

## 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
141002	NADAL® hCG Pregnancy Test 25 mIU/ml dipstick
141005	hCG positive control
141006	hCG negative control
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
144001	NADAL® hCG Pregnancy Test, Midstream 20 mIU/ml cassette
144002	NADAL® hCG2000 – TEST Midstream – Urin (á 10)
151002	NADAL® hCG Pregnancy
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
164001	NADAL® hLH Ovulation 30 mIU/ml Midstream
165001	NADAL® hLH Ovulation 30 mIU/ml dipstick
166001	NADAL® hLH Ovulation 30 mIU/ml cassette
172001	NADAL® FSH cassette
194002	NADAL® pH-Test
201001	NADAL® Syphilis dipstick
202001	NADAL® Syphilis cassette
221001A	NADAL® Strep A dipstick
222001A	NADAL® Strep A cassette
222006	NADAL® Strep A Comfort cassette
222009	Strep A positive control
222010	Strep A negative control
232001	NADAL® Strep B cassette
241005N-10	NADAL® Influenza A+B dipstick
241006	NADAL® Influenza A+B dipstick
241008	Influenza A+B positive control
241011	NADAL® Influenza A+B dipstick
242001	NADAL® Influenza A+B cassette

252001	NADAL® Mononukleose cassette
252002	NADAL® Mononukleose dipstick
262001	NADAL® H.Pylori Antikörper cassette
262002	NADAL® H.Pylori Antigen cassette
262006	NADAL® H. pylori Antigen control (3ml)
262008	H. pylori Antigen Positive control – Pylorigen
262013	H. pylori Positive Control
262014	H. pylori Negative Control
272001	NADAL® FOB cassette
272011	NADAL® Hb/Hp cassette
272012	FOB Positive Control
272013	FOB Negative Control
272015	NADAL® Hb/Hp Complex cassette
272016	NADAL® FOB plus cassette
282000	NADAL® Troponin I cassette
282001	NADAL® Troponin I cassette
282003	NADAL® Trop I, CK-MB, Myoglobin Combi- cassette
282035	Troponin I positive control
282037	Troponin I negative control
292001	NADAL® Myoglobin cassette
302001	NADAL® CK-MB cassette
311001	NADAL® CrP Dipstick
312001	NADAL® CrP cassette
312002	NADAL® high sensitive CrP cassette
322003N-30	NADAL® Tuberkulose IgG/IgM cassette
331001	NADAL® Mikroalbumin Dipstick
351003	NADAL® D-Dimer cassette
374018	qLabs aPTT-INR Control
431000	NADAL® PROM Test Dipstick
431001N-03	NADAL® PROM Test Dipstick
431001N-10	NADAL® PROM Test Dipstick
431001N-20	NADAL® PROM Test Dipstick

431003	NADAL® PROM Test Dipstick
472001N-25	NADAL® Malaria Pf Ag test cassette
472003N-25	NADAL® Malaria 4 species cassette
472030N-25	NADAL® Malaria Pf/Pan Ag 4Species cassette
481013	Adenovirus Positive Control
481015	NADAL® Rota-Adenovirus cassette
481016	NADAL® Adenovirus cassette
481017	NADAL® Rotavirus cassette
481019	NADAL® Rota-Adenovirus-Test – Feces cassette
481020	Adenovirus Positive Control
481021	Rotavirus Positive Control
491000N-10	NADAL® RSV plus Dipstick
491003N-25	NADAL® RSV Dipstick
491005	NADAL® RSV cassette
491006	RSV Positive Control
491009	NADAL® RSV-Adeno Resp cassette
491012	Negative Control RSV
495001	NADAL® MRSA Screen Latex-Agglutinationstest
501005	NADAL® E.coli O157 Positive Control (à 1)
501006	NADAL® E.coli O157 Cassette
501012	NADAL® EHEC Verotoxin 1-2, feces - cassette á 10
511004	NADAL® Cryptosporidien cassette
511005	NADAL® Cryptosporidium Positive Control (à 1)
511006	NADAL® CRYPTOSPORIDIEN – TEST
521008	NADAL® Giardia Positive Control (à 1)
521009	NADAL® Giardia cassette
521010	NADAL® Giardia-Crypto-Combo cassette
532001N-25	NADAL® Dengue cassette
532002N-25	NADAL® Dengue cassette
532003N-25	NADAL® Dengue cassette
532004N-25	NADAL® Dengue cassette

