

562003N-10	NADAL® BCA/Hb Combo Test
562003RU	NADAL® BCA/Hb Combo Test
572004N-10	NADAL® S. pneumoniae Test
572005	NADAL® Legionella/S. pneumoniae Test
580005N-25	NADAL® TSH Test
582004	NADAL® C. difficile GDH Ag Test
582008	NADAL® C. difficile Toxins A/B Test
582008_SSL	NADAL® C. difficile Toxins A/B Test
582016N-10	NADAL® C. difficile Toxin A+B/GDH Test
582022	NADAL® C. difficile Toxin A+B/GDH Test
582022N-10	NADAL® C. difficile Toxin A+B/GDH Test
600002N-30	NADAL® Rheumatoid Factor Test
600002N-30_SSL	NADAL® Rheumatoid Factor Test
611005N-10	NADAL® Gonorrhea Test
612004N-25	NADAL® CCA (Bilharzia) Test
612004N-25_SSL	NADAL® CCA (Bilharzia) Test
622040N-30	NADAL® HEV IgM Test
622040N-30_SSL	NADAL® HEV IgM Test
622070N-30	NADAL® HAV IgG/IgM Test
622070N-30_SSL	NADAL® HAV IgG/IgM Test
652001N-30	NADAL® Chagas IgG Test
652001N-30_SSL	NADAL® Chagas IgG Test
672001N-30	NADAL® Filariasis IgG/IgM Test
672001N-30_SSL	NADAL® Filariasis IgG/IgM Test
682002N-20	NADAL® Chikungunya IgM Test
692001N-30	NADAL® Typhoid IgG/IgM Test
692001N-30_SSL	NADAL® Typhoid IgG/IgM Test
692003	NADAL® Typhoid IgG/IgM Test
692003N-10	NADAL® Typhoid IgG/IgM Test
692003N-10_SSL	NADAL® Typhoid IgG/IgM Test

712001	NADAL® AFP Test
712001_SSL	NADAL® AFP Test
722003	NADAL® CEA Test
722003_SSL	NADAL® CEA Test
780022	Influenza Puffer Bulk
790001	NADAL® Celiac Disease tTG Test
790001_SSL	NADAL® Celiac Disease tTG Test
790002	NADAL® Celiac Disease tTG /Gliadine Test
790002_SSL	NADAL® Celiac Disease tTG /Gliadine Test
790004	NADAL® Celiac Disease tTG IgA Test
790004N-10	NADAL® Celiac Disease tTG IgA Test
795002	NADAL® ASO Latextest
795002_SSL	NADAL® ASO Latextest
795003	NADAL® ASO Latextest
795003_SSL	NADAL® ASO Latextest
795005	NADAL® CRP Latextest
795006	NADAL® CRP Latextest
795008	NADAL® Rheumatoid Factors Latextest
795008_SSL	NADAL® Rheumatoid Factors Latextest
795009	NADAL® Rheumatoid Factors Latextest
795009_SSL	NADAL® Rheumatoid Factors Latextest
795010	NADAL® RPR Carbon Latextest
795010_SSL	NADAL® RPR Carbon Latextest
795011	NADAL® RPR Carbon Latextest
795011_SSL	NADAL® RPR Carbon Latextest
795015	NADAL® VDRL Latextest
795015_SSL	NADAL® VDRL Latextest
795016	NADAL® VDRL Latextest
795016_SSL	NADAL® VDRL Latextest
795017	NADAL® Waaler Rose Latextest
795018	NADAL® Waaler Rose Latextest

795018_SSL	NADAL® Waaler Rose Latextest
795024	NADAL® IM Latextest
795024_SSL	NADAL® IM Latextest
795027	NADAL® TPHA Test
795027_SSL	NADAL® TPHA Test
795028	NADAL® TPHA Test
795028_SSL	NADAL® TPHA Test
795030	NADAL® Rose Bengale Latextest
840003N-10	NADAL® Trichomonas vaginalis Test
850003	NADAL® Astrovirus Test
850003_SSL	NADAL® Astrovirus Test
870001	NADAL® Lyme Borreliosis IgG/IgM Test
870004N-01	NADAL® Borreliosis Ag Test

870004N-01_SSL	NADAL® Borreliosis Ag Test
870004N-05	NADAL® Borreliosis Ag Test
920002	NADAL® Norovirus GI/GII Test
920002_SSL	NADAL® Norovirus GI/GII Test
920002N-01	NADAL® Norovirus GI/GII Test
920002N-01_SSL	NADAL® Norovirus GI/GII Test
920006	NADAL® Norovirus GI/GII Test
920006N-10	NADAL® Norovirus GI/GII Test
920007	NADAL® Norovirus GI/GII+Rota-Adenovirus Test
920007N-10	NADAL® Norovirus GI/GII+Rota-Adenovirus Test

This document is valid until 2023-04-08

Moers, 12.08.2021

nal von minden GmbH



nal von minden GmbH  
Carl-Zeiss-Straße 12  
47445 Moers  
Tel: +49 2533 99820-0  
Fax: +49 2533 99820-1  
info@nal-vonminden.de

**Sandra von Minden**

CEO

nal von minden GmbH