

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.

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| 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 |

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| 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 |

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| 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 |

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| 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 |

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| 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 |

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| 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 |

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| 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 |

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| 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 |

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| 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 |

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| 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 |

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| 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 |

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| 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 |

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| 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 |

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| 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

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