bioeksen
MOLECULAR DIAGNOSTICS

March 6, 2024

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.

Bioeksen AR GE Teknolojileri A. Ş

Canan Ketre

Chair of the Board

Digitally signed by Dolgopol Iulian
Date: 2024.05.17 10:35:29 EEST
Reason: MoldSign Signature
Location: Moldova

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Merkez Ofis / Üretim Ofisi : Huzur Mah. Metin Oktay Cad.
Nurol Life Sitesi D Blok No:3/31 Sarıyer-İstanbul-TÜRKİYE

EU DECLARATION OF CONFORMITY

2017/746 In Vitro Diagnostic Medical Device Regulation (EU) Declaration of Conformity

Manufacturer	Bioeksen AR GE Teknolojileri A.Ş.
Manufacturer's Address	**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-posta:** info@bioeksen.com.tr
Manufacturer Individual Identification Number	TR-MF-000032826
Authorised Representative	-
Authorised Representative's Address	-
Authorized Representative Identification Number	-
Product(s) Name	Bio-Speedy® *v*NAT® Viral Nucleic Acid Buffer
Product Catalog Number(s)	BS-NA-510-100 BS-NA-510-250 BS-NA-510-500 BS-NA-510-1000
Basic UDI-DI	868187745NAEXB013W
Intended Purpose	The *v*NAT® Viral Nucleic Acid Buffer is a 10x concentrated viral nucleic acid extractive and preservative liquid for nasopharyngeal swab, oropharyngeal swab, oral/saliva swab samples. The nucleic acid extractive and preservative liquid inactivates all viral, bacterial, or eukaryotic pathogens in the sample within 1 minutes after contact with the clinical specimen. The *v*NAT® Viral Nucleic Acid Buffer allows from sample to qPCR in a minute.
Technical Documentation Number	TD.016
Risk Classification of Device and Classification Rule	Class A Device according to Annex VIII Article 2.5 (Rule 5) point a of 2017/746 In Vitro Diagnostic Medical Device Regulation (EU)
GMDN Code	52521- Nucleic acid extraction/isolation kit IVD
EMDN Code	-
Conformity Assessment Route	EU Declaration of Conformity, under the responsibility of the manufacturer, according to ANNEX IV (Annex II and Annex III) of 2017/746 In Vitro Diagnostic Medical Device Regulation (EU)

Bioeksen AR GE Teknolojileri A.Ş. declares that the above mentioned device meets the previsions of 2017/746 In Vitro Diagnostic Medical Device Regulation (EU). All supporting documentation is reserved under the premises of the manufacturer and the EU declaration of conformity is issued under sole responsibility of manufacturer.

Authorized Person: Canan Zöhre Ketre Kolukırık

Position: Chairman of the Board

Seal/Signature: BİOEKSEN AR-GE TEKNOLOJİLERİ A.Ş.
Huzur Mah. Metin Oktay Cad. Nurol Life D Blok
No: 3/31 Sarıyer /İSTANBUL
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Date of Issue: 25.01.2023

Place of Issue: İstanbul

EU DECLARATION OF CONFORMITY

ATTACHMENT
List of Applied Standards

	Standard Title	Content	Scope	Excluded Items
QMS	ISO 9001:2015	Quality management systems — Requirements	Covered	-
Harmonised Standard QMS	EN ISO 13485:2016 EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	Medical devices — Quality management systems — Requirements for regulatory purposes	Partially covered.	– 7.5.5 Special Requirements for Sterile Medical Devices – 7.5.7 Special Requirements for Process Validation for Sterilization and Sterile Barrier Systems – 7.5.9.2 Special requirements for implantable medical devices
Harmonised Standard Risk Management	EN ISO 14971:2019 EN ISO 14971:2019/A11:2021	Medical devices — Application of risk management to medical devices	Covered	-
Risk Management	ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971	Covered	-
Performance Evaluation Metrological Traceability	EN ISO 17511:2020	In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples	Covered	-
Performance Evaluation	EN 13612:2002	Performance evaluation of in vitro diagnostic medical devices	Covered	-
Performance Evaluation Stability	EN ISO 23640:2015	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents	Covered	-
Harmonised Standard Labelling	EN ISO 18113-1:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements	Covered	-
Harmonised Standard Labelling	EN ISO 18113-2:2012	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use	Covered	-
Harmonised Standard Labelling	EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements	Covered	-
Post-Market Surveillance	ISO/TR 20416:2020	Medical devices — Post-market surveillance for manufacturers	Covered	-
Usability	IEC 62366-1:2015	Medical devices — Part 1: Application of usability engineering to medical devices	Covered	-
Performance Evaluation	ISO 20395:2019	Biotechnology — Requirements for evaluating the performance of quantification methods for nucleic acid target sequences — qPCR and dPCR	Partially covered.	Does not cover dPCR items.

