DICHIARAZIONE DI CONFORMITÀ UE

Noi, **TestLine Clinical Diagnostics s.r.o.** (produttore),

Křižíkova 188/68, 612 00 Brno, Repubblica Ceca, SRN: CZ-MF-000001803

dichiara sotto la propria responsabilita che i sorto elencati prodorti diagnostici in vitro sono conformi ai reguisiti della Direttiva 98/79/CE del Parlamento Europeo e del Consiglio Europeo del 27 ottobre 1998 sui dispositivi medici diagnostici in vitro che li rigua rdano o Regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio, del 5 aprile 2017, relativo ai dispositivi medico-diagnostici in vitro. La dichiarazione di conformità UE è rilasciata sotto l'esclusiva responsabilità del fabbricante ad uso delle autorità competenti, dei clienti e degli operatori economici.

Le procedure di valutazione della conformità:

General IVDs	Direttiva 98/79/CE, Allegato III
Annex II List B IVDs	Direttiva 98/79/CE, Allegato IV (Sistema di garanzia di Qualità Totale)
IVDR class A	Regolamento (UE) 2017/746 (IVDR), TD seguenti Allegati II e III, Dichiarazione di Conformità seguenti Allegato IV, CE marchio seguenti Allegato V
IVDR class B	Regolamento (UE) 2017/746 (IVDR), TD seguenti Allegato IX, Dichiarazione di Conformità seguenti Allegato IV, CE marchio seguenti Allegato V
IVDR class C	Regolamento (UE) 2017/746 (IVDR), TD seguenti Allegato IX, Dichiarazione di Conformità seguenti Allegato IV, CE marchio seguenti Allegato V

HUMAN CLIA KITS

Numero di catalogo	Nome del prodotto	Classificazione	UDI-DI di base	Codice GMDN
CL-ADP050	CLIA Adiponectin	General IVD	8595635311390C8	43540
CL-BGA100	CLIA Beta 2 Glycoprotein IgA	IVDR class B	8595635312205BR	60496
CL-BGG100	CLIA Beta 2 Glycoprotein IgG	IVDR class B	8595635312212BN	60496
CL-BGM100	CLIA Beta 2 Glycoprotein IgM	IVDR class B	8595635312229C7	60496
CL-BCSFG50	CLIA Borrelia CSF IgG	IVDR class B	8595635312137BZ	65784
CL-BCSFM50	CLIA Borrelia CSF IgM	IVDR class B	8595635312144BW	64702
CL-BRG100	CLIA Borrelia recombinant IgG	General IVD	8595635309915E5	65420
CL-BRM100	CLIA Borrelia recombinant IgM	General IVD	8595635309922E2	64702
CL-CAgS100	CLIA Campylobacter Ag Stool	General IVD	8595635311406BW	63153
CL-CLA100	CLIA Cardiolipin IgA	IVDR class B	8595635312175C9	59007
CL-CLG100	CLIA Cardiolipin IgG	IVDR class B	8595635312182C6	59007
CL-CLM100	CLIA Cardiolipin IgM	IVDR class B	8595635312199CP	59007
CL-CEN050	CLIA Centromere	General IVD	8595635309939EK	59745
CL-CPT050	CLIA C-peptide	IVDR class B	8595635312526CG	54130
CL-CMA100	CLIA CMV IgA	Annex II, List B	8595635309946EG	58428
CL-CMG100	CLIA CMV IgG	Annex II, List B	8595635309953ED	49713
CL-CMM100	CLIA CMV IgM	Annex II, List B	8595635309960EA	49724
CL-CoNA100	CLIA COVID-19 NP IgA	General IVD	8595635309762E4	65062
CL-CoNG100	CLIA COVID-19 NP IgG	General IVD	8595635309755E7	64760
CL-CoNM100	CLIA COVID-19 NP IgM	General IVD	8595635309779EM	64761
CL-CoRA100	CLIA COVID-19 RBD IgA	General IVD	8595635309793EF	65062
CL-CoRG100	CLIA COVID-19 RBD IgG	General IVD	8595635309786EJ	64760

