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. 21 0023 SJ, valid until 26.04.2024).

Manufacturer:	Federal Budget Institute of Science "Central Research Institute for Epidemiology"
Authorised Representative:	Ecoli Dx, s.r.o. Purkyňova 74/2 Praha 1, 110 00 Czech Republic Tel: +420 325 209 912 Cell: +420 739 802 523 E-mail: ecoli@ecoli.sk
Product Name:	Annex for this Declaration
Description:	Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D
Classification:	Article 9, paragraph 2 of EC Council Directive 98/79/EC on *in Vitro* Diagnostic Devices Annex II List A IVDs (According to EC Declaration of Conformity List)
Conformity Assessment Route:	Annex IV (IVDD) excluding (4, 6) 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:	EC Certificate - Full Quality Assurance System No. 11 0040 QS/NB, Annex IV excluding (4, 6), revision m, valid until 2025-05-26 EC Design-Examination Certificate No. 22 0195 CN/NB, Annex IV (4), revision -, valid until 2025-05-26
Place, Date of Issue:	Zlin, Czech Republic, 2022-05-20

Signed _____ Valid from 2022-05-20

Full name: Vasiliy G. Akimkin Valid until 2025-05-26
Title: Director

№№	Description	Model(s)
1.	**AmpliSens® *HCV*-Monitor-L** PCR kit	variant FRT-L
2.	**AmpliSens® *HBV*-Monitor-L** PCR kit	variant FRT-L

Signed _____

Full name: Vasiliy Akimkin
Title: Director