



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 for Epidemiology" 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 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 / trade name:	Annex for this Declaration
Description:	Products for general laboratory use intended for <i>in vitro</i> 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 01.06.2022

Place and date of issue:
Moscow, 01.06.2022

Vasily Akimkin
Director
Signed on behalf of Federal Budget Institute of Science
"Central Research Institute for Epidemiology"



No№	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	K2-16-200-CE	460701015K216200CECJ
		K2-16-1000-CE	460701015K2161000CEGH
		K3-1061-100-CE	460701015K31061100CELX
		K3-1062-100-CE	460701015K31062100CEMC
		K3-1063-100-CE	460701015K31063100CEMR
		K3-1064-100-CE	460701015K31064100CEN6
12.	RIBO-prep nucleic acid extraction kit	K2-9-Et-100-CE	460701015K29Et100CEMW
13.	RIBO-sorb nucleic acid extraction kit	K2-1-Et-100-CE	460701015K21Et100CEH6
14.	RIBO-zol-B nucleic acid extraction kit	K2-3-100-CE	460701015K23100CEAT
15.	REVERTA-L RT reagents kit	K3-4-50-CE	460701015K3450CEEV
		K3-4-100-CE	460701015K34100CEBR
16.	EPh Detection agarose kit	K5-200-CE	460701015K5200CEDW



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