CL-CoRM100	CLIA COVID-19 RBD IgM	General IVD	8595635309809E5	64761
CL-CRP100	CLIA CRP wide-range	General IVD	8595635311413BT	65695
CL-CysC100	CLIA Cystatin C	General IVD	8595635311420BQ	62598
CL-DNA050	CLIA dsDNA	General IVD	8595635310508BY	61266
CL-EAG100	CLIA EBV EA-D IgG	General IVD	8595635309991EM	60683
CL-EAM100	CLIA EBV EA-D IgM	General IVD	8595635310003AV	60684
CL-EBG100	CLIA EBV EBNA-1 IgG	General IVD	8595635310010AS	60683
CL-EBM100	CLIA EBV EBNA-1 IgM	General IVD	8595635310027BB	60684
CL-VCA100	CLIA EBV VCA IgA	General IVD	8595635310034B8	66047
CL-VCG100	CLIA EBV VCA IgG	General IVD	8595635310041B5	60683
CL-VCM100	CLIA EBV VCA IgM	General IVD	8595635310058BN	60684
CL-ENA100	CLIA ENA screen plus	General IVD	8595635309748EA	59748
CL-GAD100	CLIA GAD65	IVDR class B	8595635312236C4	66019
CL-GDA100	CLIA Gliadin DA IgA	General IVD	8595635310065BK	54948
CL-GDG100	CLIA Gliadin DA IgG	General IVD	8595635310072BG	54948
CL-HAgS100	CLIA Helicobacter Ag Stool	General IVD	8595635311437C9	61971
CL-HMA100	CLIA Helicobacter MONO IgA	General IVD	8595635310089BZ	65628
CL-HMG100	CLIA Helicobacter MONO IgG	General IVD	8595635310096BW	61971
CL-HSVG100	CLIA HSV 1+2 IgG	IVDR class C	8595635310126BE	49543
CL-HSVM100	CLIA HSV 1+2 IgM	IVDR class C	8595635310133BB	49547
CL-CPA100	CLIA Chlamydia pneumoniae IgA	Annex II, List B	8595635310164BN	65361
CL-CPG100	CLIA Chlamydia pneumoniae IgG	Annex II, List B	8595635310171BK	65362
CL-CPM100	CLIA Chlamydia pneumoniae IgM	Annex II, List B	8595635310188C4	65363
CL-ChtA100	CLIA Chlamydia trachomatis IgA	Annex II, List B	8595635310195BZ	63332
CL-ChtG100	CLIA Chlamydia trachomatis IgG	Annex II, List B	8595635310201B3	63328
CL-ChtM100	CLIA Chlamydia trachomatis IgM	Annex II, List B	8595635310218BL	65360
CL-CGA100	CLIA Chromogranin A	IVDR class C	8595635312335C7	67471
CL-IA100	CLIA IA2	IVDR class B	8595635312304BU	66035
CL-IL6100	CLIA IL-6	General IVD	8595635311444C6	53858
CL-INS050	CLIA Insulin	IVDR class B	8595635312410BU	54237
CL-Jo1050	CLIA Jo-1	General IVD	8595635310225BH	59067
CL-MxA050	CLIA MxA	General IVD	8595635311451C3	65778
CL-MyA100	CLIA Mycoplasma IgA	IVDR class B	8595635310232BE	66992
CL-MyG100	CLIA Mycoplasma IgG	IVDR class B	8595635310249BX	63427
CL-MyM100	CLIA Mycoplasma IgM	IVDR class B	8595635310256BU	63403
CL-PVG050	CLIA Parvovirus B19 IgG	IVDR class C	8595635310492CA	63423
CL-PVM050	CLIA Parvovirus B19 IgM	IVDR class C	8595635310485CD	63404
CL-PCT100	CLIA Procalcitonin	General IVD	8595635311475CH	58731
CL-RubG100	CLIA Rubella IgG	Annex II, List B	8595635310263BR	60990
CL-RubM100	CLIA Rubella IgM	Annex II, List B	8595635310270BN	60991
CL-Scl050	CLIA Scl-70	General IVD	8595635310287C7	59747
CL-Sm0050	CLIA Sm	General IVD	8595635310294C4	59888
CL-SSA050	CLIA SS-A	General IVD	8595635310300B6	59744
CL-Ro5250	CLIA SS-A/Ro52	General IVD	8595635310317BP	59744
CL-Ro6050	CLIA SS-A/Ro60	General IVD	8595635310324BL	59744

CL-SSB050	CLIA SS-B	General IVD	8595635310331BH	61221
CL-TBG100	CLIA TBE Virus IgG	General IVD	8595635309717DX	65639
CL-TBM050	CLIA TBE Virus IgM	General IVD	8595635309700DE	65640
CL-TeTG100	CLIA Tetanus Toxoid IgG	IVDR class B	8595635311925CT	65621
CL-TgA100	CLIA Toxoplasma IgA	IVDR class C	8595635310348C2	65364
CL-TgG100	CLIA Toxoplasma IgG	IVDR class C	8595635310355BX	52438
CL-TgM100	CLIA Toxoplasma IgM	IVDR class C	8595635310362BU	52442
CL-tTA100	CLIA Transglutaminase IgA	General IVD	8595635309731DR	58965
CL-tTG100	CLIA Transglutaminase IgG	General IVD	8595635309724DU	58965
CL-RNP050	CLIA U1RNP	General IVD	8595635310379CD	59857
CL-UMOD050	CLIA Uromodulin	General IVD	8595635311482CE	61293
CL-VZVA100	CLIA VZV IgA	IVDR class C	8595635310386CA	49634
CL-VZVG100	CLIA VZV IgG	IVDR class C	8595635310393C7	49622
CL-VZVM100	CLIA VZV IgM	IVDR class C	8595635310409BV	49628

