

Supplemental Statement to Declarations of Conformity

According to Regulation (EU) 2022/112 of the European Parliament and of the Council of January 25, 2022, devices with a Declaration of Conformity issued before May 26, 2022, that did not require the intervention of a notified body under the IVD Directive, may be placed on the market or put into service until the following dates:

- a. May 26, 2025, for Class D devices
- b. May 26, 2026, for Class C devices
- c. May 26, 2027, for Class B devices and Class A devices placed on the market in a sterile condition.

We, NovaTec Immundiagnostica GmbH, part of Gold Standard Diagnostics Europe, declare in addition to the Declarations of Conformity listed below

Declarations of Conformity issued under the sole responsibility of NovaTec Immundiagnostica GmbH and referring to Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices of 27 October 1998 are valid until the end of the respective transitional period of the product.

Dietzenbach, 2023-07-31


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Marcello Salio
(Managing Director)

Catalogue Number	Product Line	Product Name
ACMV7110	NovaLisa®	Avidity Cytomegalovirus (CMV) IgG
ADVA0010	NovaLisa®	Adenovirus IgA
ADVG0010	NovaLisa®	Adenovirus IgG
ADVM0010	NovaLisa®	Adenovirus IgM
AEBV7150	NovaLisa®	Avidity Epstein Barr Virus (VCA) IgG
AMEA7330	NovaLisa®	Avidity Measles Virus IgG
ARUB7400	NovaLisa®	Avidity Rubella Virus IgG
ASCG0020	NovaLisa®	Ascaris lumbricoides IgG
ASPG0680	NovaLisa®	Aspergillus fumigatus IgG
ASPM0680	NovaLisa®	Aspergillus fumigatus IgM
ATG1010	NovaLisa®	Anti-TG
ATOX7460	NovaLisa®	Avidity Toxoplasma gondii IgG
ATPO1020	NovaLisa®	Anti-TPO
BAR0900	NovaLisa®	Bartonella
BOPA0030	NovaLisa®	Bordetella pertussis IgA
BOPG0030	NovaLisa®	Bordetella pertussis IgG
BOPM0030	NovaLisa®	Bordetella pertussis IgM
BORG0040	NovaLisa®	Borrelia burgdorferi IgG
BORM0040	NovaLisa®	Borrelia burgdorferi IgM
BPTA0610	NovaLisa®	Bordetella pertussis toxin (PT) IgA
BPTG0610	NovaLisa®	Bordetella pertussis toxin (PT) IgG
BRUG0050	NovaLisa®	Brucella IgG
BRUM0050	NovaLisa®	Brucella IgM
CANA0060	NovaLisa®	Candida albicans IgA
CANG0060	NovaLisa®	Candida albicans IgG
CANM0060	NovaLisa®	Candida albicans IgM
CHAG0560	NovaLisa®	Chagas (Trypanosoma cruzi) IgG
CHIG0590	NovaLisa®	Chikungunya Virus IgG capture
CHIM0590	NovaLisa®	Chikungunya Virus IgM μ -capture
CHLA0070	NovaLisa®	Chlamydia trachomatis IgA
CHLA0510	NovaLisa®	Chlamydia pneumoniae IgA
CHLG0070	NovaLisa®	Chlamydia trachomatis IgG
CHLG0510	NovaLisa®	Chlamydia pneumoniae IgG
CHLM0070	NovaLisa®	Chlamydia trachomatis IgM
CHLM0510	NovaLisa®	Chlamydia pneumoniae IgM
CMVG0110	NovaLisa®	Cytomegalovirus (CMV) IgG
CMVM0110	NovaLisa®	Cytomegalovirus (CMV) IgM
CORG0090	NovaLisa®	Corynebacterium diphtheriae toxin IgG

