

EC-Declaration of Conformity

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

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

We herewith declare on our sole responsibility that all batches of the below 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.

The conformity assessment procedure for these products was carried out before 26 May 2022 in accordance with Directive 98/79/EC. Due to the previously established validity period of 24 months for each Declaration of Conformity issued by us, this is an updated version of the Declaration of Conformity issued prior to 26 May 2022. It is now valid until the end of the transitional period for this legacy product. Since 26 May 2022, no significant changes have been made to the design and intended use of the products in accordance with the requirements for legacy products.

Article Numbers (REF)	Article name
1130004N-10	NADAL® HSV 1 IgG/IgM Test
1130005N-10	NADAL® HSV 2 IgG/IgM Test
1200001	NADAL® Lactoferrin Test
1212001	NADAL® Calprotectin Test
1212002	NADAL® Calprotectin/Lactoferrin Test
1212004N-10	NADAL® Calprotectin Test
1222001	NADAL® Enterovirus Test
1232001	NADAL® Campylobacter Test
1242001	NADAL® Salmonella spp. Test
141000	NADAL® hCG Pregnancy Test
141002	NADAL® hCG Pregnancy Test
142000	NADAL® hCG Pregnancy Test
142000D-30	dedicio® hCG Pregnancy Test
142002	NADAL® hCG Pregnancy Test
143003	NADAL® hCG Pregnancy Test
143004	NADAL® hCG Pregnancy Test

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144001N-10	NADAL® hCG Pregnancy Test
151002	NADAL® hCG Pregnancy Test
151002SE	NADAL® hCG Pregnancy Test
151003	NADAL® hCG Pregnancy Test
152000	NADAL® hCG Pregnancy Test
152002	NADAL® hCG Pregnancy Test
152002BA	NADAL® hCG Pregnancy Test barcoded
153003	NADAL® hCG Pregnancy Test
165001	NADAL® hLH Ovulation Test
166001	NADAL® hLH Ovulation Test
1770001	NADAL® Mycoplasma Test
194002	NADAL® pH Test
203001	NADAL® Syphilis Test
203002	NADAL® Syphilis Test
203901N-40	NADAL® Syphilis Test
203902N-20	NADAL® Syphilis Test
2090001	NADAL® Entamoeba Test
2190010NBUL-20	NADAL® Procalcitonin Quant Test
221001A	NADAL® Strep A Test
221001D-20	dedicio® Strep A Test
221901N-40	NADAL® Strep A Test
222001A	NADAL® Strep A Test
222001D-20	dedicio® Strep A Test
222007	NADAL® Strep A plus Test
222049NBUL-20	NADAL® Strep A Scan Test
222901D-20	dedicio® Strep A Test
222901N-20	NADAL® Strep A Test
2260004NBUL-25	NADAL® Vitamin D Quant Test
232001	NADAL® Strep B Test
232001D-20	dedicio® Strep B Test
242006NBUL-10	NADAL® Influenza A/B Scan Test
242015N-10	NADAL® Influenza A/B Test
242915N-10	NADAL® Influenza A/B Test
243001N-10	NADAL® COVID-19 IgG/IgM Test
243103N-20	NADAL® COVID-19 Ag Test
243103N-25PA	NADAL® COVID-19 Ag Test
243104D-20	dedicio® COVID-19 Ag plus Test
243204N-25PA	NADAL® COVID-19 Ag+Influenza A/B plus Test
243301N-20	NADAL® COVID-19 S1-NAb Test

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252003N-20	NADAL® Mononucleosis Test
252017D-05	dedicio® Mononucleosis Test
252017N-05	NADAL® Mononucleosis Test
262001	NADAL® H. pylori Ab Test
262001D-20	dedicio® H. pylori Ab Test
262002	NADAL® H. pylori Ag Test
262002D-20	dedicio® H. pylori Ag Test
262902D-20	dedicio® H. pylori Ag Test
262902N-20	NADAL® H. pylori Ag Test
272001	NADAL® FOB Test
272001D-20	dedicio® FOB Test
272011N-25	NADAL® Hb/Hp Complex plus Test
272015	NADAL® Hb/Hp Complex Test
272016N-25	NADAL® FOB plus Test
272039N-20	NADAL® FOB10 Test
272040D-20	dedicio® FOB II Test
272042	NADAL® FOB75 Test
272043	NADAL® FOB75 II Test
272059BUL	NADAL® FOB Quant Test
272059NBUL-20	NADAL® FOB Quant Test
282003	NADAL® Cardiac Combo Test
282041D-05	dedicio® Troponin I Test
282041N-05	NADAL® Troponin I Test
282041N-10	NADAL® Troponin I Test
282041N-20	NADAL® Troponin I Test
302001	NADAL® CK-MB Test
311801D-10	dedicio® CRP Test
311801N-20	NADAL® CRP Test
311804D-10	dedicio® CRP plus Test
311804N-20	NADAL® CRP plus Test
312001	NADAL® CRP Test
312023NBUL-20	NADAL® CRP Quant Test
312024NBUL-20	NADAL® CRP Quant Test
322003N-30	NADAL® Tuberculosis IgG/IgM Test
331001	NADAL® Microalbumin Test
331004N-50	NADAL® Microalbumin Test
351003	NADAL® D-Dimer Test
351006D-05	dedicio® D-Dimer Test
351006N-05	NADAL® D-Dimer Test
351006N-10	NADAL® D-Dimer Test