HUMAN ELISA KITS

Numero di catalogo	Nome del prodotto	Classificazione	UDI-DI di base	Codice GMDN
AdA096	EIA Adenovirus IgA	General IVD	8595635308840DQ	49867
AdG096	EIA Adenovirus IgG	General IVD	8595635308857E9	49869
AdM096	EIA Adenovirus IgM	General IVD	8595635308864E6	49872
ScA096	EIA ASCA IgA	General IVD	8595635303821CH	52100
ScG096	EIA ASCA IgG	General IVD	8595635303838D2	52108
BppA96	EIA Bordetella parapertussis IgA	General IVD	8595635305054C6	50512
BppG96	EIA Bordetella parapertussis IgG	General IVD	8595635305061C3	50512
BppM96	EIA Bordetella parapertussis IgM	General IVD	8595635305078CL	50512
BpAT96	EIA Bordetella pertussis Toxin IgA	General IVD	8595635301209BF	50517
BpGT96	EIA Bordetella pertussis Toxin IgG	General IVD	8595635301179BX	50521
BpMT96	EIA Bordetella pertussis Toxin IgM	General IVD	8595635304217C3	50525
BaM192	EIA Borrelia afzelii IgM (192)	General IVD	8595635302602BU	50585
BaGVD2	EIA Borrelia afzelii VlsE IgG (192)	General IVD	8595635300561BR	50581
BsM096	EIA Borrelia b. sensu stricto IgM	General IVD	8595635302619CD	50564
BsGV96	EIA Borrelia b. sensu stricto VlsE IgG	General IVD	8595635303357CD	50560
BgM192	EIA Borrelia garinii IgM (192)	General IVD	8595635302534C4	50597
BgGVD2	EIA Borrelia garinii VlsE IgG (192)	General IVD	8595635300745C5	50593
BM0096	EIA Borrelia IgM	General IVD	8595635302626CA	50564
BrG192	EIA Borrelia recombinant IgG (192)	General IVD	8595635302633C7	50560
BrM192	EIA Borrelia recombinant IgM (192)	General IVD	8595635302640C4	50564
BGV096	EIA Borrelia VlsE IgG	General IVD	8595635302657CM	50560
CCPA96	EIA CCP IgA	General IVD	8595635302664CJ	54896
CCPG96	EIA CCP IgG	General IVD	8595635302671CF	54896
CMA096	EIA CMV IgA	Annex II, List B	8595635303210BE	49729
CMG096	EIA CMV IgG	Annex II, List B	8595635302688CY	49729
CMM096	EIA CMV IgM	Annex II, List B	8595635302695CV	49729
CoNA96	EIA COVID-19 NP IgA	General IVD	8595635309021CK	64830
CoNG96	EIA COVID-19 NP IgG	General IVD	8595635309038D4	64824

CoNM96	EIA COVID-19 NP IgM	General IVD	8595635309045CZ	64800
CoRA96	EIA COVID-19 RBD IgA	General IVD	8595635309335DD	64830
CoRG96	EIA COVID-19 RBD IgG	General IVD	8595635309328DG	64824
CoRM96	EIA COVID-19 RBD IgM	General IVD	8595635309311CX	64800
DNA096	EIA dsDNA	General IVD	8595635307478DN	54902
EAG096	EIA EBV EA-D IgG	General IVD	8595635302701BX	49657
EAM096	EIA EBV EA-D IgM	General IVD	8595635302718CG	49662
EBG096	EIA EBV EBNA-1 IgG	General IVD	8595635302725CD	49657
EBM096	EIA EBV EBNA-1 IgM	General IVD	8595635302749CT	49662
VCA096	EIA EBV VCA IgA	General IVD	8595635302756CQ	60621
VCG096	EIA EBV VCA IgG	General IVD	8595635302763CM	49657
VCM096	EIA EBV VCA IgM	General IVD	8595635302787D3	49662
ENAp12	EIA ENA profile plus	General IVD	8595635307607D9	54823
ENA096	EIA ENA screen plus	General IVD	8595635300769CK	54823
GDA096	EIA Gliadin DA IgA	General IVD	8595635303159C7	54947
GDG096	EIA Gliadin DA IgG	General IVD	8595635303166C4	54947
GIA096	EIA Gliadin IgA	General IVD	8595635303142BN	54947
GIG096	EIA Gliadin IgG	General IVD	8595635303173BZ	54947
HMA096	EIA Helicobacter MONO IgA	General IVD	8595635302800C2	51004
HMG096	EIA Helicobacter MONO IgG	General IVD	8595635302817CK	51008
HMM096	EIA Helicobacter MONO IgM	General IVD	8595635302824CG	51012
HS1G96	EIA HSV 1 IgG	General IVD	8595635309694EC	49534
HS1M96	EIA HSV 1 IgM	General IVD	8595635309625DR	49534
HS2G96	EIA HSV 2 IgG	General IVD	8595635309632DN	49534
HS2M96	EIA HSV 2 IgM	General IVD	8595635309649E7	49534
HSVG96	EIA HSV 1+2 IgG	General IVD	8595635302831CD	49534
HSVM96	EIA HSV 1+2 IgM	General IVD	8595635302848CW	49534
ChA096	EIA Chlamydia IgA	Annex II, List B	8595635302855CT	50720
ChG096	EIA Chlamydia IgG	Annex II, List B	8595635302862CQ	50722
ChM096	EIA Chlamydia IgM	Annex II, List B	8595635302879D9	50724
ChpA96	EIA Chlamydia pneumoniae IgA	Annex II, List B	8595635302886D6	50741
ChpG96	EIA Chlamydia pneumoniae IgG	Annex II, List B	8595635302893D3	50737
ChpM96	EIA Chlamydia pneumoniae IgM	Annex II, List B	8595635302909CR	50733
CpAR96	EIA Chlamydia pneumoniae REC IgA	Annex II, List B	8595635304460CE	50741
CpGR96	EIA Chlamydia pneumoniae REC IgG	Annex II, List B	8595635304477CX	50737
ChtA96	EIA Chlamydia trachomatis IgA	Annex II, List B	8595635302916CN	50773
ChtG96	EIA Chlamydia trachomatis IgG	Annex II, List B	8595635302923CK	50768
ChtM96	EIA Chlamydia trachomatis IgM	Annex II, List B	8595635302930CG	50763
InAA96	EIA Influenza A IgA	General IVD	8595635308406D4	49183
InAG96	EIA Influenza A IgG	General IVD	8595635308390DE	49178
InAM96	EIA Influenza A IgM	General IVD	8595635308413CZ	49173
InBA96	EIA Influenza B IgA	General IVD	8595635308468DS	49219
InBG96	EIA Influenza B IgG	General IVD	8595635308451D9	49214
InBM96	EIA Influenza B IgM	General IVD	8595635308475DP	49209
Jo1096	EIA Jo-1	General IVD	8595635304064C2	55005

