FEDERAL SERVICE FOR SUPERVISION OF CONSUMER RIGHTS PROTECTION AND HUMAN WELFARE
FEDERAL BUDGET INSTITUTE OF SCIENCE
«CENTRAL RESEARCH INSTITUTE FOR EPIDEMIOLOGY»
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CE

EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of 27th of October 1998 on In Vitro Diagnostic Medical Devices

Federal Budget Institute of Science "Central Research Institute for Epidemiology" hereby under own responsibility declares that the products covered by the declaration conform with Essential Requirements listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation is retained under the premises of the manufacturer.

The quality management system meets the requirements of the standard EN ISO 13485 "Medical devices – Quality management systems – Requirements for regulatory purposes" and is certified by Institute for testing and certification, Inc. (certificate No. 18 0028 SJ, valid until 2021.05.07).

Manufacturer:	Federal Budget Institute of Science "Central Research Institute for Epidemiology"
Authorized Representative:	Ecoli s.r.o. Studenohorska 12 841 03 Bratislava 47 Slovak Republic Tel.: +421 2 6478 9336 Fax: +421 2 6478 9040
Product Name:	Annex for this Declaration
Description:	Reagent kits for qualitative detection and quantification of DNA (RNA) of different infectious agents
Classification:	Article 9, paragraph 1 of EC Council Directive 98/79/EC on *in Vitro* Diagnostic Devices
Conformity Assessment Route:	Annex III (IVDD)

Signed _____

Valid from 2020.05.21

Full name: Vasiliy G. Akimkin
Title: Director

№№	Description	Product Code (for reference only)
1.	**Hemolytic** Reagent for pretreatment of whole peripheral and umbilical cord blood	137-CE
2.	**Mucolysin** Reagent for mucous material pretreatment	180-CE
3.	**RNA-medium** Medium for stabilization and preservation of blood cell mRNA	981-CE
4.	**Transport Medium for Storage and Transportation of Respiratory Swabs** Reagent for sampling, transportation, and storage of upper respiratory tract swabs	957-CE 958-CE
5.	**Transport Medium for Storage and Transportation of Respiratory Swabs** Reagent for sampling, transportation, and storage of upper respiratory tract swabs	959-CE
6.	**Transport Medium with Mucolytic Agent** Reagent for transportation and storage of clinical material	952-CE 953-CE
7.	**AmpliSens® DNA-sorb-D** nucleic acid extraction kit	K8-2331-100-CE
8.	**AmpliSens® MAGNO-sorb-URO** Nucleic Acid Extraction Kit	K4-2181-100-CE
9.	**DNA-sorb-AM** nucleic acid extraction kit	K1-11-50-CE K1-11-100-CE K1-12-100-CE
10.	**DNA-sorb-B** Nucleic acid Extraction kit	K1-2-50-CE K1-2-100-CE
11.	**DNA-sorb-C** nucleic acid extraction kit	K1-6-50-CE
12.	**EDEM** Reagents kit for extraction of DNA by express method	K2-17-100-CE K11-1581-100-CE
13.	**MAGNO-sorb** Nucleic Acid Extraction Kit	K2-16-200-CE K2-16-1000-CE
14.	**RIBO-prep** nucleic acid extraction kit	K2-9-Et-50-CE K2-9-Et-100-CE
15.	**RIBO-sorb** nucleic acid extraction kit	K2-1-Et-50-CE K2-1-Et-100-CE
16.	**RIBO-zol-B** nucleic acid extraction kit	K2-3-50-CE K2-3-100-CE
17.	**RIBO-zol-C** nucleic acid extraction kit	K2-13-50-CE K2-13-100-CE
18.	**REVERTA-L** RT reagents kit	K3-4-50-CE K3-4-100-CE
19.	**EPh** Detection agarose kit	K5-200-CE K6-200-CE
20.	**AmpliSens® *Adenovirus*-EPh PCR kit**	V23-50-R0,5-CE V23-50-R0,2-CE
21.	**AmpliSens® All bacto-screen-FRT** PCR kit	H-2631-1-CE H-2632-1-4-CE
22.	**AmpliSens® All-screen-FEP** PCR kit	B45-FEP-CE
23.	**AmpliSens® All-screen-FRT** PCR kit	R-B45(RG,iQ)-CE
24.	**AmpliSens® All viro-screen-FRT** PCR kit	H-2761-1-CE
25.	**AmpliSens® ARVI-screen-FRT** PCR kit	R-V57-100-F(RG,iQ,Dt)-CE
26.	**AmpliSens® Ascaridosis-FRT** PCR kit	H-1971-1-CE

