



virion\serion

Declaration of Conformity

We hereby declare that the products listed in the attached pages of this document fulfil the obligations of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices

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Dr Judith Stürmer
Product Safety Officer

Date: 8th January 2010

Articles with CE-Label

Article-Nr.	Description
1111	M.PNEUMONIAE Ag
1112	INFLUENZA VIRUS A Ag
1113	INFLUENZA VIRUS B Ag
1114	INFLUENZA VIRUS-POOL Ag
1115	PARAINFLUENZA-POOL Ag
1116	PARAINFLUENZA VIRUS 1 Ag
1117	PARAINFLUENZA VIRUS 2 Ag
1118	PARAINFLUENZA VIRUS 3 Ag
1121	ADENO VIRUSES Ag
1122	CHLAMYDIA Ag
1123	C.BURNETII Phase 2 Ag
1124	RSV Ag
1125	PAROTITIS-VIRUS Ag
1126	PICORNA-VIRUS Ag
1127	POLIO-VIRUS Ag
1130	CMV Ag
1132	EBV Ag
1154	HSV 1+2 Ag
1172	COXSACKIE B1-VIRUS Ag
1173	COXSACKIE B2-VIRUS Ag
1174	COXSACKIE B3-VIRUS Ag
1175	COXSACKIE B4-VIRUS Ag
1176	COXSACKIE B5-VIRUS Ag
1177	COXSACKIE B6-VIRUS Ag
1178	COXSACKIE-POOL Ag
1180	ECHOVIRUS-POOL Ag
1190	MEASLES-VIRUS Ag
1191	VZV Ag
1192	TBE VIRUS Ag
1193	ROTA-VIRUS Ag
1201	Y.PSEUDO. Ag
1203	Y. ENTERO.03 Ag
1206	CAMP.JEJUNI Ag
1207	CAMP.INTEST.(FETUS) Ag
1209	Y. ENTERO.09 Ag
1220	SH. DYSENTERIAE Ag
1224	LEG.PNEUMOPHILA Ag
1227	C.BURNETII Phase 1 Ag
1234	LISTERIA MONOCYTO. Ag
1253	N. GONORRHOEAE Ag
1297	BRUCELLA Ag
1331	TOXOPLASMA GONDII Ag
2112	INFLUENZA VIRUS A CAg
2113	INFLUENZA VIRUS B CAg
2114	INFLUENZA VIRUS-POOL CAg
2115	PARAINFLUENZA VIRUS-POOL CAg
2116	PARAINFLUENZA VIRUS 1 CAg
2117	PARAINFLUENZA VIRUS 2 CAg

Articles with CE-Label

Article-Nr.	Description
2118	PARAINFLUENZA VIRUS 3 CAg
2121	ADENO VIRUS CAg
2122	CHLAMYDIA CAg
2123	C.BURNETII Phase 2 CAg
2124	RSV CAg
2125	PAROTITIS-VIRUS CAg
2126	PICORNA-VIRUS CAg
2127	POLIO-VIRUS CAg
2130	CMV CAg
2132	EBV CAg
2154	HSV 1+2 CAg
2178	COXSACKIE-POOL CAg
2179	COXSACKIE B1-B6 CAg
2180	ECHOVIRUS-POOL CAg
2190	MEASLES-VIRUS CAg
2191	VZV CAg
2192	TBE VIRUS CAg
2193	ROTA-VIRUS CAg
2227	C.BURNETII Phase 1 CAg
2331	TOXOPLASMA GONDII CAg
3111	M. PNEUMONIAE pos.con.
3112	INFLUENZA VIRUS A pos.con.
3113	INFLUENZA VIRUS B pos.con.
3114	INFLUENZA VIRUS-POOL pos.con.
3115	PARAINFLUENZAVIRUS-POOL pos.c.
3116	PARAINFLUENZA VIRUS 1 pos.con.
3117	PARAINFLUENZA VIRUS 2 pos.con.
3118	PARAINFLUENZA VIRUS 3 pos.con.
3120	L. BIFLEXA pos.con.
3121	ADENO-VIRUS pos.con.
3122	CHLAMYDIA pos.con.
3123	C.BURNETII Phase 2 pos.con.
3124	RSV pos.con.
3125	PAROTITIS-VIRUS pos.con.
3126	PICORNA-VIRUS pos.con.
3127	POLIO-VIRUS pos.con.
3130	CMV pos.con.
3132	EBV pos.con.
3154	HSV 1+2 pos.con.
3172	COXSACKIE B1 pos.con.
3173	COXSACKIE B2 pos.con.
3174	COXSACKIE B3 pos.con.
3175	COXSACKIE B4 pos.con.
3176	COXSACKIE B5 pos.con.
3177	COXSACKIE B6 pos.con.
3178	COXSACKIE-POOL pos.con.
3180	ECHOVIRUS-POOL pos.con.
3190	MEASLES-VIRUS pos.con.

