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 Email: ecoli@ecoli.sk
Product Name:	Annex for this Declaration
Description:	Reagent kits for genotyping and differentiating DNA and RNA types of viruses
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 20.05.22

Full name: Vasiliy Akimkin
Title: Director

№№	Description	Model(s)
1.	**AmpliSens® *HCV*-genotype-FRT** PCR kit	variant FRT-g1-6
2.	**AmpliSens® *HBV*-genotype-FRT** PCR kit	variant FRT-50 F

Signed _____

Full name: Vasiliy Akimkin
Title: Director