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27.	**AmpliSens® Ascaridosis-FEP** PCR kit	H-1971-2-CE
28.	**AmpliSens® *Bacillus anthracis*-FRT** PCR kit	R-B41(RG)-CE
29.	**AmpliSens® *Bordetella* multi-FRT** PCR kit	R-B84-100-F(RG,iQ,Dt)-CE
30.	**AmpliSens® *Borrelia burgdorferi sensu lato*-FRT** PCR kit	R-B37(RG)-CE
31.	**AmpliSens® *Borrelia miyamotoi*-FRT** PCR kit	H-2791-1-CE H-2792-1-4-CE
32.	**AmpliSens® *Brucella* spp.-FRT** PCR kit	R-B10(RG)-CE
33.	**AmpliSens® *C.albicans* / *C.glabrata* / *C.krusei*-MULTIPRIME-FRT** PCR kit	R-F3(RG)-CE R-F3-F(RG,iQ)-CE
34.	**AmpliSens® *Candida albicans*-EPh** PCR kit	F1-100-R0,5-CE F1-100-R0,2-CE
35.	**AmpliSens® *Candida albicans*-FEP** PCR kit	F1-100-R0,5-FEP-CE F1-100-R0,2-FEP-CE
36.	**AmpliSens® *Candida albicans*-FRT** PCR kit	R-F1(RG)-CE R-F1-F(RG,iQ)-CE
37.	**AmpliSens® *CCHFV*-FRT** PCR Kit	R-V22-50-F(RG,iQ,Mx,Dt)-CE
38.	**AmpliSens® *Corynebacterium diphtheriae* / tox-genes-FRT** PCR kit	H-2842-1-CE H-2843-1-4-CE
39.	**AmpliSens® *Cov*-Bat-FRT** PCR kit	H-2242-1-CE
40.	**AmpliSens® *Coxiella burnetii*-FRT** PCR kit	R-B85-50-F(RG,iQ,Mx,Dt)-CE
41.	**AmpliSens® *Cryptococcus neoformans*-FRT** PCR kit	R-F4-F(RG,iQ)-CE
42.	**AmpliSens® *Dengue virus* type-FRT** PCR kit	R-V63(RG,CFX)-CE
43.	**AmpliSens® *Dengue virus*-FRT** PCR kit	H-2391-1-CE H-2392-1-4-CE
44.	**AmpliSens® *EBOV* Zaire-FRT** PCR kit	R-V69-50-F-CE
45.	**AmpliSens® *EBV*-screen/monitor-FRT** PCR kit	R-V9-100-S(RG,iQ,Mx)-CE
46.	**AmpliSens® *EHEC*-FRT** PCR kit	R-B59(RG,iQ)-CE
47.	**AmpliSens® *Enterovirus* 71-FRT** PCR kit	R-V64-F-CE
48.	**AmpliSens® *Enterovirus*-FEP** PCR kit	V16-50-R0,5-FEP-CE V16-50-R0,2-FEP-CE
49.	**AmpliSens® *Enterovirus*-FRT** PCR kit	R-V16-F-CE R-V16(RG)-CE
50.	**AmpliSens® *Enterovirus* / *Parechovirus*-FRT** PCR kit	H-3751-1-2-CE
51.	**AmpliSens® ESBL CTX-M-FRT** PCR kit	HN-3571-1-CE
52.	**AmpliSens® Escherichioses-FRT** PCR kit	R-B62(RG,iQ)-CE
53.	**AmpliSens® F2/F5-SNP-FRT** PCR kit	S-3451-1-CE S-3452-1-4-CE
54.	**AmpliSens® FiloA-screen-FRT** PCR kit	H-2781-1-4-CE
55.	**AmpliSens® Florocenosis / Aerobes-FRT** PCR kit	R-B88-100-FT-CE
56.	**AmpliSens® Florocenosis / Bacterial vaginosis-FRT** PCR kit	R-B74-100-FT(RG)-CE
57.	**AmpliSens® Florocenosis / *Candida*-FRT** PCR kit	R-F5-100-FT(RG,CFX)-CE
58.	**AmpliSens® Florocenosis / *Mycoplasma*-FRT** PCR kit	R-B75-100-FT(RG,iQ,Mx)-CE
59.	**AmpliSens® *Gardnerella vaginalis*-FEP** PCR kit	B7-100-R0,5-FEP-CE B7-100-R0,2-FEP-CE
60.	**AmpliSens® *Gardnerella vaginalis*-FRT** PCR kit	R-B7(RG)-CE R-B7-F(RG,iQ)-CE