Articles with CE-Label

Article-Nr.	Description
3191	VZV pos.con.
3192	TBE VIRUS pos.con.
3193	ROTA-VIRUS pos.con.
3201	Y. PSEUDO. pos.con.
3203	Y. ENTERO.03 pos.con.
3206	CAMP.JEJUNI pos.con.
3207	CAMP.INTEST.(FETUS) pos.con.
3209	Y. ENTERO.09 pos.con.
3224	LEG.PNEUMOPHILA pos.con.
3227	C.BURNETII Phase 1 pos.con.
3234	LISTERIA MONOCYTO. pos.con.
3253	N. GONORRHOEAE pos.con.
3297	BRUCELLA pos.con.
3331	TOXOPLASMA GONDII pos.con.
4111	M.PNEUMONIAE neg.con.
4112	INFLUENZA VIRUS A neg.con.
4113	INFLUENZA VIRUS B neg.con.
4114	INFLUENZA VIRUS-POOL neg.con.
4115	PARAINFLUENZA-POOL neg.con.
4116	PARAINFLUENZA VIRUS 1 neg.con.
4117	PARAINFLUENZA VIRUS 2 neg.con.
4118	PARAINFLUENZA VIRUS 3 neg.con.
4121	ADENO VIRUS neg.con.
4122	CHLAMYDIA neg.con.
4123	C.BURNETII Phase 2 neg.con.
4124	RSV neg.con.
4125	PAROTITIS-VIRUS neg.con.
4126	PICORNA-VIRUS neg.con.
4127	POLIO-VIRUS neg.con.
4130	CMV neg.con.
4132	EBV neg.con.
4154	HSV 1+2 neg.con.
4172	COXSACKIE B1 neg.con.
4173	COXSACKIE B2 neg.con.
4174	COXSACKIE B3 neg.con.
4175	COXSACKIE B4 neg.con.
4176	COXSACKIE B5 neg.con.
4177	COXSACKIE B6 neg.con.
4178	COXSACKIE Pool neg.con.
4180	ECHOVIRUS POOL neg.con.
4190	MEASLES-VIRUS neg.con.
4191	VZV neg.con.
4192	TBE VIRUS neg.con.
4193	ROTA VIRUS neg.con.
4201	Y. PSEUDO. neg.con.
4203	Y. ENTERO.03 neg.con.
4206	CAMP.JEJUNI neg.con.
4207	CAMP.INTEST.(FETUS) neg.con.

Articles with CE-Label

Article-Nr.	Description
4209	Y. ENTERO.09 neg.con.
4224	LEG.PNEUMOPHILA neg.con.
4227	C.BURNETII Phase 1 neg.con.
4234	LISTERIA MONOCYTO. neg.con.
4253	N. GONORRHOEAE neg.con.
4297	BRUCELLA neg.con.
4331	TOXOPLASMA GONDII neg.con.
9000	HAEMOLYTIC SYSTEM
9001	COMPLEMENT, stabilized
9002	HAEMOLYTIC AMBOCEPTOR
9004	SHEEP-ERYTHROCYTES (50%)
9005	READY TO USE ERYTHROCYTE SUSP
9006	CFT BUFFER concentrated 20x
9008	Erythrocytes Susp. (1%) 50ml
9009	HEPES Buffer CFT
9060	COXSACKIE A9 Ag
9061	COXSACKIE A9 pos.con.
9062	COXSACKIE A9 neg.con.
9070	L. GRIPPOTYPHOSA Ag
9071	LEPTOSPIRA pos.con.
9072	LEPTOSPIRA neg.con.
9080	L. ICTERO. Ag
9090	L. CANICOLA Ag
9100	L. POMONA Ag
9110	L. SERJOE Ag
9120	L. BIFLEXA Ag
9260	COXSACKIE A9 CAg
A117	Candida Antigen Kit
A1231	INFLUENZA A-VIRUS Ag Kit
A1232	INFLUENZA B-VIRUS Ag Kit
A1237	Quadrogen Kit
A127	M.PNEUMONIAE Ag Kit
BR102G	MEASLES VIRUS IgG Reference Se
BR102M	MEASLES IgM Reference Serum
BR103G	PAROTITIS VIRUS IgG Reference
BR103M	PAROTITIS VIRUS IgM Reference
BR104A	VZV VIRUS IgA Reference Serum
BR104G	VZV VIRUS IgG Reference Serum
BR104M	VZV VIRUS IgM Reference Serum
BR105A	HSV VIRUS 1+2 IgA Reference Se
BR105G	HSV VIRUS 1+2 IgG Reference Se
BR105M	HSV VIRUS 1+2 IgM Reference Se
BR1051G	HSV VIRUS 1 IgG Reference Seru
BR1051M	HSV VIRUS 1 IgM Reference Seru
BR1052G	HSV VIRUS 2 IgG Reference Seru
BR1052M	HSV VIRUS 2 IgM Reference Seru
BR106G	LEGIONELLA PNEUM. 1-7 IgG Refe
BR106M	LEGIONELLA PNEUM. 1-7 IgM Refe