Performance Evaluation	ISO 16142-2:2017	Medical devices — Recognized essential principles of safety and performance of medical devices — Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards	Partially covered.	Table B.1 — General principles for all medical devices 18.3 (l)
Clinical Studies	BS ISO 20916:2019	In vitro diagnostic medical devices — Clinical performance studies using specimens from human subjects — Good study practice	Covered	-
Stability	CLSI EP25-A	Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline, CLSI, Wayne, PA, 2009	Covered	-
Stability	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	Partially covered.	5.12 Sterile 6.5.3 (c) 6.6.2 (d) (7) 6.6.2 (g) 6.6.2 (h)
Performance Evaluation	MDCG 2021-21	Guidance on performance evaluation of SARS-CoV-2 in vitro diagnostic medical devices	Covered	-
Performance Evaluation	CLSI MM3 A3: 3ED 2015	Molecular Diagnostic Methods for Infectious Diseases	Covered	-
Performance Evaluation	CLSI EP17 A2: 2ED 2012	Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures	Covered	-
Performance Evaluation	CLSI EP07 3ED: 2018	Interference Testing in Clinical Chemistry, 3rd Edition	Not covered	-
Performance Evaluation	CLSI EP5 A3: 3ED 2014	Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline—Third Edition	Covered	-

EU DECLARATION OF CONFORMITY

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® COVID-19/Flu RT-qPCR
Description	: Bio-Speedy® COVID-19/Flu RT-qPCR
	Ref No: BS-SY-SI-100
	Ref No: BS-SY-SI-250
	Ref No: BS-SY-SI-500
	Ref No: BS-SY-SI-1000
Classification	: Other (Neither listed in the Annex II, Nor Self-testing device), GMDN code: 47922- Multiple respiratory virus 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
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Place of Issue: İstanbul

Valid from: 25.05.2022

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

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

Cat No: BS-SY-SI-100/BS-SY-SI-250/BS-SY-SI-500/BS-SY-SI-1000

COVID-19/Flu RT-qPCR

Package Insert

Table 1. Kit Content

Component	Intended Use	100 Reactions	250 Reactions	500 Reactions	1000 Reactions
2X Prime Script Mix	Optimized ready-to-use mix for RT-qPCR assay	1 x 1000 µL	2 x 1250 µL	4 x 1250 µL	8 x 1250 µL
CVD19/FLU Oligo Mix	**FAM**: SARS-CoV-2 **HEX:** Human (IC-Internal Control) **ROX:** Influenza A **CY5:** Influenza B	1 x 500 µL	1 x 1250 µL	2 x 1250 µ	4 x 1250 µL
NTC	Negative Control	1 x 1000 µL	1 x 1000 µL	1 x 1000 µL	1 x 1000 µL
PC-CVD19/FLU	Positive Control (PC)	1 x 250 µL	1 x 250 µL	1 x 500 µL	2 x 500 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) – (+8) °C	(-22) – (-18) °C	12 Months
CVD19/FLU Oligo Mix		(-22) – (-18) °C	
NTC		(+2) – (+8) °C	
PC-CVD19/FLU		(+2) – (+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

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)	**Inclusivity and Exclusivity**	Validated on the reference strains and the field isolates
Automated/Manual	Manual		
Intended Users	Professional use	**Limit of Detection (LoD)**	Table 5
Target Population	Individuals with the suspected infection	**Sensitivity and Specificity**	%100.00 ve %100.00

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	***vNAT® Transfer Tube*** (Cat. No: BS-NA-513m)	3 months at (+2) – (+8) °C 1 year at -20 °C	Nucleic acid preparation is not required. The sample can be used directly in qPCR.	250
	Viral Transport Medium (VTM) (CDC SOP#: DSR-052-05)	3 days at (+2) – (+8) °C 1 year at -70 °C	***RINA™ M14 Nucleic Acid Extraction Device*** (Robot Catalog 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 (BAL) and nasopharyngeal aspirate	Preservative-free sterile containers/tubes	(+2) – (+8) °C'de 3 gün -70 °C'de 1 yıl		500

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

Revision Date: 2023-07-31/Rev.01
Published Date: 2022-08-15

1. 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. RT-qPCR Program Details

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 qPCR Mix	5 µL	**Enzyme Activation**	1 Cycle	52 °C	3 min	
		Pre-Incubation	1 Cycle	95 °C	10 sec	
Oligo Mix	2.5 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	2.5 µL	**Denaturation**	30 Cycles	95 °C	1 sec	
		Annealing and Extension		55 °C	15 sec	
Total Reaction Volume	**10 µL**	**Detection (Reading)**		(FAM-Green)/(HEX-Yellow) (ROX-Orange)/(CY5-Red)		https://www.bioeksen.com.tr/files/L_TD_43P/

WARNING: The 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

All default analysis options (e.g., auto-calculated threshold) in the Mic software should not be changed to calculate Cq values.