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61.	**AmpliSens® Genoscreen-*IL*28B-FRT** PCR kit	R-O5-100-F(RG,iQ,Dt,CFX)-CE
62.	**AmpliSens® *HAV*-FRT** PCR kit	R-V4(RG,iQ)-CE
63.	**AmpliSens® *Helicobacter pylori*-FRT** PCR kit	R-B9(RG,iQ)-CE
64.	**AmpliSens® Hemochromatosis-FRT** PCR kit	S-2451-1-CE S-2452-1-4-CE
65.	**AmpliSens® *HGV*-FRT** PCR kit	R-V2-50-F(RG,iQ,Mx,Dt)-CE
66.	**AmpliSens® *HHV6*-screen-titre-FRT** PCR kit	R-V10-T(RG,iQ,Mx)-CE
67.	**AmpliSens® *HHV7*-screen/monitor-FRT** PCR kit	H-2431-1-1-CE
68.	**AmpliSens® *HPV* 16/18-FRT** PCR kit	R-V12-100-CE R-V12-F-CE R-V12(RG,iQ,Mx)-CE
69.	**AmpliSens® *HPV* 6/11-FRT** PCR kit	R-V11-100-CE R-V11-Mod(RG,iQ,Mx)-CE R-V11(RG,iQ,Mx)-CE
70.	**AmpliSens® *HPV* HCR genotype-EPh** PCR kit	V25-50F-CE
71.	**AmpliSens® *HPV* HCR genotype-FRT** PCR kit	R-V25(RG,iQ,Mx)-CE
72.	**AmpliSens® *HPV* HCR genotype-titre-FRT** PCR kit	R-V67-F-CE H-2261-1-13-CE
73.	**AmpliSens® *HPV* HCR screen-EPh** PCR kit	V31-100F-CE
74.	**AmpliSens® *HPV* HCR screen-FEP** PCR kit	V31-3x-FEP-CE V31-FEP-CE
75.	**AmpliSens® *HPV* HCR screen-titre-14-FRT** PCR kit	H-2311-1-13-CE
76.	**AmpliSens® *HPV* HCR screen-titre-FRT** PCR kit	R-V31-T-2x(RG,iQ,SC)-CE R-V31-T-4x(RG,iQ,Mx)-CE R-V31-F-CE
77.	**AmpliSens® *HSV* I, II-FRT** PCR kit	R-V8(RG)-CE R-V8-F(RG,iQ)-CE
78.	**AmpliSens® *HSV*-typing-FEP** PCR kit	V38-100-R0,5-FEP-CE V38-100-R0,2-FEP-CE
79.	**AmpliSens® *HSV*-typing-FRT** PCR kit	R-V38(RG)-CE R-V38-F(RG,iQ)-CE
80.	**AmpliSens® *Human enterovirus*-FEP** PCR kit	H-2771-2-2-CE H-2772-2-5-CE H-2773-2-CE
81.	**AmpliSens® *Human enterovirus*-FRT** PCR kit	H-2771-1-2-CE H-2773-1-CE H-2774-1-4-CE
82.	**AmpliSens® *Influenza virus* A/H1-swine-FEP** PCR kit	V55-50-R0,5-FEP-CE V55-50-R0,2-FEP-CE
83.	**AmpliSens® *Influenza virus* A/H1-swine-FRT** PCR kit	R-V55(RG)-CE R-V55-F(SC)-CE
84.	**AmpliSens® *Influenza virus* A-type-FRT** PCR kit	R-V54-100-F(RG,iQ,Dt,SC)-CE
85.	**AmpliSens® *Influenza virus* A-type-H5, H7, H9-FRT** PCR kit	R-V66-F-CE
86.	**AmpliSens® *Influenza virus* A H5N1-FRT** PCR kit	R-V33(SC)-CE
87.	**AmpliSens® *Influenza virus* A/B-FRT** PCR kit	R-V36-50-Mod-CE R-V36-100-F-Mod(RG,iQ,Dt, CFX,SC)-CE
88.	**AmpliSens® *JCV-BKV* screen-monitor-FRT** PCR kit	H-2441-1-1-CE