MeG096	EIA Measles IgG	General IVD	8595635307881DX	49287
MeM096	EIA Measles IgM	General IVD	8595635307898EG	49280
MiA096	EIA Milk IgA	General IVD	8595635303180BW	67721
MiG096	EIA Milk IgG	General IVD	8595635303197CF	58945
MiM096	EIA Milk IgM	General IVD	8595635303203BH	67722
MuA096	EIA Mumps IgA	General IVD	8595635307997EK	49338
MuG096	EIA Mumps IgG	General IVD	8595635308000C4	49338
MuM096	EIA Mumps IgM	General IVD	8595635308017CM	49338
MyA096	EIA Mycoplasma IgA	General IVD	8595635302947CZ	51212
MyG096	EIA Mycoplasma IgG	General IVD	8595635302954CW	51207
MyM096	EIA Mycoplasma IgM	General IVD	8595635302961CT	51202
MyAR96	EIA Mycoplasma REC IgA	General IVD	8595635307522CY	51212
MyGR96	EIA Mycoplasma REC IgG	General IVD	8595635307539DH	51207
MyMR96	EIA Mycoplasma REC IgM	General IVD	8595635307515D3	51202
PaiA96	EIA Parainfluenza mix IgA	General IVD	8595635308529DM	49388
PaiG96	EIA Parainfluenza mix IgG	General IVD	8595635308512D4	49384
PaiM96	EIA Parainfluenza mix IgM	General IVD	8595635308536DJ	49380
PVG096	EIA Parvovirus B19 IgG	General IVD	8595635310515BV	50157
PVM096	EIA Parvovirus B19 IgM	General IVD	8595635310546C8	50164
PCG096	EIA PCP IgG	General IVD	8595635303869DD	51783
RFA096	EIA RF IgA	General IVD	8595635302978DC	55107
RFG096	EIA RF IgG	General IVD	8595635302985D9	55107
RFM096	EIA RF IgM	General IVD	8595635302992D6	55107
RSA096	EIA RSV IgA	General IVD	8595635308949EF	49519
RSG096	EIA RSV IgG	General IVD	8595635308932DW	49513
RSM096	EIA RSV IgM	General IVD	8595635308956EC	49508
RubG96	EIA Rubella IgG	Annex II, List B	8595635305016BW	50265
RubM96	EIA Rubella IgM	Annex II, List B	8595635305023BT	50268
Scl096	EIA Scl-70	General IVD	8595635304101BF	55126
Sm0096	EIA Sm	General IVD	8595635304118BY	55160
SSA096	EIA SS-A	General IVD	8595635304026BS	55129
SSB096	EIA SS-B	General IVD	8595635304071BX	55132
TBG096	EIA TBE Virus IgG	General IVD	8595635303005BB	49027
TBM096	EIA TBE Virus IgM	General IVD	8595635303012B8	49023
TeTG96	EIA Tetanus Toxoid IgG	General IVD	8595635309410D2	50874
TcA096	EIA Toxocara IgA	General IVD	8595635303999DT	52418
TcG096	EIA Toxocara IgG	General IVD	8595635303036BN	52418
TgA096	EIA Toxoplasma IgA	Annex II, List B	8595635303043BK	52444
TgE096	EIA Toxoplasma IgE	Annex II, List B	8595635303050BG	52444
TgG096	EIA Toxoplasma IgG	Annex II, List B	8595635303067BZ	52444
TgM096	EIA Toxoplasma IgM	Annex II, List B	8595635303074BW	52444
tTA096	EIA Transglutaminase IgA	General IVD	8595635303715CH	55223
tTG096	EIA Transglutaminase IgG	General IVD	8595635303722CE	55223
TpG096	EIA Treponema pallidum IgG	General IVD	8595635303081BT	51804
TpM096	EIA Treponema pallidum IgM	General IVD	8595635303098CC	51809

Tp0096	EIA Treponema pallidum TOTAL	General IVD	8595635303104BE	51798
RNP096	EIA U1RNP	General IVD	8595635304095CD	55165
VZVA96	EIA VZV IgA	General IVD	8595635304224BY	49639
VZVG96	EIA VZV IgG	General IVD	8595635304231BV	49639
VZVM96	EIA VZV IgM	General IVD	8595635304248CE	49639
YeA096	EIA Yersinia IgA	General IVD	8595635309441DD	51900
YeG096	EIA Yersinia IgG	General IVD	8595635309458DW	51904
YeM096	EIA Yersinia IgM	General IVD	8595635309465DT	51912

