

EC DECLARATION OF CONFORMITY



We, **TestLine Clinical Diagnostics s.r.o.** (manufacturer),

Křižíkova 68, 612 00 Brno, Czech Republic,

hereby declare on our own responsibility that the below in vitro diagnostic medical devices meet the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices which apply to them.

Conformity assessment procedure:

General IVDs Directive 98/79/EC, Annex III

Annex II List B IVDs Directive 98/79/EC, Annex IV (Full QA System)

HUMAN ELISA KITS

This is also valid for EIA kits version Smartkit.

Cat. number	Product name	Classification	GMDN code
AdA096	EIA Adenovirus IgA	General	49867
AdG096	EIA Adenovirus IgG	General	49869
AdM096	EIA Adenovirus IgM	General	49872
ScA096	EIA ASCA IgA	General	52100
ScG096	EIA ASCA IgG	General	52108
BppA96	EIA Bordetella parapertussis IgA	General	50512
BppG96	EIA Bordetella parapertussis IgG	General	50512
BppM96	EIA Bordetella parapertussis IgM	General	50512
BpAT96	EIA Bordetella pertussis Toxin IgA	General	50517
BpGT96	EIA Bordetella pertussis Toxin IgG	General	50521
BpMT96	EIA Bordetella pertussis Toxin IgM	General	50525
BaM192	EIA Borrelia afzelii IgM (192)	General	50585
BaGVD2	EIA Borrelia afzelii VlsE IgG (192)	General	50581
BgM192	EIA Borrelia garinii IgM (192)	General	50597
BgGVD2	EIA Borrelia garinii VlsE IgG (192)	General	50593
BM0096	EIA Borrelia IgM	General	50564
BrG192	EIA Borrelia recombinant IgG (192)	General	50560
BrM192	EIA Borrelia recombinant IgM (192)	General	50564
BGV096	EIA Borrelia VlsE IgG	General	50560
CCPA96	EIA CCP IgA	General	54896
CCPG96	EIA CCP IgG	General	54896
CEN096	EIA Centromere	General	54886
CMA096	EIA CMV IgA	Annex II List B	49729
CMG096	EIA CMV IgG	Annex II List B	49729
CMM096	EIA CMV IgM	Annex II List B	49729
CoNA96	EIA COVID-19 NP IgA	General	64830

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CoNG96	EIA COVID-19 NP IgG	General	64824
CoNM96	EIA COVID-19 NP IgM	General	64800
CoRA96	EIA COVID-19 RBD IgA	General	64830
CoRG96	EIA COVID-19 RBD IgG	General	64824
CoRM96	EIA COVID-19 RBD IgM	General	64800
DNA096	EIA dsDNA	General	54902
EAG096	EIA EBV EA-D IgG	General	49682
EAM096	EIA EBV EA-D IgM	General	49682
EBG096	EIA EBV EBNA-1 IgG	General	49677
EBM096	EIA EBV EBNA-1 IgM	General	49677
VCA096	EIA EBV VCA IgA	General	49657
VCG096	EIA EBV VCA IgG	General	49657
VCM096	EIA EBV VCA IgM	General	49657
ENA012	EIA ENA profile	General	54823
ENAp12	EIA ENA profile plus	General	54823
ENA096	EIA ENA screen plus	General	54823
GDA096	EIA Gliadin DA IgA	General	54947
GDG096	EIA Gliadin DA IgG	General	54947
GIA096	EIA Gliadin IgA	General	54947
GIG096	EIA Gliadin IgG	General	54947
HMA096	EIA Helicobacter MONO IgA	General	51004
HMG096	EIA Helicobacter MONO IgG	General	51008
HMM096	EIA Helicobacter MONO IgM	General	51012
HSV96	EIA HSV 1+2 IgG	General	49534
HSVM96	EIA HSV 1+2 IgM	General	49534
ChA096	EIA Chlamydia IgA	Annex II List B	50720
ChG096	EIA Chlamydia IgG	Annex II List B	50722
ChM096	EIA Chlamydia IgM	Annex II List B	50724
ChpA96	EIA Chlamydia pneumoniae IgA	Annex II List B	50741
ChpG96	EIA Chlamydia pneumoniae IgG	Annex II List B	50737
ChpM96	EIA Chlamydia pneumoniae IgM	Annex II List B	50733
CpAR96	EIA Chlamydia pneumoniae REC IgA	Annex II List B	50741
CpGR96	EIA Chlamydia pneumoniae REC IgG	Annex II List B	50737
ChtA96	EIA Chlamydia trachomatis IgA	Annex II List B	50773
ChtG96	EIA Chlamydia trachomatis IgG	Annex II List B	50768
ChtM96	EIA Chlamydia trachomatis IgM	Annex II List B	50763
InAA96	EIA Influenza A IgA	General	49183
InAG96	EIA Influenza A IgG	General	49178
InAM96	EIA Influenza A IgM	General	49173
InBA96	EIA Influenza B IgA	General	49219
InBG96	EIA Influenza B IgG	General	49214
InBM96	EIA Influenza B IgM	General	49209
Jo1096	EIA Jo-1	General	55005
MeG096	EIA Measles IgG	General	49287

