FEDERAL SERVICE FOR SUPERVISION OF CONSUMER RIGHTS PROTECTION AND HUMAN WELFARE
FEDERAL BUDGET INSTITUTE OF SCIENCE
«CENTRAL RESEARCH INSTITUTE FOR EPIDEMIOLOGY»
111123, Moscow, 3A Novogireevskaya street, Tel.: +7 495 974 96 42, Fax: +7 495 305 54 23,
e-mail: obtk@pcr.ru

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. 15 0125 SJ/a, valid until 2018.05.20).

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) 02/64 789 336 fax: (+421) 02/64 789 040 email: ecoli@ecoli.sk
Product Name:	Annex for this Declaration
Description:	Reagent kits for qualitative detection and quantification of DNA (RNA) of different infectious agents or HLA B*5701 DNA in human specimens
Classification:	Article 9, paragraph 3 of EC Council Directive 98/79/EC on *in Vitro* Diagnostic Devices Annex II List B IVDs (According to EC Declaration of Conformity List)
Conformity Assessment Route:	Annex IV (IVDD) Full QA System
Notified Body:	Institute for testing and certification, Inc. třida Tomáše Bati 299 Louky, 763 02 Zlin, Czech Republic e-mail: itc@itczlin.cz Notified Body No. 1023
EC Certificate:	No. 11 0040 QS/NB revision g, valid until 2021.06.16
Place, Date of Issue:	Zlin, Czech Republic, 2017.11.30

Signed _____

Full name: Vasiliy G. Akimkin
Title: Interim Director

Valid from 2018.01.26
Valid until 2021.06.16

№№	Description	Product Code
1.	AmpliSens® *Rubella virus*-FRT PCR kit	R-V24-S(RG,iQ,Mx)-CE
2.	AmpliSens® *Toxoplasma gondii*-FRT PCR kit	R-P1(RG,iQ,Mx)-CE
3.	AmpliSens® *CMV*-FEP PCR kit	V7-100-R0,2-FEP-CE V7-100-R0,5-FEP-CE
4.	AmpliSens® *CMV*-FRT PCR kit	R-V7(RG)-CE R-V7-F(RG,iQ)-CE
5.	AmpliSens® *HSV / CMV*-MULTIPRIME-FEP PCR kit	V60-100-R0,5-FEP-CE V60-100-R0,2-FEP-CE
6.	AmpliSens® *HSV / CMV*-MULTIPRIME-FRT PCR kit	R-V60(RG)-CE R-V60-F(RG,iQ)-CE
7.	AmpliSens® *CMV*-screen/monitor-FRT PCR kit	R-V7-100-S(RG,iQ,Mx)-CE
8.	AmpliSens® *EBV / CMV / HHV*6-screen-FRT PCR kit	R-V48(RG,iQ,Mx)-CE
9.	AmpliSens® *Chlamydia trachomatis*-FEP PCR kit	B1-100-R0,2-FEP-CE B1-100-R0,5-FEP-CE
10.	AmpliSens® *Chlamydia trachomatis*-FRT PCR kit	R-B1(RG)-CE R-B1-F(RG,iQ)-CE
11.	AmpliSens® *C.trachomatis / Ureaplasma*-MULTIPRIME-FEP PCR kit	B47-100-R0,2-FEP-CE B47-100-R0,5-FEP-CE
12.	AmpliSens® *C.trachomatis / M.genitalium*-MULTIPRIME-FEP PCR kit	B66-100-R0,5-FEP-CE B66-100-R0,2-FEP-CE
13.	AmpliSens® *C.trachomatis / Ureaplasma / M.genitalium*-MULTIPRIME-FEP PCR kit	B46-100-R0,2-FEP-CE B46-100-R0,5-FEP-CE
14.	AmpliSens® *C.trachomatis / Ureaplasma / M.genitalium*-MULTIPRIME-FRT PCR kit	R-B46(RG)-CE R-B46-F(RG,iQ)-CE
15.	AmpliSens® *C.trachomatis / Ureaplasma / M.hominis*-MULTIPRIME-FEP PCR kit	B43-100-R0,2-FEP-CE B43-100-R0,5-FEP-CE
16.	AmpliSens® *C.trachomatis / Ureaplasma / M.hominis*-MULTIPRIME-FRT PCR kit	R-B43(RG)-CE R-B43-F(RG,iQ)-CE
17.	AmpliSens® *C.trachomatis / Ureaplasma / M.genitalium / M.hominis*-MULTIPRIME-FRT PCR kit	R-B60(RG)-CE R-B60-F(RG)-CE
18.	AmpliSens® *N.gonorrhoeae / C.trachomatis / M.genitalium / T.vaginalis*-MULTIPRIME-FRT PCR kit	R-B61(RG)-CE R-B61-F(RG)-CE
19.	AmpliSens® *N.gonorrhoeae / C.trachomatis / M.genitalium*-MULTIPRIME-FEP PCR kit	B67-100-R0,5-FEP-CE B67-100-R0,2-FEP-CE
20.	AmpliSens® *N.gonorrhoeae / C.trachomatis / M.genitalium*-MULTIPRIME-FRT PCR kit	R-B67(RG)-CE R-B67-F(RG,iQ)-CE
21.	AmpliSens® Genoscreen HLA B*5701-FRT PCR kit	R-O2(RG,iQ)-CE
22.	AmpliSens® *Mycoplasma pneumoniae / Chlamydophila pneumoniae*-FEP PCR kit	B42-50-R0,5-FEP-CE B42-50-R0,2-FEP-CE B42-Mod-50-R0,2-FEP-CE; B42-Mod-50-R0,5-FEP-CE
23.	AmpliSens® *Mycoplasma pneumoniae / Chlamydophila pneumoniae*-FRT PCR kit	R-B42-4x(RG)-CE R-B42-100-F-CE
24.	AmpliSens® *T.vaginalis / N.gonorrhoeae / C.trachomatis*-MULTIPRIME-FEP PCR kit	B83-100-R0,5-FEP-CE B83-100-R0,2-FEP-CE
25.	AmpliSens® *T.vaginalis / N.gonorrhoeae / C.trachomatis*-MULTIPRIME-FRT PCR kit	R-B83(RG)-CE R-B83-F(RG,iQ)-CE