Articles with CE-Label

Article-Nr.	Description
BR107G	Echinococcus IgG Reference Ser
BR108G	TETANUS IgG Reference Serum
BR109AVID	CMV Referenzserum Avid
BR109G	CMV VIRUS IgG Reference Serum
BR109M	CMV VIRUS IgM Reference Serum
BR110AVID	Toxoplasma Referenzserum Avid
BR110G	TOXOPLASMA GONDII IgG Referenc
BR110M	TOXOPLASMA GONDII IgM Referenc
BR112G	TBE VIRUS IgG Reference Serum
BR112M	TBE VIRUS IgM Reference Serum
BR113A	RSV VIRUS IgA Reference Serum
BR113G	RSV VIRUS IgG Reference Serum
BR116A	BRUCELLA IgA Reference Serum
BR116G	BRUCELLA IgG Reference Serum
BR116M	BRUCELLA IgM Reference Serum
BR117A	CANDIDA IgA Reference Serum
BR117G	CANDIDA IgG Reference Serum
BR117M	CANDIDA IgM Reference Serum
BR118A	H.PYLORI IgA Reference Serum
BR118G	H.PYLORI IgG Reference Serum
BR118M	H.PYLORI IgM Reference Serum
BR120A	B.PERTUSSIS IgA Reference Seru
BR120G	B.PERTUSSIS IgG Reference Seru
BR120M	B.PERTUSSIS IgM Reference Seru
BR1201G	B.pertussis toxin IgG referenc
BR121G	B.BURGDORFERI IgG Reference Se
BR121M	B.BURGDORFERI IgM Reference Se
BR122G	PARVOVIRUS B19 IgG Reference S
BR122M	PARVOVIRUS B19 IgM Reference S
BR1231A	INFLUENZA A VIRUS IgA Referenc
BR1231G	INFLUENZA A VIRUS IgG Referenc
BR1232A	INFLUENZA B VIRUS IgA Referenc
BR1232G	INFLUENZA B VIRUS IgG Referenc
BR125G	LEPTOSPIRA IgG Reference Serum
BR125M	LEPTOSPIRA IgM Reference Serum
BR126A	PARAINFLUENZA 1,2,3 IgA Refere
BR1261G	PARAINFLUENZA 1 IgG Reference
BR1262G	PARAINFLUENZA 2 IgG Reference
BR1263G	PARAINFLUENZA 3 IgG Reference
BR127A	M.PNEUMONIAE IgA Reference Se
BR127G	M.PNEUMONIAE IgG Reference Ser
BR127M	M.PNEUMONIAE IgM Reference Ser
BR128A	ADENOVIRUS IgA Reference Serum
BR128G	ADENOVIRUS IgG Reference Serum
BR129AVID	Rubella Reference Serum Avidit
BR129G	RUBELLA VIRUS IgG Reference Se
BR129M	RUBELLA VIRUS IgM Reference Se
BR130G	DIPHTHERIA IgG Reference Serum