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MeM096	EIA Measles IgM	General	49280
MiA096	EIA Milk IgA	General	41410
MiG096	EIA Milk IgG	General	41410
MiM096	EIA Milk IgM	General	41410
MuA096	EIA Mumps IgA	General	49338
MuG096	EIA Mumps IgG	General	49338
MuM096	EIA Mumps IgM	General	49338
MyA096	EIA Mycoplasma IgA	General	51212
MyG096	EIA Mycoplasma IgG	General	51207
MyM096	EIA Mycoplasma IgM	General	51202
MyAR96	EIA Mycoplasma REC IgA	General	51212
MyGR96	EIA Mycoplasma REC IgG	General	51207
MyMR96	EIA Mycoplasma REC IgM	General	51202
PCG096	EIA PCP IgG	General	51783
RFA096	EIA RF IgA	General	55107
RFG096	EIA RF IgG	General	55107
RFM096	EIA RF IgM	General	55107
RF0096	EIA RF screen	General	54845
RubG96	EIA Rubella IgG	Annex II List B	50265
RubM96	EIA Rubella IgM	Annex II List B	50268
Scl096	EIA Scl-70	General	55126
Sm0096	EIA Sm	General	55160
SSA096	EIA SS-A	General	55129
Ro5296	EIA SS-A/Ro52	General	55129
Ro6096	EIA SS-A/Ro60	General	55129
SSB096	EIA SS-B	General	55132
TBG096	EIA TBE Virus IgG	General	49027
TBM096	EIA TBE Virus IgM	General	49023
TBE096	EIA TBEV Ig	General	49031
TeTG96	EIA Tetanus Toxoid IgG	IVD	50874
Tg0096	EIA Thyroglobulin IgG	General	54372
TPOx96	EIA Thyroid Peroxidase IgG	General	55203
TcA096	EIA Toxocara IgA	General	52418
TcG096	EIA Toxocara IgG	General	52418
TgA096	EIA Toxoplasma IgA	Annex II List B	52444
TgE096	EIA Toxoplasma IgE	Annex II List B	52444
TgG096	EIA Toxoplasma IgG	Annex II List B	52444
TgM096	EIA Toxoplasma IgM	Annex II List B	52444
tTA096	EIA Transglutaminase IgA	General	55223
tTG096	EIA Transglutaminase IgG	General	55223
TpG096	EIA Treponema pallidum IgG	General	51804
TpM096	EIA Treponema pallidum IgM	General	51809
Tp0096	EIA Treponema pallidum TOTAL	General	51798
RNP096	EIA U1RNP	General	55165

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VZVA96	EIA VZV IgA	General	49639
VZVG96	EIA VZV IgG	General	49639
VZVM96	EIA VZV IgM	General	49639
YA0096	EIA Yersinia enterocolitica IgA	General	51900
YG0096	EIA Yersinia enterocolitica IgG	General	51904
YM0096	EIA Yersinia enterocolitica IgM	General	51912

