FEDERAL BUDGET INSTITUTE OF SCIENCE
«CENTRAL RESEARCH INSTITUTE OF EPIDEMIOLOGY»
OF THE FEDERAL SERVICE FOR SURVEILLANCE ON CONSUMER RIGHTS PROTECTION AND HUMAN WELLBEING
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CE

EU DECLARATION OF CONFORMITY

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

Federal Budget Institute of Science «Central Research Institute of Epidemiology» of the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing hereby under own responsibility declares that the products covered by the present declaration conform with General safety and performance requirements listed in Annex I of Regulation (EU) 2017/746. Supporting documentation is retained under the premises of the manufacturer, as well as the authorised representative.

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 TÜV AUSTRIA Standards & Compliance, LLC. (Certificate registration No. TASC-C-20230720001, valid until 2026-07-19).

Manufacturer:	Federal Budget Institute of Science «Central Research Institute of Epidemiology» of the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing (FBIS CRIE of Rospotrebnadzor)
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 / trade name:	Annex for this Declaration
Description:	Products for general laboratory use intended for *in vitro* diagnostic procedures (reagents for sampling, transportation, storage and pretreatment of clinical material; reagents kits for nucleic acid extraction and reverse transcription; detection agarose kit)
Risk class:	Class A (Annex VIII of Regulation (EU) 2017/746)

Valid from 2023-07-20
Valid until 2026-07-19

Place and date of issue:
Moscow, 2023-07-20

Vasiliy Akimkin
Director
Signed on behalf of FBIS CRIE of Rospotrebnadzor

Digitally signed by Olaru Victoria
Date: 2025.05.15 19:12:45 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

№№	Product / trade name	Product Code (for reference only)	Basic UDI-DI
1.	**Hemolytic** Reagent for pretreatment of whole peripheral and umbilical cord blood	137-CE	460701015137CEGQ
2.	**Mucolysin** Reagent for mucous material pretreatment	180-CE	460701015180CEGQ
3.	**Transport Medium for Storage and Transportation of Respiratory Swabs** Reagent for sampling, transportation, and storage of upper respiratory tract swabs	958-CE	460701015958CEL3
4.	**Transport Medium with Mucolytic Agent** Reagent for transportation and storage of clinical material	952-CE	460701015952CEK5
5.	**AmpliSens® DNA-sorb-D** nucleic acid extraction kit	K8-2331-100-CE	460701015K82331100CESD
6.	**AmpliSens® MAGNO-sorb-URO** Nucleic Acid Extraction Kit	K4-2181-100-CE	460701015K42181100CEQ8
		K4-2182-100-CE	460701015K42182100CEQM
7.	**DNA-sorb-AM** nucleic acid extraction kit	K1-11-100-CE	460701015K111100CE9K
		K1-12-100-CE	460701015K112100CE9Y
8.	**DNA-sorb-B** Nucleic acid Extraction kit	K1-2-100-CE	460701015K12100CE9V
9.	**DNA-sorb-C** nucleic acid extraction kit	K1-6-50-CE	460701015K1650CEER
10.	**EDEM** Reagents kit for extraction of DNA by express method	K11-1581-100-CE	460701015K111581100CEV3
11.	**MAGNO-sorb** Nucleic Acid Extraction Kit	K3-1061-100-CE	460701015K31061100CELX
		K3-1062-100-CE	460701015K31062100CEMC
		K3-1063-100-CE	460701015K31063100CEMR
		K3-1064-100-CE	460701015K31064100CEN6
12.	**PEERO-prep** reagent kit for sample preparation	K15-1611-40-CE	460701015K15161140CEPG
13.	**RIBO-prep** nucleic acid extraction kit	K2-9-Et-100-CE	460701015K29Et100CEMW
14.	**RIBO-sorb** nucleic acid extraction kit	K2-1-Et-100-CE	460701015K21Et100CEH6
15.	**RIBO-zol-B** nucleic acid extraction kit	K2-3-100-CE	460701015K23100CEAT
16.	**REVERTA-L** RT reagents kit	K3-4-50-CE	460701015K3450CEEV
		K3-4-100-CE	460701015K34100CEBR
17.	**EPh** Detection agarose kit	K5-200-CE	460701015K5200CEDW

Vasiliy Akimkin
Director
Signed on behalf of FBIS CRIE of Rospotrebnadzor