Articles with CE-Label

Article-Nr.	Description
BR1311A	C.BURNETII Phase 1 IgA Referen
BR1311G	C.BURNETII Phase 1 IgG Referen
BR1312G	C.BURNETII Phase 2 IgG Referen
BR1312M	C.BURNETII Phase 2 IgM Referen
BR132A	ASPERGILLUS FUM. IgA Reference
BR132G	ASPERGILLUS FUM. IgG Reference
BR132M	ASPERGILLUS FUM. IgM Reference
BR133A	Enterovirus IgA Reference Seru
BR133G	Enterovirus IgG Reference Seru
BR133M	Enterovirus IgM Ref. Serum
BR134A	COXSACKIEVIRUS IgA Reference S
BR134G	COXSACKIEVIRUS IgG Reference S
BR134M	COXSACKIEVIRUS IgM Reference S
BR135A	ECHOVIRUS IgA Reference Serum
BR135G	ECHOVIRUS IgG Reference Serum
BR135M	ECHOVIRUS IgM Reference Serum
BR1361G	EBV VCA IgG Reference Serum
BR1361M	EBV VCA IgM Reference Serum
BR1362G	EBV EBNA 1 IgG Reference Serum
BR1363G	EBV-EA IgG Reference Serum
BR137A	CHLAMYDIA IgA Reference Serum
BR137G	CHLAMYDIA IgG Reference Serum
BR1371A	C. pneumoniae IgA Ref.-Serum
BR1371G	C. pneumoniae IgG Ref.-Serum
BR138A	YERSINIA IgA Reference Serum
BR138G	YERSINIA IgG Reference Serum
BR138M	Yersinia IgM Reference Serum
BR139A	C. jejuni IgA Reference Serum
BR139G	C. jejuni IgG Reference Serum
BR139M	C. jejuni IgM Reference Serum
BR143G	Thyroperoxidase IgG Ref.-Serum
BR144G	Thyroglobulin IgG Ref.-Serum
B109AVID	CMV Aviditätsreagenz
B110AVID	Toxoplasma Avidity
B129AVID	Rubella avidity
B231	dilution buffer
B231BOR	dilution buffer Borrelia
B231EA	dilution buffer EBV early ag
B231PM	dil. buffer Parvovirus IgM
B231-S1	Dilution Buffer S1
B231-S2	Verd. Puffer S2
B231-S3	Verd. Puffer S3
B232	wash solution
B235	stop solution 15ml
B236	Substrate RTU
ESR102G	MEASLES VIRUS IgG Kit
ESR102M	MEASLES VIRUS IgM Kit
ESR103G	PAROTITIS IgG Kit

Articles with CE-Label

Article-Nr.	Description
ESR103M	PAROTITIS IgM Kit
ESR104A	VZV IgA Kit
ESR104G	VZV IgG Kit
ESR104M	VZV IgM Kit
ESR105A	HSV 1/2 IgA Kit
ESR105G	HSV 1/2 IgG Kit
ESR105M	HSV 1/2 IgM Kit
ESR1051G	HSV 1 IgG Kit
ESR1051M	HSV 1 IgM Kit
ESR1052G	HSV 2 IgG Kit
ESR1052M	HSV 2 IgM Kit
ESR106G	L. PNEU. 1-7 IgG Kit
ESR106M	L. PNEU. 1-7 IgM Kit
ESR107G	ECHINOCOCCUS IgG Kit
ESR108G	TETANUS IgG Kit
ESR109G	CMV IgG Kit
ESR109M	CMV IgM Kit
ESR110G	TOXOPLASMA IgG Kit
ESR110M	TOXOPLASMA IgM Kit
ESR112G	TBE IgG Kit
ESR112M	TBE IgM Kit
ESR113A	RSV IgA Kit
ESR113G	RSV IgG Kit
ESR116A	BRUCELLA IgA Kit
ESR116G	BRUCELLA IgG Kit
ESR116M	BRUCELLA IgM Kit
ESR117A	CANDIDA IgA Kit
ESR117G	CANDIDA IgG Kit
ESR117M	CANDIDA IgM Kit
ESR118A	H. PYLORI IgA Kit
ESR118G	H. PYLORI IgG Kit
ESR118M	H. PYLORI IgM Kit
ESR120A	B. PERTUSSIS IgA Kit
ESR120G	B. PERTUSSIS IgG Kit
ESR120M	B. PERTUSSIS IgM Kit
ESR1201G	B. PERTUSSIS TOXIN IgG Kit
ESR121G	B. BURGDORF. IgG Kit
ESR121M	B. BURGDORF. IgM Kit
ESR122G	PARVOVIRUS B19 IgG Kit
ESR122M	PARVOVIRUS B19 IgM Kit
ESR1231A	INFLUENZA A-VIRUS IgA Kit
ESR1231G	INFLUENZA A-VIRUS IgG Kit
ESR1232A	INFLUENZA B-VIRUS IgA Kit
ESR1232G	INFLUENZA B-VIRUS IgG Kit
ESR125G	LEPTOSPIRA IgG Kit
ESR125M	LEPTOSPIRA IgM Kit
ESR126A	PARAINFLUENZAVIRUS IgA Kit
ESR1261G	PARAINFLUENZAVIRUS 1 IgG Kit

