EC DECLARATION OF CONFORMITY

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Medical Diagnostic Devices

Bioeksen AR GE Teknolojileri A.Ş. hereby declares under its own responsibility that the products covered by this declaration conform with "Essential Requirements" listed in Annex I of EC Directive 98/79/EC (IVD Directive). Supporting documentation (technical documentation) is retained under the premises of the manufacturer.

Manufacturer	: Bioeksen AR GE Teknolojileri Anonim Şirketi
Central Office	: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul TÜRKİYE
Manufacturing Site	: Huzur Mahallesi Metin Oktay Caddesi Nurol Life No:3/10, Sarıyer/İstanbul TÜRKİYE
	Web: www.bioeksen.com.tr, E-mail: info@bioeksen.com.tr
Product(s) Name	: Bio-Speedy® Respiratory Tract RT-qPCR MX-24T Panel
Description	: Bio-Speedy® Respiratory Tract RT-qPCR MX-24T Panel
	Ref No: BS-SY-MX24T-25
	Ref No: BS-SY-MX24T-100
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 61527 - Multiple-type respiratory pathogen nucleic acid IVD, kit, nucleic acid technique (NAT)
	Article 9, paragraph 1 of EC Council Directive
	98/79/EC on In Vitro Medical Diagnostic Devices
Conformity Assessment Route	: According to Annex III of the IVD Directive 98/79/EC
	EC declaration of conformity under manufacturer responsibility
Applied Standards	: All standards stated in the annex on the other page are strictly
	implemented in our company.

We hereby declare that the above-mentioned product/s meet the provisions of the EC Council Directive 98/79/EC for in vitro medical diagnostic devices. All supporting documentation is retained under the premises of the manufacturer and the manufacturer is exclusively responsible for the declaration of conformity.

Signature:

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer / İSTANBUL
Maslak V.D. 176 093 2853 Tic. Sicil No: 904277-0
Mersis No: 0176 0932 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

Place of Issue: İstanbul

Valid from: 25.05.2022

Digitally signed by Monastîrschii Viorica
Date: 2023.05.04 16:27:41 EEST
Reason: MoldSign Signature
Location: Moldova

Authorized Person: Canan Zöhre Ketre Kolukırık

Chairman of the Board

bioeksen

CE IVD

EC DECLARATION OF CONFORMITY

Attachment
List of Applied Standards

No.	Title of standards	Contents
1	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2	EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
3	EN ISO 17511:2020	In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials
4	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices
5	EN ISO 23640:2015	In vitro diagnostic medical devices – Evaluation of stability of in vitro diagnostic reagents
6	EN ISO 18113-1:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
7	EN ISO 18113-2:2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
8	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
9	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices
10	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases
11	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures
12	CLSI EP07 3ED: 2018	Interference Testing in Clinical Chemistry, 3rd Edition
13	CLSI EP5 A3: 3ED 2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition

bioeksen
MOLECULAR DIAGNOSTICS

LETTER OF AUTHORIZATION

By this means, the manufacturer Bioeksen AR GE Teknolojileri A.Ş, located in Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi No:3/31 Sarıyer - İstanbul, authorizes the company SRL SANMEDICO to have a registered office at A. Corobceanu Street 7A, apt. 9, Chişinău MD-2012, Moldova.

As our representative and distributor carry out the necessary procedures in Moldova for the registration, importation, distribution, sales, and promotion of the products manufactured and/or assembled by Bioeksen AR GE Teknolojileri A.Ş in the Country of Moldova.

This authorization is valid for 1 year from the date of signature.

Name: Canan Z. Kotte

Firm: Bioeksen AR GE Teknolojileri A. Ş

Date: 3.02.2023

Position: Executive Manager

BİOEKSEN AR GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer / İSTANBUL
Maslak V.D. 176 093 2853 Tic. Sicil No: 904277-0
Mersis No: 0176 0932 8530 0001
info@bioeksen.com.tr - www.bioeksen.com.tr

Tel. : +90 (212) 285 10 17
Fax: +90 (212) 285 10 18

www.bioeksen.com.tr
info@bioeksen.com.tr

Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi
D Blok No:3/31 Sarıyer-Istanbul-TURKEY

For in vitro diagnostic use only.
For professional use only.