Catalogue Number	Product Line	Product Name
CORG5009	NovaLisa®	Corynebacterium diphtheriae toxin 5S IgG
COVA0940	NovaLisa®	SARS-CoV-2 (COVID-19) IgA
COVG0940	NovaLisa®	SARS-CoV-2 (COVID-19) IgG
COX1G0600	NovaLisa®	Coxiella burnetii (Q-Fever) Phase 1 IgG
COX2G0600	NovaLisa®	Coxiella burnetii (Q-Fever) Phase 2 IgG
COX2M0600	NovaLisa®	Coxiella burnetii (Q-Fever) Phase 2 IgM
DENG0120	NovaLisa®	Dengue Virus IgG
DENM0120	NovaLisa®	Dengue Virus IgM
DVM0640	NovaLisa®	Dengue Virus IgM μ -capture
EBVA0150	NovaLisa®	Epstein Barr Virus (VCA) IgA
EBVG0080	NovaLisa®	Epstein Barr Virus (EA-D) IgG
EBVG0150	NovaLisa®	Epstein Barr Virus (VCA) IgG
EBVG0580	NovaLisa®	Epstein Barr Virus (EBNA) IgG
EBVM0150	NovaLisa®	Epstein Barr Virus (VCA) IgM
ECHG0130	NovaLisa®	Echinococcus IgG
ENTG0140	NovaLisa®	Entamoeba histolytica IgG
FIL0760	NovaLisa®	Filariasis
FT41050	NovaLisa®	Free T4
HANG0670	NovaLisa®	Hantavirus IgG
HANM0670	NovaLisa®	Hantavirus IgM
HELG0220	NovaLisa®	Helicobacter pylori IgG
HELM0220	NovaLisa®	Helicobacter pylori IgM
HEVG0780	NovaLisa®	Hepatitis E Virus (HEV) IgG
HEVM0780	NovaLisa®	Hepatitis E Virus (HEV) IgM
HSV1G0500	NovaLisa®	Herpes simplex virus 1 (HSV 1) IgG
HSV1M0500	NovaLisa®	Herpes simplex virus 1 (HSV 1) IgM
HSV2G0540	NovaLisa®	Herpes simplex virus 2 (HSV 2) IgG
HSV2M0540	NovaLisa®	Herpes simplex virus 2 (HSV 2) IgM
HSVG0250	NovaLisa®	Herpes simplex virus 1+2 (HSV) IgG
HSVM0250	NovaLisa®	Herpes simplex virus 1+2 (HSV) IgM
INFA0290	NovaLisa®	Influenza Virus A IgA
INFA0300	NovaLisa®	Influenza Virus B IgA
INFG0290	NovaLisa®	Influenza Virus A IgG
INFG0300	NovaLisa®	Influenza Virus B IgG
INFM0290	NovaLisa®	Influenza Virus A IgM
INFM0300	NovaLisa®	Influenza Virus B IgM
LEGG0650	NovaLisa®	Legionella pneumophila IgG

Catalogue Number	Product Line	Product Name
LEGM0650	NovaLisa®	Legionella pneumophila IgM
LEIG0310	NovaLisa®	Leishmania infantum IgG
LEPG0660	NovaLisa®	Leptospira IgG
LEPM0660	NovaLisa®	Leptospira IgM
MAL0620	NovaLisa®	Malaria
MEAG0330	NovaLisa®	Measles Virus IgG
MEAM0330	NovaLisa®	Measles Virus IgM
MUMG0340	NovaLisa®	Mumps Virus IgG
MUMM0340	NovaLisa®	Mumps Virus IgM
MYCA0350	NovaLisa®	Mycoplasma pneumoniae IgA
MYCG0350	NovaLisa®	Mycoplasma pneumoniae IgG
MYCM0350	NovaLisa®	Mycoplasma pneumoniae IgM
NS1D4020	NovaLisa®	Dengue Virus NS1 Antigen
PAIA0360	NovaLisa®	Parainfluenza Virus 1,2,3 IgA
PAIG0360	NovaLisa®	Parainfluenza Virus 1,2,3 IgG
PARG0370	NovaLisa®	Parvovirus B19 IgG
PARM0370	NovaLisa®	Parvovirus B19 IgM
PCORG009	NovaLisa®	Corynebacterium diphtheriae toxin 5S IgG plus
PHELG022	NovaLisa®	Helicobacter pylori IgG plus
PTETG043	NovaLisa®	Clostridium tetani toxin 5S IgG plus
PTICG044	NovaLisa®	TBE / FSME IgG plus
RFM3010	NovaLisa®	Rheumatoid Factor IgM
RSVA0380	NovaLisa®	Respiratory Syncytial-Virus IgA
RSVG0380	NovaLisa®	Respiratory Syncytial-Virus IgG
RSVM0380	NovaLisa®	Respiratory Syncytial-Virus IgM
RUBG0400	NovaLisa®	Rubella Virus IgG
RUBM0400	NovaLisa®	Rubella Virus IgM μ -capture
SCHG0410	NovaLisa®	Schistosoma mansoni IgG
SCHM0410	NovaLisa®	Schistosoma mansoni IgM
STRO0690	NovaLisa®	Strongyloides
TAEG0420	NovaLisa®	Taenia solium IgG
TETG0430	NovaLisa®	Clostridium tetani toxin IgG
TETG5043	NovaLisa®	Clostridium tetani toxin 5S IgG
TICG0440	NovaLisa®	TBE/FSME IgG
TICM0440	NovaLisa®	TBE/FSME IgM
TOCG0450	NovaLisa®	Toxocara canis IgG
TOXA0460	NovaLisa®	Toxoplasma gondii IgA
TOXG0460	NovaLisa®	Toxoplasma gondii IgG

Catalogue Number	Product Line	Product Name
TOXM0460	NovaLisa®	Toxoplasma gondii IgM µ-capture
TRIG0480	NovaLisa®	Trichinella spiralis IgG
TSH1030	NovaLisa®	TSH
VZVA0490	NovaLisa®	Varicella-Zoster Virus (VZV) IgA
VZVG0490	NovaLisa®	Varicella-Zoster Virus (VZV) IgG
VZVM0490	NovaLisa®	Varicella-Zoster Virus (VZV) IgM
YERA0990	NovaLisa®	Yersinia enterocolitica IgA
YERG0990	NovaLisa®	Yersinia enterocolitica IgG
ZVG0790	NovaLisa®	Zika Virus IgG capture
ZVM0790	NovaLisa®	Zika Virus IgM µ-capture