Articles with CE-Label

Article-Nr.	Description
ESR1262G	PARAINFLUENZAVIRUS 2 IgG Kit
ESR1263G	PARAINFLUENZAVIRUS 3 IgG Kit
ESR127A	M. PNEUMONIAE IgA Kit
ESR127G	M. PNEUMONIAE IgG Kit
ESR127M	M. PNEUMONIAE IgM Kit
ESR128A	ADENOVIRUS IgA Kit
ESR128G	ADENOVIRUS IgG Kit
ESR129G	RUBELLA IgG Kit
ESR129M	RUBELLA IgM Kit
ESR130G	DIPHTHERIA IgG Kit
ESR1311A	C. BURNETII PH. I IgA Kit
ESR1311G	C. BURNETII PH. I IgG Kit
ESR1312G	C. BURNETII PH. II IgG Kit
ESR1312M	C. BURNETII PH. II IgM Kit
ESR132A	ASPERGILLUS FUM. IgA Kit
ESR132G	ASPERGILLUS FUM. IgG Kit
ESR132M	ASPERGILLUS FUM. IgM Kit
ESR133A	ENTEROVIRUS IgA Kit
ESR133G	ENTEROVIRUS IgG Kit
ESR133M	ENTEROVIRUS IgM Kit
ESR134A	COXSACKIEVIRUS IgA Kit
ESR134G	COXSACKIEVIRUS IgG Kit
ESR134M	COXSACKIEVIRUS IgM Kit
ESR135A	ECHOVIRUS IgA Kit
ESR135G	ECHOVIRUS IgG Kit
ESR135M	ECHOVIRUS IgM Kit
ESR1361A	EBV-VCA IgA Kit
ESR1361G	EBV-VCA IgG Kit
ESR1361M	EBV-VCA IgM Kit
ESR1362G	EBV-EBNA 1 IgG Kit
ESR1363G	EBV-EA IgG Kit
ESR137A	CHLAMYDIA IgA Kit
ESR137G	CHLAMYDIA IgG Kit
ESR1371A	Chlamydia pneumoniae IgA Kit
ESR1371G	Chlamydia pneumoniae IgG Kit
ESR1371M	Chlamydia pneumoniae IgM Kit
ESR1372A	Chlamydia trachomatis IgA Kit
ESR1372G	Chlamydia trachomatis IgG Kit
ESR1372M	Chlamydia trachomatis IgM Kit
ESR138A	YERSINIA IgA Kit
ESR138G	YERSINIA IgG Kit
ESR138M	Yersinia IgM Kit
ESR139A	CAMPYLOBACTER JEJUNI IgA Kit
ESR139G	CAMPYLOBACTER JEJUNI IgG Kit
ESR139M	CAMPYLOBACTER JEJUNI IgM Kit
ESR140G	Bacillus anthracis IgG Kit
ESR142G	FRANCISELLA TULARENSIS IgG Kit
ESR142M	FRANCISELLA TULARENSIS IgM Kit

Articles with CE-Label

Article-Nr.	Description
ESR143G	Thyroperoxidase IgG Kit
ESR144G	Thyroglobulin IgG Kit
ESR145G	Hantavirus Puumala IgG Kit
ESR145M	Hantavirus Puumala IgM Kit
KIGAR +	IgA Conjugate 13 ml +
KIGAR ++	IgA Conjugate 13 ml ++
KIGAR +++	IgA Conjugate 13 ml +++
KIGGR +	IgG Conjugate 13 ml +
KIGGR ++	IgG Conjugate 13 ml ++
KIGGR +++	IgG Conjugate 13 ml +++
KIGMR +	IgM Conjugate 13 ml +
KIGMR ++	IgM Conjugate 13 ml ++
KIGMR +++	IgM Conjugate 13 ml +++
MK2000	MA SETUP Kit
MK2020G	MA DTPt IgG Kit
MK2080G	MA EBV IgG Kit
MK2100M	MA EBV IgM Kit
MK2140G	MA Borrelia b. IgG Kit
MK2160M	MA Borrelia b. IgM Kit
MK2360G	MA Liquor/CSF IgG Kit
MK2400G	MA HSV 1/2 IgG Kit
MK2420G	MA Bacillus anthracis IgG Kit
MK2440G	MA F. tularensis IgG Kit
MK2460G	MA Hantavirus Puumala IgG Kit
MK2480G	MA Brucella IgG Kit
ST121.1	Serion Borrelia Schnelltest 10
ST121.2	Serion Borrelia Schnelltest 25
T200	RF-Absorbent with CoAg
T4	RF-Absorbent with CoAg
Z200	RF-Absorbent
Z4	RF-Absorbent
9001.5	COMPLEMENT, stabilized