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89.	**AmpliSens® *Legionella pneumophila*-FEP** PCR kit	B50-R0,2-FEP-CE B50-50-R0,5-FEP-CE
90.	**AmpliSens® *Legionella pneumophila*-FRT** PCR kit	R-B50(RG)-CE
91.	**AmpliSens® *Leptospira*-FRT** PCR kit	R-B49(RG,iQ)-CE
92.	**AmpliSens® Leucosis Quantum *M-bcr*-FRT** PCR kit	TR-O1(RG,iQ,Mx,A)-CE
93.	**AmpliSens® *Listeria monocytogenes*-screen/monitor-FRT** PCR kit	H-2161-1-1-CE
94.	**AmpliSens® MDR A.b.-OXA-FRT PCR kit**	HN-3871-1-CE HN-3872-1-4-CE
95.	**AmpliSens® MDR KPC/OXA-48-FRT** PCR kit	R-C2(RG,CFX)-CE
96.	**AmpliSens® MDR MBL-FRT** PCR kit	R-C1(RG,CFX)-CE
97.	**AmpliSens® *MRSA*-screen-titre-FRT** PCR kit	R-B78-100-FT(RG,iQ)-CE
98.	**AmpliSens® *MTC*-diff-FRT** PCR kit	R-B80(RG,iQ,Dt,SC)-CE
99.	**AmpliSens® MTC-MDR-FRT** PCR kit	H-3611-1-CE H-3612-1-4-CE
100.	**AmpliSens® *MTC*-FEP** PCR kit	B57-FEP-CE
101.	**AmpliSens® *MTC*-FRT** PCR kit	R-B57(RG,iQ,SC,Dt)-CE
102.	**AmpliSens® MTHFR-SNP-FRT** PCR kit	S-3721-1-CE S-3722-1-4-CE
103.	**AmpliSens® *Mycoplasma genitalium*-FEP** PCR kit	B4-100-R0,5-FEP-CE B4-100-R0,2-FEP-CE
104.	**AmpliSens® *Mycoplasma genitalium*-FRT** PCR kit	R-B4(RG)-CE R-B4-F(RG,iQ)-CE
105.	**AmpliSens® *Mycoplasma hominis*-FEP** PCR kit	B3-100-R0,5-FEP-CE B3-100-R0,2-FEP-CE
106.	**AmpliSens® *Mycoplasma hominis*-FRT** PCR kit	R-B3(RG)-CE R-B3-F(RG,iQ)-CE
107.	**AmpliSens® *N.meningitidis* / *H.influenzae* / *S.pneumonia*-FRT** PCR kit	R-B25(RG,iQ)-CE
108.	**AmpliSens® *Neisseria gonorrhoeae*-screen-FEP** PCR kit	B51-100-R0,5-FEP-CE B51-100-R0,2-FEP-CE
109.	**AmpliSens® *Neisseria gonorrhoeae*-screen-FRT** PCR kit	R-B51(RG)-CE R-B51-F(RG,iQ)-CE
110.	**AmpliSens® NmABCW-FRT** PCR kit	H-3861-1-3-CE
111.	**AmpliSens® *Norovirus* GI / GII-FRT** PCR kit	H-2751-1-3-CE
112.	**AmpliSens® *Parvovirus* B19-FRT** PCR kit	R-V49(RG,iQ,Mx)-CE
113.	**AmpliSens® *Pneumocystis jirovecii* (*carinii*)-FRT** PCR kit	R-F2-Mod(RG,iQ,Mx)-CE
114.	**AmpliSens® Pneumo-quantum-FRT** PCR kit	H-2811-1-1-CE H-2812-1-1-CE H-2813-1-14-CE
115.	**AmpliSens® *Poliovirus*-FRT** PCR kit	R-V58(RG,iQ)-CE
116.	**AmpliSens® *Pseudomonas aeruginosa*-screen-titre-FRT** PCR kit	R-B76-50-FT(RG,iQ)-CE
117.	**BRCA-screen** kit	S-1619-6-CE
118.	**PEERO-prep** reagent kit for sample preparation	K15-1611-40-CE
119.	**AmpliSens® Pyroscreen PHARMA-screen-Imatinib kit**	S-16121-6-CE
120.	**AmpliSens® Pyroscreen PHARMA-screen-transport kit**	S-16119-6-CE

