Declaration of Conformity

According to annex III of the Council Directive 98/79/EC on in vitro diagnostic medical device We,

Name: "DNA-Technology Research&Production", LLC
Address: 142281, Moscow region, Protvino, Zheleznodorozhnaya street 20
Country: Russia

Declare under our sole responsibility that the following in vitro diagnostic medical devices other than those covered by annex II and devices for performance evaluation

#	Catalogue reference number	Commercial Name	Short description and intended use	Class
1.	R1-P029-S3/6EU R1-P029-XA/5EU	BacScreen Pneumo REAL-TIME PCR Detection Kit	BacScreen Pneumo REAL-TIME PCR Detection Kit is designed for DNA analysis of bacteria from classes Bacilli, Betaproteobacteria, Chlamydia, Gammaproteobacteria and Mollicutes causing respiratory nosocomial and community-acquired infections and their complications (sepsis), in human biological material (sputum, aspirates, bioptates, exudates, smears/scrapes, washings from respiratory tract), bacterial cultures from this biomaterial and hemocultures, by real-time polymerase chain reaction	neither A or B according II IVD 98/79/EC
2.	R1-H803-S3/9EU R1-H803-23/9EU R1-H803-UA/9EU	Fetal Gender REAL-TIME PCR Detection Kit	Fetal Gender REAL-TIME PCR Detection Kit is intended for the detection of multi-copy fragment of Y chromosome in samples of cell-free fetal DNA extracted from the blood of pregnant women by Real-Time PCR method.	neither A or B according II IVD 98/79/EC
3.	R1-H802-S3/9EU R1-H802-23/9EU	Fetal RHD Genotyping REAL-TIME PCR Kit	Fetal RHD Genotyping REAL-TIME PCR Kit is designed to detect cell-free fetal DNA of RHD gene in the blood of Rhd-negative pregnant women with an aid of Polymerase Chain Reaction (PCR) method in order to predict the risk of Rh-disease and hemolytic disease of the fetus and newborn	neither A or B according II IVD 98/79/EC
4.	R1-H810-S3/9EU R1-H810-23/9EU	NeoScreen SMA/TREC/KREC REAL-TIME PCR Detection Kit	NeoScreen SMA/TREC/KREC REAL-TIME PCR Detection Kit is designed to detect homozygous deletion of exon 7 of the SMN1 gene and assess the content of T cell receptor excision circles (TREC) and kappadeleting recombination excision circle (KREC) in newborn biological material (whole blood, dried blood spots) for screening for spinal muscular atrophy and primary immunodeficiencies by real-time PCR	neither A or B according II IVD 98/79/EC

5.	P-029-N/2EU	PREP-CITO DBS DNA Extraction Kit	The PREP-CITO DBS DNA Extraction Kit is intended for human genomic DNA extraction from dried blood spots (DBS) for further analysis with polymerase chain reaction (PCR)	neither A or B according II IVD 98/79/EC
6.	P-119-A/9EU P-119-N/9EU P-119-P/9EU P-120-P/9EU P-121-P/9EU	PREP-MB DWP DNA/RNA Extraction Kit	PREP-MB DWP DNA/RNA Extraction Kit is designed to extract NA from biological materials: nasopharyngeal, oropharyngeal swabs	neither A or B according II IVD 98/79/EC
7.	P-103-N/4EU P-103-A/8EU	PREP-MB MAX DNA Extraction Kit	PREP-MB MAX DNA Extraction Kit is intended for human, bacterial, viral, and fungal DNAextraction from human biological material (whole peripheral blood; smears/scrapings from urogenitaltract and rectum; urine; ejaculate; milk; faeces) for further PCR analysis.	neither A or B according II IVD 98/79/EC
8.	P-027/2EU	PREP-NA-FET DNA Extraction Kit	The PREP-NA-FET DNA Extraction Kit is intended for fetal DNA purification from peripheral blood of pregnant women.	neither A or B according II IVD 98/79/EC
9.	P-901-1/1EU P-901-R/1EU P-901-N/1EU	STOR-F transport medium	The STOR-F transport medium is intended for transport and storage of human biological samples (scrapes/smears of epithelial cells from urogenital tract, oropharynx, nasopharynx, rectum, skin, conjunctiva of the eye) followed by nucleic acids analysis (human DNA, DNA of microorganisms, RNA of viruses) by polymerase chain reaction method	neither A or B according II IVD 98/79/EC

Meet the provisions of the Council Directive 98/79/EC concerning medical devices which apply to them.

Undersigned declares to fulfill the obligations imposed by Annex III section 2 to 5:

- availability of the technical documentation set in Annex III (section 3), allowing the assessment of conformity of the product with the requirements of the Directive.
- the manufacturer shall take necessary measures to ensure that the manufacturing process follows the principles of quality assurance as appropriate for the products manufactured (Annex III section 4).
- the manufacturer shall institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective actions (Annex III section 5).

Conformity assessment was performed according to Article 9 (7) and Annex III, section 3.

Our current Quality System is formatted to international standards:

- ISO 9001:2015
- ISO 13485:2016

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Date: 06.05.2022
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