HUMAN SMART ELISA KITS

Numero di catalogo	Nome del prodotto	Classificazione	UDI-DI di base	Codice GMDN
SK-AdA096	SmartEIA Adenovirus IgA	General IVD	8595635308871E3	49867
SK-AdG096	SmartEIA Adenovirus IgG	General IVD	8595635308888EL	49869
SK-AdM096	SmartEIA Adenovirus IgM	General IVD	8595635308895EH	49872
SK-ScA096	SmartEIA ASCA IgA	General IVD	8595635306570D4	52100
SK-ScG096	SmartEIA ASCA IgG	General IVD	8595635306587DM	52108
SK-BppA96	SmartEIA Bordetella parapertussis IgA	General IVD	8595635306068CQ	50512
SK-BppG96	SmartEIA Bordetella parapertussis IgG	General IVD	8595635306051C7	50512
SK-BppM96	SmartEIA Bordetella parapertussis IgM	General IVD	8595635306044CA	50512
SK-BpAT96	SmartEIA Bordetella pertussis Toxin IgA	General IVD	8595635306020BU	50517
SK-BpGT96	SmartEIA Bordetella pertussis Toxin IgG	General IVD	8595635306037CD	50521
SK-BpMT96	SmartEIA Bordetella pertussis Toxin IgM	General IVD	8595635306075CM	50525
SK-BaM096	SmartEIA Borrelia afzelii IgM	General IVD	8595635305672D6	50585
SK-BaGV96	SmartEIA Borrelia afzelii VlsE IgG	General IVD	8595635305740CW	50581
SK-BsM096	SmartEIA Borrelia b. sensu stricto IgM	General IVD	8595635305689DP	50564
SK-BsGV96	SmartEIA Borrelia b. sensu stricto VlsE IgG	General IVD	8595635305733CZ	50560
SK-BgM096	SmartEIA Borrelia garinii IgM	General IVD	8595635305665D9	50597
SK-BgGV96	SmartEIA Borrelia garinii VlsE IgG	General IVD	8595635305757DF	50593
SK-BM0096	SmartEIA Borrelia IgM	General IVD	8595635305696DL	50564
SK-BrG096	SmartEIA Borrelia recombinant IgG	General IVD	8595635305702CN	50560
SK-BrM096	SmartEIA Borrelia recombinant IgM	General IVD	8595635305719D7	50564
SK-BGV096	SmartEIA Borrelia VlsE IgG	General IVD	8595635305726D4	50560
SK-CCPA96	SmartEIA CCP IgA	General IVD	8595635306303CB	54896
SK-CCPG96	SmartEIA CCP IgG	General IVD	8595635306297D9	54896
SK-CMA096	SmartEIA CMV IgA	Annex II, List B	8595635306266CW	49729
SK-CMG096	SmartEIA CMV IgG	Annex II, List B	8595635306280CQ	49729
SK-CMM096	SmartEIA CMV IgM	Annex II, List B	8595635306273CT	49729
SK-CoNA96	SmartEIA COVID-19 NP IgA	General IVD	8595635309083D9	64830
SK-CoNG96	SmartEIA COVID-19 NP IgG	General IVD	8595635309090D6	64824
SK-CoNM96	SmartEIA COVID-19 NP IgM	General IVD	8595635309106CU	64800

SK-CoRA96	SmartEIA COVID-19 RBD IgA	General IVD	8595635309274DJ	64830
SK-CoRG96	SmartEIA COVID-19 RBD IgG	General IVD	8595635309267DM	64824
SK-CoRM96	SmartEIA COVID-19 RBD IgM	General IVD	8595635309250D4	64800
SK-DNA096	SmartEIA dsDNA	General IVD	8595635307461D5	54902
SK-EAG096	SmartEIA EBV EA-D IgG	General IVD	8595635305917DD	49657
SK-EAM096	SmartEIA EBV EA-D IgM	General IVD	8595635305924DA	49662
SK-EBG096	SmartEIA EBV EBNA-1 IgG	General IVD	8595635305931D7	49657
SK-EBM096	SmartEIA EBV EBNA-1 IgM	General IVD	8595635305948DQ	49662
SK-VCA096	SmartEIA EBV VCA IgA	General IVD	8595635305955DM	60621
SK-VCG096	SmartEIA EBV VCA IgG	General IVD	8595635305962DJ	49657
SK-VCM096	SmartEIA EBV VCA IgM	General IVD	8595635305979E3	49662
SK-ENAp12	SmartEIA ENA profile plus	General IVD	8595635307591DK	54823
SK-ENA096	SmartEIA ENA screen plus	General IVD	8595635306082CJ	54823
SK-GDA096	SmartEIA Gliadin DA IgA	General IVD	8595635306549DD	54947
SK-GDG096	SmartEIA Gliadin DA IgG	General IVD	8595635306556DA	54947
SK-GIA096	SmartEIA Gliadin IgA	General IVD	8595635306532CU	54947
SK-GIG096	SmartEIA Gliadin IgG	General IVD	8595635306563D7	54947
SK-HMA096	SmartEIA Helicobacter MONO IgA	General IVD	8595635306372CW	51004
SK-HMG096	SmartEIA Helicobacter MONO IgG	General IVD	8595635306365CZ	51008
SK-HMM096	SmartEIA Helicobacter MONO IgM	General IVD	8595635306358D4	51012
SK-HS1G96	SmartEIA HSV 1 IgG	General IVD	8595635309656E4	49534
SK-HS1M96	SmartEIA HSV 1 IgM	General IVD	8595635309663DZ	49534
SK-HS2G96	SmartEIA HSV 2 IgG	General IVD	8595635309670DW	49534
SK-HS2M96	SmartEIA HSV 2 IgM	General IVD	8595635309687EF	49534
SK-HSVG96	SmartEIA HSV 1+2 IgG	General IVD	8595635306341CK	49534
SK-HSVM96	SmartEIA HSV 1+2 IgM	General IVD	8595635306334CN	49534
SK-ChA096	SmartEIA Chlamydia IgA	Annex II, List B	8595635305764DC	50720
SK-ChG096	SmartEIA Chlamydia IgG	Annex II, List B	8595635305771D9	50722
SK-ChM096	SmartEIA Chlamydia IgM	Annex II, List B	8595635305788DS	50724
SK-ChpA96	SmartEIA Chlamydia pneumoniae IgA	Annex II, List B	8595635305795DP	50741
SK-ChpG96	SmartEIA Chlamydia pneumoniae IgG	Annex II, List B	8595635305801CR	50737
SK-ChpM96	SmartEIA Chlamydia pneumoniae IgM	Annex II, List B	8595635305818DA	50733
SK-CpAR96	SmartEIA Chlamydia pneumoniae REC IgA	Annex II, List B	8595635305894DS	50741
SK-CpGR96	SmartEIA Chlamydia pneumoniae REC IgG	Annex II, List B	8595635305900CU	50737
SK-ChtA96	SmartEIA Chlamydia trachomatis IgA	Annex II, List B	8595635305863DF	50773
SK-ChtG96	SmartEIA Chlamydia trachomatis IgG	Annex II, List B	8595635305870DC	50768
SK-ChtM96	SmartEIA Chlamydia trachomatis IgM	Annex II, List B	8595635305887DV	50763
SK-InAA96	SmartEIA Influenza A IgA	General IVD	8595635308376DL	49183
SK-InAG96	SmartEIA Influenza A IgG	General IVD	8595635308369DP	49178
SK-InAM96	SmartEIA Influenza A IgM	General IVD	8595635308383DH	49173
SK-InBA96	SmartEIA Influenza B IgA	General IVD	8595635308437DF	49219
SK-InBG96	SmartEIA Influenza B IgG	General IVD	8595635308420CW	49214
SK-InBM96	SmartEIA Influenza B IgM	General IVD	8595635308444DC	49209
SK-Jo1096	SmartEIA Jo-1	General IVD	8595635306310C8	55005