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121.	**AmpliSens® Pyroscreen PHARMA-screen-Warfarin kit**	S-16120-6-CE
122.	**AmpliSens® *Rickettsia conorii*-FRT** PCR kit	H-2741-1-CE H-2742-1-4-CE
123.	**AmpliSens® *Rickettsia* spp. *SFG*-FRT PCR kit**	H-3741-1-CE H-3742-1-4-CE
124.	**AmpliSens® *Rotavirus / Norovirus / Astrovirus*-FRT** PCR kit	R-V40(RG,iQ)-CE
125.	**AmpliSens® *Shigella* spp. and *EIEC / Salmonella* spp. / *Campylobacter* spp.-FRT** PCR kit	R-B44(RG,iQ)-CE
126.	**AmpliSens® *Streptococcus agalactiae*-screen-titre-FRT** PCR kit	R-B77-100-FT(RG,iQ)-CE
127.	**AmpliSens® *Streptococcus pyogenes*-screen/monitor-FRT** PCR kit	H-2171-1-1-CE H-2172-1-14-CE
128.	**AmpliSens® *T.vaginalis / N.gonorrhoeae*-MULTIPRIME-FRT** PCR kit	R-B65(RG)-CE R-B65-F(RG,iQ)-CE
129.	**AmpliSens® TBE-FRT** PCR kit	R-V52(RG)-CE
130.	**AmpliSens® *TBEV, B.burgdorferi sl, A.phagocytophilum, E.chaffeensis / E.muris*-FRT** PCR kit	R-V59(RG,iQ,Mx,Dt)-CE R-V59-50-F(RG,iQ,Mx,Dt)-CE
131.	**AmpliSens® *Treponema pallidum*-FRT** PCR kit	R-B20(RG)-CE R-B20-F(RG,iQ)-CE
132.	**AmpliSens® *Trichomonas vaginalis*-EPh** PCR kit	B6-100-R0,5-CE B6-100-R0,2-CE
133.	**AmpliSens® *Trichomonas vaginalis*-FEP** PCR kit	B6-100-R0,5-FEP-CE B6-100-R0,2-FEP-CE
134.	**AmpliSens® *Trichomonas vaginalis*-FRT** PCR kit	R-B6(RG)-CE R-B6-F(RG,iQ)-CE
135.	**AmpliSens® *U.parvum / U.urealyticum*-FEP** PCR kit	B19-100-R0,5-FEP-CE B19-100-R0,2-FEP-CE
136.	**AmpliSens® *U.parvum / U.urealyticum*-FRT** PCR kit	R-B19(RG)-CE R-B19-F(RG,iQ)-CE
137.	**AmpliSens® *Ureaplasma* spp.-FRT** PCR kit	R-B2(RG)-CE R-B2-F(RG,iQ)-CE
138.	**AmpliSens® *Ureaplasma* spp.-screen-titre-FRT** PCR kit	R-B2-100-FT(RG,iQ,Mx)-CE
139.	**AmpliSens® *Vibrio cholerae*-FRT** PCR kit	R-B53(RG)-CE
140.	**AmpliSens® *VZV*-FRT** PCR kit	R-V61-50-F(RG)-CE
141.	**AmpliSens® WNV-FRT** PCR kit	R-V53(RG,iQ,Mx)-CE
142.	**AmpliSens® *Yellow fever virus*-FRT** PCR kit	H-2461-1-CE H-2462-1-4-CE
143.	**AmpliSens® *Yersinia enterocolitica / Y.pseudotuberculosis*-FRT** PCR kit	R-B64(RG,iQ)-CE
144.	**AmpliSens® *Yersinia pestis*-FRT** PCR kit	R-B79(RG,iQ,Dt)-CE
145.	**AmpliSens® *Zika virus*-FRT** PCR kit	H-2411-1-CE