

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	Gonorrhea 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® Streptococcust 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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