The shape of the amplification curves should be examined for all reaction wells returning with Cq values. All the sigmoidal curves above the threshold should be recorded as "positive" and their Cq values should be recorded. Non-sigmoidal curves should be recorded as "negative".

Table 7. Expected Performance of Kit Controls

Control Type	Control Name	Purpose	Expected Results and Cq Values	
			IC (HEX)	Target
Negative Control	NTC	Contamination control during RT-qPCR	**Not detected** (No Cq)	**Not detected** (No Cq)
Positive Control	PC	Reagent integrity	**Detected** (Cq≤26)	**Detected** (Cq≤26)
Internal/Extraction Control	IC	To monitor the integrity of nucleic acid extraction and RT-qPCR from each sample	**Detected** (Cq≤26) If the IC Cq>26, check the target Cq.	If the target has a valid Cq value according to the result interpretation criteria, IC is valid.

If any control does not work as described above, the run is reported as follows:

1. **Contamination:** If Cq≤26 in any NTC test channel.
   Recommended action: Repeat the analysis paying attention to the "Warnings and Limitations" section.
2. **Reagent Problem**: In case a sigmoidal curve with a Cq≤26 cannot be obtained for any of all the samples tested in the run, including the controls.
   Recommended action: Test the "**PC-CVD19/FLU"** provided with the kit setting up the PC reaction 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.
3. **Invalid:** If the sample has a Cq>26 in the HEX channel of the test tube and no Cq in the other channels.
   Recommended action: 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.

If all the controls are valid, the results are interpreted as follows:

Table 8. Interpretation of Patient Results

Target	Internal Control (IC)	Result Interpretation
Positive (+)	**Positive (+)** or **Negative (-)**	Results are valid Target is detected
Negative (-)	**Positive (+)**	Results are valid Target is not detected

The results generated by the qPCR instruments can be reported manually, as explained earlier, or automatically using the "**Sigmoida**" software. To obtain the "Sigmoida" software installer, please send an email to support@bioeksen.com.tr.

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. The use of cotton or calcium alginate swabs or swabs with wooden sticks can lead to false negative results 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
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.

Cat No: BS-NA-510-100/BS-NA-510-250/BS-NA-510-500/BS-NA-510-1000

vNAT® Viral Nucleic Acid Buffer

Package Insert

1. Product Content

Table 1: Product Content, Storage Requirements, and Shelf Life

Component	Amount				Transport Conditions	Storage Conditions	Shelf Life
vNAT® Viral Nucleic Acid Buffer	100 Test (1 X 10mL)	250 Test (1 X 25mL)	500 Test (1 X 50mL)	1000 Test (1 X 100mL)	2-50°C	15-30 °C	18 Months

2. Intended Use and Test Principle

The ***vNAT® Viral Nucleic Acid Buffer*** is a ***10x concentrated*** viral nucleic acid extractive and preservative liquid for nasopharyngeal swab, oropharyngeal swab, oral/saliva swab samples. The nucleic acid extractive and preservative liquid inactivates all viral, bacterial, or eukaryotic pathogens in the sample within 1 minutes after contact with the clinical specimen. The ***vNAT® Viral Nucleic Acid Buffer*** allows from sample to qPCR in a minute**.**

3. Analytical Specifications

vNAT® Viral Nucleic Acid Buffer is validated for detection kits produced by Bioeksen R&D Technologies Inc.

4. Sampling Protocol

Clinical samples are collected from individuals by a healthcare provider in accordance with the CDC Specimen Collection Guidelines: https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html.

5. Sample Transportation, Storage, and Application Protocol

The specimens in the ***vNAT® Viral Nucleic Acid Buffer*** can be stored at 2-8°C and ship to the laboratory on ice pack. If a specimen is frozen at -70°C or lower, ship overnight to the laboratory on dry ice. It is important that specimens are not exposed to continuous freeze-thaw exposure.

⚠ **WARNING:**

a) The VTM validated with the vNAT buffer is in accordance with the CDC directive and do not contain phenol-red (Preparation of viral transport medium, Centers for Disease Control and Prevention, SOP#: DSR-052-06).
b) The Amies medium should not contain charcoal.