SK-MeG096	SmartEIA Measles IgG	General IVD	8595635307867E5	49287
SK-MeM096	SmartEIA Measles IgM	General IVD	8595635307874E2	49280
SK-MiA096	SmartEIA Milk IgA	General IVD	8595635306426CU	67721
SK-MiG096	SmartEIA Milk IgG	General IVD	8595635306433CR	58945
SK-MiM096	SmartEIA Milk IgM	General IVD	8595635306440CN	67722
SK-MuA096	SmartEIA Mumps IgA	General IVD	8595635307904DJ	49338
SK-MuG096	SmartEIA Mumps IgG	General IVD	8595635307911DF	49338
SK-MuM096	SmartEIA Mumps IgM	General IVD	8595635307928DY	49338
SK-MyA096	SmartEIA Mycoplasma IgA	General IVD	8595635306396DC	51212
SK-MyG096	SmartEIA Mycoplasma IgG	General IVD	8595635306402CE	51207
SK-MyM096	SmartEIA Mycoplasma IgM	General IVD	8595635306419CX	51202
SK-MyAR96	SmartEIA Mycoplasma REC IgA	General IVD	8595635307553DB	51212
SK-MyGR96	SmartEIA Mycoplasma REC IgG	General IVD	8595635307560D8	51207
SK-MyMR96	SmartEIA Mycoplasma REC IgM	General IVD	8595635307546DE	51202
SK-PaiA96	SmartEIA Parainfluenza mix IgA	General IVD	8595635308499E5	49388
SK-PaiG96	SmartEIA Parainfluenza mix IgG	General IVD	8595635308482DL	49384
SK-PaiM96	SmartEIA Parainfluenza mix IgM	General IVD	8595635308505D7	49380
SK-PVG096	SmartEIA Parvovirus B19 IgG	General IVD	8595635310539CB	50157
SK-PVM096	SmartEIA Parvovirus B19 IgM	General IVD	8595635310560C2	50164
SK-PCG096	SmartEIA PCP IgG	General IVD	8595635306389DF	51783
SK-RFA096	SmartEIA RF IgA	General IVD	8595635306129CK	55107
SK-RFG096	SmartEIA RF IgG	General IVD	8595635306112C2	55107
SK-RFM096	SmartEIA RF IgM	General IVD	8595635306105C5	55107
SK-RSA096	SmartEIA RSV IgA	General IVD	8595635308918E4	49519
SK-RSG096	SmartEIA RSV IgG	General IVD	8595635308901DK	49513
SK-RSM096	SmartEIA RSV IgM	General IVD	8595635308925DZ	49508
SK-RubG96	SmartEIA Rubella IgG	Annex II, List B	8595635306013BX	50265
SK-RubM96	SmartEIA Rubella IgM	Annex II, List B	8595635306006C2	50268
SK-Scl096	SmartEIA Scl-70	General IVD	8595635306198D6	55126
SK-Sm0096	SmartEIA Sm	General IVD	8595635306181CM	55160
SK-SSA096	SmartEIA SS-A	General IVD	8595635306211C5	55129
SK-SSB096	SmartEIA SS-B	General IVD	8595635306204C8	55132
SK-TBG096	SmartEIA TBE Virus IgG	General IVD	8595635306457D7	49027
SK-TBM096	SmartEIA TBE Virus IgM	General IVD	8595635306464D4	49023
SK-TeTG96	SmartEIA Tetanus Toxoid IgG	General IVD	8595635309403D5	50874
SK-TcA096	SmartEIA Toxocara IgA	General IVD	8595635305986DY	52418
SK-TcG096	SmartEIA Toxocara IgG	General IVD	8595635305993DV	52418
SK-TgA096	SmartEIA Toxoplasma IgA	Annex II, List B	8595635305856DJ	52444
SK-TgE096	SmartEIA Toxoplasma IgE	Annex II, List B	8595635305849DM	52444
SK-TgG096	SmartEIA Toxoplasma IgG	Annex II, List B	8595635305832D4	52444
SK-TgM096	SmartEIA Toxoplasma IgM	Annex II, List B	8595635305825D7	52444
SK-tTA096	SmartEIA Transglutaminase IgA	General IVD	8595635306518D2	55223
SK-tTG096	SmartEIA Transglutaminase IgG	General IVD	8595635306525CX	55223
SK-TpG096	SmartEIA Treponema pallidum IgG	General IVD	8595635306488DJ	51804
SK-TpM096	SmartEIA Treponema pallidum IgM	General IVD	8595635306495DF	51809