Cat No: BS-SY-MX24T-25/BS-SY-MX24T-100

Respiratory Tract RT-qPCR MX-24T Panel

Package Insert

Table 1. Kit Content

Component	Intended Use	25 Reactions	100 Reactions
COVID/Flu Oligo Mix	Specific nucleic acid amplification and detection: **FAM**: SARS-CoV-2 **HEX:** Human (IC-Internal Control) **ROX:** Influenza B **CY5:** Influenza A	1 x 125 µL	1 x 500 µL
COR Oligo Mix	**FAM**: Human Coronavirus 229E **HEX:** Human Coronavirus OC43 **ROX:** Human Coronavirus NL63 **CY5:** Human Coronavirus HKU1	1 x 125 µL	1 x 500 µL
PAR Oligo Mix	**FAM:** Human Parainfluenza 1 **HEX:** Human Parainfluenza 2 **ROX:** Human Parainfluenza 3 **CY5:** Human Parainfluenza 4	1 x 125 µL	1 x 500 µL
MEA Oligo Mix	**FAM:** Human Metapneumovirus **HEX:** Human Enterovirus/Human Rhinovirus Oligo Set 1 **CY5:** Human Adenovirus	1 x 125 µL	1 x 500 µL
BPR Oligo Mix	**FAM:** Human Bocavirus **ROX:** Human Parechovirus **CY5:** Human Enterovirus/Human Rhinovirus Oligo Set 2	1 x 125 µL	1 x 500 µL
LMC Oligo Mix	**FAM:** *Legionella pneumophila* **ROX:** *Mycoplasma pneumoniae* **CY5:** *Chlamydophila pneumoniae*	1 x 125 µL	1 x 500 µL
HBS Oligo Mix	**FAM:** *Haemophilus influenzae* **ROX:** *Bordetella pertussis* **CY5:** *Streptococcus pneumoniae*	1 x 125 µL	1 x 500 µL
RSV Oligo Mix	**FAM:** Respiratory syncytial virus A/B	1 x 125 µL	1 x 500 µL
2X Prime Script Mix	Optimized ready-to-use mix for RT-qPCR assay	2 x 1000 µL	7 x 1250 µL
PC-COVID/FLU / PC-COR / PC-PAR / PC-MEA / PC-BPR / PC-LMC / PC-HBS / PC-RSV	Positive Control (PC)	1 x 100 µL	
NTC	Negative Control	1 x 1000 µL	

Table 2. Transport Condition, Storage Condition, and Shelf Life of the Components

Component	Transport Condition	Storage Condition*	Shelf Life
2X Prime Script Mix	(-22) °C – (+8) °C	(-22) °C – (-18) °C	12 Months
Oligo Mix		(-22) °C – (-18) °C	
NTC		(+2) °C – (+8) °C	
PC		(+2) °C – (+8) °C	

*Each reagent stored at storage temperature can be used until the expiration date indicated on the tube following the first opening. The kit's expiration date is determined by the expiration date of the reagents

Table 3. Components Required but Not Included with The Test

Components Required but Not Included with The Test
1. Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS) or/and CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) Real-Time PCR systems
2. Micropipettes and compatible filtered pipette tips (nuclease-free) suitable for transferring 1-10, 10-100, and 100-1000 µL of liquid
3. A centrifuge or Mini-spin
4. Vortex
5. Reaction tubes and caps/films specific to qPCR instruments and compatible with reaction volume

Revision Date: 2023-03-22/Rev.17
Published Date: 2021-02-23

For in vitro diagnostic use only.
For professional use only.

Table 4. Intended Use, Test Principle, and Analytical Specifications

Function	Aid to diagnosis	**Sample Type(s)**	Table 5
Analyte(s)	Table 1	**Nucleic Acid Preparation Method(s)**	Table 5
Qualitative/Quantitative	Qualitative	**Validated PCR Instrument(s)**	Table 3
Test Principle	Reverse transcription and Real-Time PCR (RT-qPCR)	**Results Interpretation and Reporting**	Automated (Sigmoida software)
Automated/Manual	Manual	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Intended Users	Professional use	**Limit of Detection (LoD)**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	98.95% and 99.13%

Table 5. Collection, Storage, and Transfer of Clinical Specimens / Nucleic Acid Preparation Methods and the Respected LoD Values

Sample Type**	Sample Transfer	Sample Storage	Nucleic Acid Preparation Method	LoD (cp/mL)
Combined nasopharyngeal and oropharyngeal swabs	***v*NAT® *Transfer Tube*** (Cat. No: BS-NA-513m/BS-NA-513)	3 months at (+2) – (+8) °C 1 year at -20 °C	Nucleic acid preparation is not needed, samples can be used directly in RT-qPCR.	250
	Viral Transport Medium (VTM) (CDC SOP#: DSR-052-05 without antibiotics)	3 days at (+2) – (+8) °C 1 year at -70 °C	***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Model No: RINA-M14-01, Kit Cat. No: RN-NA-101) ***Zybio EXM3000 Nucleic Acid Isolation System*** (Robot Model No: EXM3000, Kit Cat. No: ZFNAE01)	125
Bronchoalveolar lavage, nasopharyngeal aspirate, and sputum	Preservative-free sterile containers	3 days at (+2) – (+8) °C 1 year at -70 °C		500

**Clinical specimens should be collected by a healthcare provider in accordance with national/international clinical specimen collection regulations.

1. RT-qPCR Application Protocol

Before starting the assay, please consider the following:

1. The kit was validated only for the template nucleic acid volume which is 25% of the total qPCR volume.
2. The kit cannot be used with real-time PCR instruments without periodic maintenance records.
3. The kit for Bio-Rad Real-Time PCR systems has been validated with white reaction tubes specific to these systems. Clear reaction tubes result in 5-10 times lower fluorescence signal in Bio-Rad instruments compared to white reaction tubes. In addition, device-specific reaction tubes should be used in the BMS device. The kit's stated analytical performance can only be achieved using validated tubes.
4. To test for contamination, a negative control reaction containing NTC (Nuclease-free Water) must be set up in each run.