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431006N-03	NADAL® PROM Amniotic fluid Test
431006N-10	NADAL® PROM Amniotic fluid Test
431006N-20	NADAL® PROM Amniotic fluid Test
431006TR-01	NADAL® PROM Amniotic fluid Test
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
481016	NADAL® Adenovirus Test
481017	NADAL® Rotavirus Test
491005	NADAL® RSV Test
491005D-20	dedicio® RSV Test
491008BUL	NADAL® RSV Test
491008N-20	NADAL® RSV Test
491008NBUL-20	NADAL® RSV Scan Test
491009	NADAL® RSV-Adenovirus Respiratory Test
491905D-20	dedicio® RSV Test
491905N-20	NADAL® RSV Test
501006	NADAL® E. coli O157 Test
511006	NADAL® Cryptosporidium Test
521011N-10	NADAL® Giardia Test
532019N-10	NADAL® Dengue NS1 Ag+IgG/IgM Test
532919N-10	NADAL® Dengue NS1 Ag+IgG/IgM Test
542020N-25	NADAL® Tetanus Test
552020	NADAL® Legionella Test
562003D-10	dedicio® BCA/Hb Combo Test
562003N-10	NADAL® BCA/Hb Combo Test
562006DGE-10	dedicio® BCA/Hb Combo Basic Test
572004D-10	dedicio® S. pneumoniae 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 Toxin A/B Test
582008D-10	dedicio® C. difficile Toxin A/B Test
582022D-10	dedicio® C. difficile Toxin A/B+GDH Test

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582022N-10	NADAL® C. difficile Toxin A/B+GDH Test
611005N-10	NADAL® Gonorrhea Test
622070N-30	NADAL® HAV IgG/IgM Test
682002N-20	NADAL® Chikungunya IgM Test
790004	NADAL® Celiac Disease tTG IgA Test
790004N-10	NADAL® Celiac Disease tTG IgA Test
795003	NADAL® ASO Latextest
795005	NADAL® CRP Latextest
795006	NADAL® CRP Latextest
795008	NADAL® Rheumatoid Factors Latextest
795009	NADAL® Rheumatoid Factors Latextest
795011	NADAL® RPR Carbon Test
795015	NADAL® VDRL Test
795017	NADAL® Waaler-Rose Test
795018	NADAL® Waaler-Rose Test
795024	NADAL® IM Latextest
795027	NADAL® TPHA Test
840003N-10	NADAL® Trichomonas vaginalis Test
850003	NADAL® Astrovirus Test
870001N-10	NADAL® Lyme Borreliosis IgG/IgM Test
920002	NADAL® Norovirus GI/GII Test
920006N-10	NADAL® Norovirus GI/GII Test
920007N-10	NADAL® Norovirus GI/GII+Rota-Adenovirus Test
790004	NADAL® Celiac Disease tTG IgA Test
790004N-10	NADAL® Celiac Disease tTG IgA Test
795003	NADAL® ASO Latextest
795005	NADAL® CRP Latextest
795006	NADAL® CRP Latextest
795008	NADAL® Rheumatoid Factors Latextest
795009	NADAL® Rheumatoid Factors Latextest
795011	NADAL® RPR Carbon Test
795015	NADAL® VDRL Test
795017	NADAL® Waaler-Rose Test
795018	NADAL® Waaler-Rose Test
795024	NADAL® IM Latextest
795027	NADAL® TPHA Test
840003N-10	NADAL® Trichomonas vaginalis Test
850003	NADAL® Astrovirus Test
870001N-10	NADAL® Lyme Borreliosis IgG/IgM Test

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920002	NADAL® Norovirus GI/GII Test
920006N-10	NADAL® Norovirus GI/GII Test
920007N-10	NADAL® Norovirus GI/GII+Rota-Adenovirus Test

This document is valid until 2025-05-26.

Moers, 2023-02-22

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