HUMAN IMUNOBLOT KITS

Cat. number	Product name	Classification	GMDN code
TcGB16	BLOT Toxocara IgG	General	52421
TgAB16	BLOT Toxoplasma IgA	Annex II List B	52458
TgGB16	BLOT Toxoplasma IgG	Annex II List B	52458
TgMB16	BLOT Toxoplasma IgM	Annex II List B	52458
ANAL20	BLOT-LINE ANA	General	54810
ApGL10	BLOT-LINE Anaplasma IgG	General	51345
ApML10	BLOT-LINE Anaplasma IgM	General	51341
ANC3L20	BLOT-LINE ANCA-3	General	55063
BpAL20	BLOT-LINE Bordetella IgA	General	50512
BpGL20	BLOT-LINE Bordetella IgG	General	50512
BpML20	BLOT-LINE Bordetella IgM	General	50512
BaGL20	BLOT-LINE Borrelia afzelii IgG	General	50555
BaML20	BLOT-LINE Borrelia afzelii IgM	General	50555
BsGL20	BLOT-LINE Borrelia b. sensu stricto IgG	General	50555
BsML20	BLOT-LINE Borrelia b. sensu stricto IgM	General	50555
BgGL20	BLOT-LINE Borrelia garinii IgG	General	50555
BgML20	BLOT-LINE Borrelia garinii IgM	General	50555
BGL020	BLOT-LINE Borrelia/HGA IgG	General	50555
BML020	BLOT-LINE Borrelia/HGA IgM	General	50555
EBAL20	BLOT-LINE EBV IgA	IVD	62754
EBGL20	BLOT-LINE EBV IgG	General	49669
EBML20	BLOT-LINE EBV IgM	General	49667
ENAL20	BLOT-LINE ENA plus	General	54824
HpAL20	BLOT-LINE Helicobacter IgA	General	51020
HpGL20	BLOT-LINE Helicobacter IgG	General	51020
CAL020	BLOT-LINE Chlamydia IgA	Annex II List B	50720
CGL020	BLOT-LINE Chlamydia IgG	Annex II List B	50722
CpAL20	BLOT-LINE Chlamydia pneumoniae IgA	Annex II List B	50720
CpGL20	BLOT-LINE Chlamydia pneumoniae IgG	Annex II List B	50722
CpML20	BLOT-LINE Chlamydia pneumoniae IgM	Annex II List B	50748
CtAL20	BLOT-LINE Chlamydia trachomatis IgA	Annex II List B	50792
CtGL20	BLOT-LINE Chlamydia trachomatis IgG	Annex II List B	50792
MyAL20	BLOT-LINE Mycoplasma IgA	General	51197
MyGL20	BLOT-LINE Mycoplasma IgG	General	51197
MyML20	BLOT-LINE Mycoplasma IgM	General	51197

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TpGL20	BLOT-LINE Treponema IgG	General	51818
TpML20	BLOT-LINE Treponema IgM	General	51818
YAL020	BLOT-LINE Yersinia IgA	General	51890
YGL020	BLOT-LINE Yersinia IgG	General	51890
YML020	BLOT-LINE Yersinia IgM	General	51890
BD-BpAL24	BlueBLOT-LINE Bordetella IgA	General	50512
BD-BpGL24	BlueBLOT-LINE Bordetella IgG	General	50512
BD-BGL024	BlueBLOT-LINE Borrelia IgG	General	50555
BD-BML024	BlueBLOT-LINE Borrelia IgM	General	50555
BD-EBGL24	BlueBLOT-LINE EBV IgG	General	49669
BD-EBML24	BlueBLOT-LINE EBV IgM	General	49667
BD-HpAL24	BlueBLOT-LINE Helicobacter IgA	General	51020
BD-HpGL24	BlueBLOT-LINE Helicobacter IgG	General	51020
BD-CAL024	BlueBLOT-LINE Chlamydia IgA	Annex II List B	50720
BD-CGL024	BlueBLOT-LINE Chlamydia IgG	Annex II List B	50722
BD-TpGL24	BlueBLOT-LINE Treponema IgG	General	51818
BD-TpML24	BlueBLOT-LINE Treponema IgM	General	51818
BD-YAL024	BlueBLOT-LINE Yersinia IgA	General	51890
BD-YGL024	BlueBLOT-LINE Yersinia IgG	General	51890