Program the qPCR device as follows and add the reagents into the qPCR tubes, close the tubes, place them into the qPCR instrument and start the run (Table 6)

Table 6. Reaction Setup and Real-Time PCR Program

Reaction Setup		RT-qPCR Program				QR Code for Thermal Protocol and Plate Setup
		CFX96 Touch™/CFX96™ Dx/CFX Opus 96™/CFX Opus 96™ Dx (Bio-Rad) and Magnetic Induction Cycler (Mic) (Bio Molecular System - BMS)				
Reagent	**Volume/Rxn**	**Step**	**Cycle No.**	**Temperature**	**Duration**	
2X Prime Script Mix	10 µL	**Reverse Transcription**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
Oligo Mix	5 µL	**Denaturation**	12 Touchdown Cycles: 1 °C decrement in annealing temperature per cycle	95 °C	1 sec	
		Annealing and Extension		67 °C to 56 °C	15 sec	
Template Nucleic Acid/NTC/PC	5 µL	**Denaturation**	35 Cycles	95 °C	1 sec	
		Annealing and Extension		55 °C	15 sec	
Total Reaction Volume	**20 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow)/(ROX-Orange)/(CY5-Red)		https://www.bioeksen.com.tr/files/BS_TD_3RT153555

WARNING: The RT-qPCR thermal programs (Bio-Rad and BMS-Mic) and the plate setup (Bio-Rad) file should be downloaded from the QR code or link above.

2. Interpretation of the Assay Results with The "Sigmoida" Software

Result files must be opened with the "**Sigmoida**" software provided by the manufacturer, and the analysis must be performed automatically by the software. Below are examples of results that can be achieved with the Sigmoida software. Below are examples of results that can be achieved with the Sigmoida software;

Negative: The sample tested is negative for the tested agent.
Positive: The sample tested is positive for the tested agent.
Contamination: Repeat the analysis paying attention to the "Warnings and Limitations" section.
Invalid: Sampling isn't successfully done or there is a problem during the sample transportation. A new sample from the same patient should be collected and tested again.
Reagent Problem: Test the PCs provided with the kit setting up the PC reactions as shown in Table 6. If the test result is positive, the run is valid. In case the software generates a "Reagent Problem" again, contact the manufacturer.

For in vitro diagnostic use only.
For professional use only.

3. Warnings and Limitations

1. False-negative results may occur if inadequate numbers (lower than the LoD) of organisms are present in the specimen.
2. Mutations within the target regions could affect primer and/or probe binding resulting in failure to detect the presence of agents.
3. Cotton or calcium alginate swabs or swabs with wooden sticks should not be used since they may contain substances that inactivate some pathogens and inhibit PCR.
4. A false-negative result may occur if a specimen is improperly collected, transported, or handled.
5. The clinical specimens shall be collected by a healthcare provider in accordance with the specimen collection guidelines.
6. Test procedures should be performed by personnel trained in the use of the kit.
7. Except for liquid transfers, sample tubes should always be kept closed.
8. Filtered and nuclease-free pipette tips should be used for sample transfer.
9. The components in the kit should not be used together with different lot numbers or chemicals of the same name but from different manufacturers.
10. ***The caps of the reaction tubes must not be opened after the PCR run.*** The PCR tubes should be placed in a bag and thrown away after the bag is tightly closed.
11. The surfaces of the workbenches should be wiped with freshly diluted 10% bleach (0.5% NaClO) at the beginning and end of each day.
12. Disposal of waste must be carried out in accordance with local, state, and federal regulations.

4. Explanation of Symbol

Symbol	Title of Symbol	Symbol	Title of Symbol	Symbol	Title of Symbol
CE	European Conformity CE Mark	LOT	Batch code		Keep away from sunlight
IVD	*In vitro* diagnostic *medical device*	REF	Catalogue number		Protect from heat and radioactive sources
	Manufacturer	NON STERILE	Non-*sterile*		Do not use if package is damaged and consult *instructions for use*
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep dry
CONTROL –	Negative control		Caution		Keep upright
CONTROL +	Positive control		Temperature limit	Σ	Contains sufficient for *<n>* tests
CONTROL	Control				

5. Manufacturer and Technical Support

Bioeksen AR GE Teknolojileri A.Ş
Address: Huzur Mah. Metin Oktay Cad. Nurol Life Sitesi D Blok No:3/31, 34396 Sarıyer/İstanbul-TÜRKİYE
Phone: +90 (212) 285 10 17, **Fax:** +90 (212) 285 10 18
Web: www.bioeksen.com.tr, **e-mail:** info@bioeksen.com.tr,
Technical Support: support@bioeksen.com.tr

Notice to User: Please inform us about product-related incidents at "**vigilance@bioeksen.com.tr**" within 24 hours.

For in vitro diagnostic use only.
For professional use only.