SK-Tp0096	SmartEIA Treponema pallidum TOTAL	General IVD	8595635306501CH	51798
SK-RNP096	SmartEIA U1RNP	General IVD	8595635306242CG	55165
SK-VZVA96	SmartEIA VZV IgA	General IVD	8595635306150CA	49639
SK-VZVG96	SmartEIA VZV IgG	General IVD	8595635306143CD	49639
SK-VZVM96	SmartEIA VZV IgM	General IVD	8595635306136CG	49639
SK-YeA096	SmartEIA Yersinia IgA	General IVD	8595635309472DQ	51900
SK-YeG096	SmartEIA Yersinia IgG	General IVD	8595635309489E9	51904
SK-YeM096	SmartEIA Yersinia IgM	General IVD	8595635309496E6	51912

HUMAN IMUNOBLOT KITS

Numero di catalogo	Nome del prodotto	Classificazione	UDI-DI di base	Codice GMDN
TcGB16	BLOT Toxocara IgG	General IVD	8595635300684CA	52421
ANAL20	BLOT-LINE ANA	General IVD	8595635300790CA	67753
ApGL10	BLOT-LINE Anaplasma IgG	General IVD	8595635305153C9	51345
ApML10	BLOT-LINE Anaplasma IgM	General IVD	8595635305146CC	51341
ANC3L20	BLOT-LINE ANCA-3	General IVD	8595635307034CE	67720
BpAL20	BLOT-LINE Bordetella IgA	General IVD	8595635304446CL	50512
BpGL20	BLOT-LINE Bordetella IgG	General IVD	8595635304453CH	50512
BpML20	BLOT-LINE Bordetella IgM	General IVD	8595635305610CG	50512
BaGL20	BLOT-LINE Borrelia afzelii IgG	General IVD	8595635301032AY	50576
BaML20	BLOT-LINE Borrelia afzelii IgM	General IVD	8595635301049BH	50576
BsGL20	BLOT-LINE Borrelia b. sensu stricto IgG	General IVD	8595635304187CK	50555
BsML20	BLOT-LINE Borrelia b. sensu stricto IgM	General IVD	8595635304194CG	50555
BgGL20	BLOT-LINE Borrelia garinii IgG	General IVD	8595635301056BE	50596
BgML20	BLOT-LINE Borrelia garinii IgM	General IVD	8595635301063BB	50600
BGL020	BLOT-LINE Borrelia/HGA IgG	General IVD	8595635300721BP	50555
BML020	BLOT-LINE Borrelia/HGA IgM	General IVD	8595635300738C8	50555
CMGL20	BLOT-LINE CMV IgG	Annex II, List B	8595635309533DK	49735
CMML20	BLOT-LINE CMV IgM	Annex II, List B	8595635309526DN	49735
EBAL20	BLOT-LINE EBV IgA	General IVD	8595635309212CU	62754
EBGL20	BLOT-LINE EBV IgG	General IVD	8595635307652DE	49669
EBML20	BLOT-LINE EBV IgM	General IVD	8595635307645DH	49667
HpAL20	BLOT-LINE Helicobacter IgA	General IVD	8595635306792DQ	51020
HpGL20	BLOT-LINE Helicobacter IgG	General IVD	8595635306785DT	51020
CAL020	BLOT-LINE Chlamydia IgA	Annex II, List B	8595635304422C6	50720
CGL020	BLOT-LINE Chlamydia IgG	Annex II, List B	8595635304439CP	50722
CpAL20	BLOT-LINE Chlamydia pneumoniae IgA	Annex II, List B	8595635304408CC	50720
CpGL20	BLOT-LINE Chlamydia pneumoniae IgG	Annex II, List B	8595635304415C9	50722
CpML20	BLOT-LINE Chlamydia pneumoniae IgM	Annex II, List B	8595635305184CL	50748
CtAL20	BLOT-LINE Chlamydia trachomatis IgA	Annex II, List B	8595635304033BP	50792
CtGL20	BLOT-LINE Chlamydia trachomatis IgG	Annex II, List B	8595635304040BL	50792
MyAL20	BLOT-LINE Mycoplasma IgA	General IVD	8595635308307CZ	51197
MyGL20	BLOT-LINE Mycoplasma IgG	General IVD	8595635308314CW	51197
MyML20	BLOT-LINE Mycoplasma IgM	General IVD	8595635308321CT	51197
TgAL20	BLOT-LINE Toxoplasma IgA	Annex II, List B	8595635309595E9	52458

