

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 / Germany
 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
1130004N-10	NADAL® HSV 1 IgG/IgM Test
113005N-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-10_SSL	NADAL® Calprotectin Test
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 microcuvette
141000	NADAL® hCG Pregnancy Test
141000_SSL	NADAL® hCG Pregnancy Test
141000N-10	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
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
172003N-10_SSL	NADAL® FSH Menopause Test
1770001	NADAL® Mycoplasma Test
1770001_SSL	NADAL® Mycoplasma Test
194002	NADAL® pH-Test
1941333	NADAL® Infectious Diseases
	extraction tube
1941338	Infectious Diseases extraction tube
1941950	NADAL® Influenza A/B Buffer
1941951	Influenza A/B Test (4mm)
1941970	Infectious Diseases (Bacterial)
	Extraction tube

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
2190010NBUL-20	NADAL® Procalcitonin Quant Test
2190011NBUL-20	NADAL® Procalcitonin Test
2201001N-10	NADAL® IgE Test
2210001N-20	NADAL® Ebola Test
2210001N-20_SSL	NADAL® Ebola Test
2210002	NADAL® Ebola Accessoires
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
222015N-20_SSL	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
241015	NADAL® Influenza A/B Test
241015N-10	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
252003	NADAL® Mononucleosis Test
252003_SSL	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 extraction tube

272007_SSL	NADAL® FOB & Hb/Hp extraction tube
272007N-10	NADAL® FOB & Hb/Hp extraction tube
272007N-20	NADAL® FOB & Hb/Hp extraction tube
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 patient set
272037_SSL	NADAL® FOB & Hb/Hp patient set
272038	NADAL® FOB/Transferrin Test
272038_SSL	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
272048	FOB extraction tube
272048_SSL	FOB extraction tube
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	Whole blood buffer
282018_SSL	Whole blood buffer
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
311013	CRP Puffer
311013_SSL	CRP Puffer
312001	NADAL® CrP Test
312001_SSL	NADAL® CrP Test
312002	NADAL® High Sensitivity CrP Test
312002_SSL	NADAL® High Sensitivity CrP Test
312017	NADAL® CRP Quant RFID Chip
312017_SSL	NADAL® CRP Quant RFID Chip
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
331001_SSL	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
351006N-25_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
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-10	NADAL® Malaria PF/Pan Ag 4 Species plus Test
472040N-25	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 latex test
495001_SSL	NADAL® MRSA latex test
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
521009	NADAL® Giardia Test
521009_SSL	NADAL® Giardia Test
521010	NADAL® Crypto/Giardia Test
521010_SSL	NADAL® Crypto/Giardia Test
532001N-25	NADAL® Dengue IgG/IgM Test
532001N-	NADAL® Dengue IgG/IgM Test

25_SSL	
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
542020N-25	NADAL® Tetanus Test
542020N-25_SSL	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
562003N-10	NADAL® BCA/Hb Combo Test
562003RU	NADAL® BCA/Hb Combo Test
572004N-10	NADAL® S. pneumonia 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
692003	NADAL® Typhoid IgG/IgM Test
692003N-10	NADAL® Typhoid IgG/IgM Test
712001	NADAL® AFP Test
712001_SSL	NADAL® AFP Test
722003	NADAL® CEA Test
722003_SSL	NADAL® CEA Test
790001	NADAL® Celiac Disease tTG Test
790001_SSL	NADAL® Celiac Disease tTG Test
790004	NADAL® Celiac Disease tTG IgA Test
790004N-10	NADAL® Celiac Disease tTG IgA Test
795002	NADAL® ASO latex test
795002_SSL	NADAL® ASO latex test
795003	NADAL® ASO latex test
795003_SSL	NADAL® ASO latex test
795005	NADAL® CRP latex test
795006	NADAL® CRP latex test
795008	NADAL® Rheumatoid Factors latex test
795008_SSL	NADAL® Rheumatoid Factors latex test

	test
795009	NADAL® Rheumatoid Factors latex test
795009_SSL	NADAL® Rheumatoid Factors latex test
795010	NADAL® RPR Carbon latex test
795010_SSL	NADAL® RPR Carbon latex test
795011	NADAL® RPR Carbon latex test
795011_SSL	NADAL® RPR Carbon latex test
795015	NADAL® VDRL latex test
795015_SSL	NADAL® VDRL latex test
795016	NADAL® VDRL latex test
795016_SSL	NADAL® VDRL latex test
795017	NADAL® Waaler Rose latex test
795018	NADAL® Waaler Rose latex test
795018_SSL	NADAL® Waaler Rose latex test
795024	NADAL® IM latex test
795024_SSL	NADAL® IM latex test
795027	NADAL® TPHA Test
795027_SSL	NADAL® TPHA Test
795028	NADAL® TPHA Test
795028_SSL	NADAL® TPHA Test
795030	NADAL® Rose Bengale latex test
840003N-10	NADAL® Trichomonas vaginalis Test
850003	NADAL® Astrovirus Test
850003_SSL	NADAL® Astrovirus Test
870001	NADAL® Lyme Borreliosis IgG/IgM 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 **2024-01-26**

Moers, 27.01.2022
nal von minden GmbH



Sandra von Minden
CEO