HUMAN MICROBLLOT KITS

Cat. number	Product name	Classification	GMDN code
ANAMA96	Microblot-Array ANA	General	54810
ANA44MA96	Microblot-Array ANA 44	General	54810
ANA45MA96	Microblot-Array ANA 45	General	54810
ANApMA96	Microblot-Array ANA plus	General	54810
BaGMA96	Microblot-Array Borrelia afzelii IgG	General	50555
BaMMA96	Microblot-Array Borrelia afzelii IgM	General	50555
BsGMA96	Microblot-Array Borrelia b. sensu stricto IgG	General	50555
BsMMA96	Microblot-Array Borrelia b. sensu stricto IgM	General	50555
BgGMA96	Microblot-Array Borrelia garinii IgG	General	50555
BgMMA96	Microblot-Array Borrelia garinii IgM	General	50555
BGMA096	Microblot-Array Borrelia IgG	General	50555
BMMA096	Microblot-Array Borrelia IgM	General	50555
CoVAMA96	Microblot-Array COVID-19 IgA	IVD	64867
CoVGMA96	Microblot-Array COVID-19 IgG	IVD	64867
CoVMA96	Microblot-Array COVID-19 IgM	IVD	64867
EBAMA96	Microblot-Array EBV IgA	General	62754
EBGMA96	Microblot-Array EBV IgG	General	62754
EBMMA96	Microblot-Array EBV IgM	General	62754
CAMA096	Microblot-Array Chlamydia IgA	Annex II List B	50720
CGMA096	Microblot-Array Chlamydia IgG	Annex II List B	50722

ANTIGENS AND COMPONENTS FOR CFR, AGGLUTINATION AND MICROAGGLUTINATION

Cat. number	Product name	Classification	GMDN code
Bp0500	Barbital buffer for CF – 5× conc.	General	58208
BppAg5	Bordetella parapertussis-AR-Ag	General	50511
BppP01	Bordetella parapertussis-AR-Positive Control lyophil.	General	50511
BpeAg5	Bordetella pertussis-AR-Ag	General	50511
BpeP01	Bordetella pertussis-AR-Positive Control lyophil.	General	50511
KFAs00	CF - AMBOCEPTORset (0,5 ml)	General	52448
KFAs01	CF - AMBOCEPTORset (1ml)	General	52448
KFC001	CF - COMPLEMENT (1ml)	General	58366
CMvKF1	CMV - CF - Ag lyofil.	Annex II List B	49710
TgKF02	Toxo - CF - Ag lyophil. (0,2 ml)	Annex II List B	52448
TgKF05	Toxo - CF - Ag lyophil. (0.5 ml)	Annex II List B	52448
Tg-KF1	Toxo - CF - Ag lyophil. (1 ml)	Annex II List B	52448
TgKFN2	Toxo - CF - Negative Control lyophil.	Annex II List B	52448
TgKFP2	Toxo - CF - Positive Control lyophil.	Annex II List B	52448

TESTS FOR BACTERIOLOGY

Cat. number	Product name	Classification	GMDN code
Hs0050	HIPPUstrip	General	51747
Is0100	INDOXYLstrip	General	56773
LM0020	LEPTOSPIRA-MEDIUM	General	51112
LMb100	LEPTOSPIRA-MEDIUM BULK	General	51112
LMm020	LEPTOSPIRA-MEDIUM MEDIKOVANÉ	General	51112
Os0100	OXIstrip	General	50423
Ps0050	PYRstrip	General	58597
Ts0300	TRIBUstrip	General	50423
Ut0050	UREASAtest 50	General	52787
BLs100	β-LACTAstrip	General	58599

COMPONENTS AND CONSUMABLE

Cat. number	Product name	Classification	GMDN code
rp0090	Dilution buffer for GIEMSA	General	41750
Gi00L1	GIEMSA - 10x. conc. solution	General	41750
Gir0L1	GIEMSA-ready	General	41750
Gs0000	GRAM – kompletní sada roztoků	General	41750
RFs010	RF - sorb (10 ml)	General	54848
RFs002	RF - sorb (2 ml)	General	54848

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CERTIFIED CONTROL SERUM

Cat. number	Product name	Classification	GMDN code
CKSTLX	CERTIFIED CONTROL SERUM ^{TLX}	General	53754
CKSTLX	CERTIFIED CONTROL SERUM ^{TLX}	Annex II List B	53754

KITS FOR IMMUNOLOGY

Cat. number	Product name	Classification	GMDN code
RIDCIP	RID CIC Profiling kit (5x32)	General	54894
CIK240	TA Immunocomplex	General	54894

SOFTWARE

Cat. number	Product name	Classification	GMDN code
SwAI01	Antibody index - software	General	42838
SwIm03	Immunoblot Software	General	42838

INSTRUMENTS

Cat. number	Product name	Classification	GMDN code
ARCXIX096	Array Reader C-series	General	57862

Brno, 23 October 2020

A handwritten signature in blue ink, appearing to read 'Suchánková', is written over the printed name.

Simona Suchánková

Quality manager

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