532011	NADAL® Dengue IgG/IgM cassette
532011N-25	NADAL® Dengue IgG/IgM cassette
532012N-25	NADAL® Dengue NS1 Ag Cassette Test
542001N-25	NADAL® Tetanus cassette
542005	NADAL® Tetanus cassette
552005	NADAL® Legionella Urin Antigen cassette
552006	NADAL® Legionella Urin Antigen cassette
552012	Generic Negative Control
552015	Legionella positive control
552020	NADAL® Legionella Urine Antigen test
562003	NADAL® BCA/HB inkl.
572004N-10	NADAL® Streptococcus pneumoniae cassette
572007	Streptococcus pneumoniae positive control
580004	NADAL® TSH Test cassette
582004	NADAL® Clostridium Difficile GDH
582005	Clostridium difficile Toxin A+ B Positive control
582007	Clostridium difficile GDH Positive Control
582008	NADAL® Clostridium Difficile Toxins A&B cassette
582011	Clostridium Difficile Toxin A positive control
582012	Clostridium Difficile Toxin B positive control
582009	NADAL® Clostridium perfringens Ag- cassette
600002N-30	NADAL® Rheumatoid Factor test cassette
600001	NADAL® Rheumafaktoren Dipstick
611003N-10	NADAL® Gonorrhö cassette
611006	Gonorrhoea positive control
612001N-25	NADAL® CCA (Bilharzia) cassette
622000	NADAL® HAV-test Hepatitis A IgM cassette
622001N-30	NADAL® HAV IgM test cassette

622040N-30	HEV-TEST Hepatitis E IgM cassette
652001N-30	NADAL® Chagas IgG cassette
662001N-30	NADAL® Leishmania cassette
672001N-30	NADAL® Filariasis cassette
682001N-30	NADAL® Chikungunya Cassette
682002N-20	NADAL® Chikungunya IgM Cassette
692001N-30	NADAL® Typhus Cassette
692001P	Typhus IgG/IgM Cassette
702001N-30	NADAL® Leptospira Cassette
712001	NADAL® AFP Cassette
722003	NADAL® CEA Cassette
790001	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
795009	NADAL® RF 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
795043	NADAL® Streptococust Latex
850003	NADAL®Astrovirus Test Cassette
860001	NADAL® Bence Jones Proteinurie Dipstick

870001	NADAL® Lyme Borreliose Cassette
900001	NADAL® <i>h-FABP</i> Cassette
900004N-10	NADAL® <i>h-FABP</i> Cassette
920001	NADAL® Norovirus Cassette
920002	NADAL® Norovirus I+ II Cassette
920003	Norovirus Genotyp I Positive control
920004	Norovirus Genotyp II Positive control
41010-L	Reactif G Dipstick
41020-L	Reactif GP Dipstick
41021-M	Reactif 2 Dipstick
41022-L	Reactif 2B Dipstick
41030-L	Reactif 3 Dipstick
41040-L	Reactif 4 Dipstick
41050-L	Reactif 5B Dipstick
41080-L	Reactif 8SG Dipstick
41101-L	Reactif 10SL Dipstick
41110-L	Reactif 11M Dipstick
41130-S	Reactif 13 Dipstick
42100-A	Ratisbonne 10 M
1010002N-20	NADAL® Cholera O1/O139 cassette
1120001	NADAL®Candida Albicans (Cassette á 20)
1120003N-20	NADAL®Candida Albicans (Cassette á 20)
1130001	NADAL® HSV 1 und 2 Herpes-Simplex-Virus (TK á20)07
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)
1200002	NADAL® Lactoferrin Positiv Control (à 1)

1201001N-10	NADAL® Ferritin Test (semiquantitativ) cassette
1201002N-10	NADAL® Ferritin test (ualitative) cassette
1212001	NADAL® Calprotectin – Test – Feces (TK á 10)
1212002	NADAL® Calprotectin +Lactoferrin Test Feces (TK á 10)
1212003	NADAL® Calprotectin Positiv Control (à 1)
1222001	NADAL® Enterovirus – Test – Feces (TK á 10)
1222002	NADAL® Enterovirus Positiv Control (à 1)
1232001	NADAL® Campylobacter – Test – Feces (TK á 10)
1232002	NADAL® Campylobacter Positiv Control (à 1)
1242001	NADAL® Salmonella spp. – Test – Feces (TK á 10)
1242002	NADAL® Salmonella Typhi-Test – Feces (TK á 10)
1242003	NADAL® Salmonella spp. Positiv Control (à 1)
1252001	NADAL® Listeria-Test – Feces (TK á 10)
1252002	NADAL® Listeria Positiv Control (à 1)
1262001	NADAL® Shigella-Test - Feces (TK à 10)
1262002	NADAL® Shigella Dysenteriae-Test – Feces (TK à 10)
1262003	NADAL® Shigella Positiv Control (à 1)
1320001	NADAL® HB Hämoglobin Analyzer(á 1)
1320002	NADAL® HB Hämoglobin Dipstick (á 50)
1320003	NADAL® HB Kontroll Dipstick (á 2)
1320004	NADAL® HB Kapillarröhrchen 10 µl (á 50)
1670001N-30	NADAL® Toxo IgG/IgM Test cassette
2090001	NADAL® Entamoeba, feces – test cassette (á 10)

2140001	NADAL® Cardiac 2DT QUANT - Cassette
2140003	NADAL® Cardiac 3DTB QUANT - Cassette
2201001N- 10	NADAL® IgE – Immunglobulin E test cassette
2210001	NADAL® Ebola Antigen test cassette

This document is valid until 20.03.2018

Moers, 25.10.2016  
nal von minden GmbH



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