TgGL20	BLOT-LINE Toxoplasma IgG	Annex II, List B	8595635309588EC	52458
TgML20	BLOT-LINE Toxoplasma IgM	Annex II, List B	8595635309571DT	52458
TpGL20	BLOT-LINE Treponema IgG	General IVD	8595635301124B6	51818
TpML20	BLOT-LINE Treponema IgM	General IVD	8595635301131B3	51818
YAL020	BLOT-LINE Yersinia IgA	General IVD	8595635307232CL	51890
YGL020	BLOT-LINE Yersinia IgG	General IVD	8595635307249D5	51890
YML020	BLOT-LINE Yersinia IgM	General IVD	8595635307256D2	51890
BD-BpAL24	BlueBLOT-LINE Bordetella IgA	General IVD	8595635306860DG	50512
BD-BpGL24	BlueBLOT-LINE Bordetella IgG	General IVD	8595635306914DE	50512
BD-BGL024	BlueBLOT-LINE Borrelia IgG	General IVD	8595635305214C4	50555
BD-BML024	BlueBLOT-LINE Borrelia IgM	General IVD	8595635305207C7	50555
BD-EBGL24	BlueBLOT-LINE EBV IgG	General IVD	8595635308239D9	49669
BD-EBML24	BlueBLOT-LINE EBV IgM	General IVD	8595635308222CQ	49667
BD-HpAL24	BlueBLOT-LINE Helicobacter IgA	General IVD	8595635307812DC	51020
BD-HpGL24	BlueBLOT-LINE Helicobacter IgG	General IVD	8595635307805DF	51020
BD-CAL024	BlueBLOT-LINE Chlamydia IgA	Annex II, List B	8595635306815DB	50720
BD-CGL024	BlueBLOT-LINE Chlamydia IgG	Annex II, List B	8595635306846DN	50722
BD-MyAL24	BlueBLOT-LINE Mycoplasma IgA	General IVD	8595635309816E2	51197
BD-MyGL24	BlueBLOT-LINE Mycoplasma IgG	General IVD	8595635309823DX	51197
BD-MyML24	BlueBLOT-LINE Mycoplasma IgM	General IVD	8595635309830DU	51197
BD-TpGL24	BlueBLOT-LINE Treponema IgG	General IVD	8595635306921DB	51818
BD-TpML24	BlueBLOT-LINE Treponema IgM	General IVD	8595635306938DU	51818
BD-YAL024	BlueBLOT-LINE Yersinia IgA	General IVD	8595635308291DB	51890
BD-YGL024	BlueBLOT-LINE Yersinia IgG	General IVD	8595635308277DH	51890

HUMAN MICROBLOT KITS

Numero di catalogo	Nome del prodotto	Classificazione	UDI-DI di base	Codice GMDN
ANAMA96	Microblot-Array ANA	General IVD	8595635308079DB	67753
ANApMA96	Microblot-Array ANA plus	General IVD	8595635308086D8	67753
AIGAMA48	Microblot-Array Autoimmune gastroenteritis panel IgA	IVDR class B	8595635311994DE	65925
AIGGMA48	Microblot-Array Autoimmune gastroenteritis panel IgG	IVDR class B	8595635312007BK	65925
BpAMA48	Microblot-Array Bordetella IgA	General IVD	8595635310614BY	50512
BpGMA48	Microblot-Array Bordetella IgG	General IVD	8595635310621BV	50512
BpMMA48	Microblot-Array Bordetella IgM	General IVD	8595635310638CE	50512
BGMA096	Microblot-Array Borrelia IgG	General IVD	8595635306600CL	50555
BMMA096	Microblot-Array Borrelia IgM	General IVD	8595635306617D5	50555
CMGMA48	Microblot-Array CMV IgG	IVDR class C	8595635311703C7	49718
CMMMA48	Microblot-Array CMV IgM	IVDR class C	8595635311710C4	49728
CoVAMA96	Microblot-Array COVID-19 IgA	General IVD	8595635309342DA	64867
CoVGMA96	Microblot-Array COVID-19 IgG	General IVD	8595635309359DT	64867
CoVMMA96	Microblot-Array COVID-19 IgM	General IVD	8595635309366DQ	64867
EBAMA96	Microblot-Array EBV IgA	General IVD	8595635308734DQ	62754
EBGMA96	Microblot-Array EBV IgG	General IVD	8595635308772DY	62754
EBMMA96	Microblot-Array EBV IgM	General IVD	8595635308765E3	62754

HpAMA48	Microblot-Array Helicobacter IgA	General IVD	8595635310577CK	51020
HpGMA48	Microblot-Array Helicobacter IgG	General IVD	8595635310584CG	51020
HSGMA48	Microblot-Array HSV 1+2 IgG	IVDR class C	8595635311741CF	49542
HSMMA48	Microblot-Array HSV 1+2 IgM	IVDR class C	8595635311758CY	49551
CAMA096	Microblot-Array Chlamydia IgA	Annex II, List B	8595635306945DR	50720
CGMA096	Microblot-Array Chlamydia IgG	Annex II, List B	8595635306952DN	50722
LKMMA48	Microblot-Array Liver profile	IVDR class B	8595635311697D5	54834
MyAMA48	Microblot-Array Mycoplasma IgA	General IVD	8595635311284C8	51197
MyGMA48	Microblot-Array Mycoplasma IgG	General IVD	8595635311277CB	51197
MyMMA48	Microblot-Array Mycoplasma IgM	General IVD	8595635311321BM	51197
YAMA048	Microblot-Array Yersinia IgA	General IVD	8595635310676CN	51890
YGMA048	Microblot-Array Yersinia IgG	General IVD	8595635310683CK	51890

TESTS FOR BACTERIOLOGY

Numero di catalogo	Nome del prodotto	Classificazione	UDI-DI di base	Codice GMDN
Ut0050	UREASAtest 50	IVDR class A	859563530ureasaZ9	52787
Utb100	UREASAtest bulk	IVDR class A	859563530ureasaZ9	52787

SOFTWARE

Numero di catalogo	Nome del prodotto	Classificazione	UDI-DI di base	GMDN code
SwAI01	Antibody Index Software	IVDR class A	8595635304996DU	42838
SwIm03	Immunoblot Software	IVDR class A	8595635311338C6	42838

INSTRUMENTS

Numero di catalogo	Nome del prodotto	Classificazione	UDI-DI di base	Codice GMDN
ARCXIX096	Array Reader C–series	IVDR class A	8595635311345C3	57862

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