Standard Protocol (Samples in VTM/Saline/Amies)

1. Vortex the sample tube at the highest speed for 3 seconds.
2. Transfer 100 µl of the ***vNAT® Viral Nucleic Acid Buffer*** into a clean tube.
3. Add 900 µL of the sample to the tube containing 100 µL ***vNAT® Viral Nucleic Acid Buffer***.
4. Mix the sample and the ***vNAT® Viral Nucleic Acid Buffer*** well by vortexing/shaking/pipetting.
5. Incubate the tube for 1 minute at room temperature.
6. 1000 µl mixture is ready to use in PCR reaction.

Protocol for Dry Swab Samples

1. Transfer the swab sample into a tube containing 100 µl ***vNAT® Viral Nucleic Acid Buffer*** + 900 µl nuclease-free water.
2. Apply the steps 1-6 of the "**Standard Protocol**".

6. 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*		Keep dry
	Use-by date		Consult *instructions for use* or consult electronic *instructions for use*		Keep it upright
	Temperature limit		Contains sufficient for <*n*> tests		Caution

7. Manufacturer and Technical Support

Bioeksen R&D Technologies Incorporated Company
Address: Resitpasa Mh. Katar Cd., 4/B-105. 34467, Sariyer, Istanbul, TURKEY.
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.

ТОВ «ХЕМА» код ЄДРПОУ 36038442
Адреса 03179, м. Київ, вул. Академіка Єфремова, 23
Для кореспонденції: 03179, а/с 49
З питань замовлення продукції: 050-422-62-16, 067-422-62-16
Тел.: +38 (095) 60-99-555 Факс: +38 (044) 422-62-16
e-mail:info@xema.com.ua
www.xema.in.ua

STATEMENT

We, XEMA LLC, as a manufacturer of in vitro diagnostic medical devices, having a registered office at Akademika Yefremova St. 23, Kyiv, Ukraine assign SRL SANMEDICO having a registered office at A. Corobceanu Street 7A, apt. 9, Chişinău MD-2012, Moldova, as authorized representative in correspondence with legislative requirements of the Republic of Moldova.

We declare that the company mentioned above is authorized to register, notify, renew, or modify the registration of medical devices on the territory of the Republic of Moldova.

This Statement shall come into force on the date of its signing. The duration of this Statement is 3 years from the date of signing.

Date: 06.09.2023

Signature:

Director Xema LLC
Oleksandra Zavaliei

ТОВ «УКРМЕДСЕРТ»

СЕРТИФІКАТ

про відповідність системи управління якістю

Зареєстрований у Реєстрі
«29» червня 2022 р.
№ UA.SM.214-21
Дійсний до «03» серпня 2024 р.
Перше видання: «04» серпня 2021 р.

ЦИМ СЕРТИФІКАТОМ ВІДПОВІДНОСТІ ПОСВІДЧУЄТЬСЯ,
ЩО СИСТЕМА УПРАВЛІННЯ ЯКОСТІ СТОСОВНО

проектування та розроблення, виробництва та дистрибуції медичних виробів для діагностики in vitro

впроваджена:

ТОВ «ХЕМА»

за адресою: **вул. Академіка Єфремова, 23, м. Київ, 03179, Україна**

відповідає вимогам ISO 13485:2016;
ДСТУ EN ISO 13485:2018 (EN ISO 13485:2016, IDT; ISO 13485:2016, IDT).

Контроль відповідності сертифікованої системи управління якістю вимогам зазначеного стандарту здійснюється шляхом нагляду, періодичність і процедури якого регламентуються процедурами органу з оцінки відповідності.

Сертифікат видано Органом з оцінки відповідності ТОВ «УКРМЕДСЕРТ», акредитованим Національним агентством з акредитації України, атестат від 24.12.2019 № 8О047, адреса: вул. Драгоманова, будинок 1-А, оф. 2, м. Київ, 02059, Україна, тел./факс: +38-067-595-02-30, https://ukrmedcert.org.ua.

Директор **І.М. Хотенюк**

Чинність сертифіката відповідності можна перевірити в Реєстрі на сайті https://ukrmedcert.org.ua та за тел. +38-067-595-02-30

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Vertretung und Repräsentanz

Certificate

Of Marketing Authorization of Medical Product

within Germany, the member states of the European Union
and the other states having a contractual agreement with the European Economic Area

Nr. AR/IVD/XEMA LLC/01/2023

Issued on the basis of the Declaration of conformity and registration taking into account account Article 11 of Regulation (EU) 2017/746 (IVDR) on In Vitro Diagnostic, and Medical Device Implementing Act (MPDG)

Ausgestellt auf Grund der Konformitätserklärung und Registrierung unter Berücksichtigung der der Verordnung (EU) 2017/746 (IVDR) über In-vitro-Diagnostika und Medizinprodukterecht-Durchführungsgesetz (MPDG)

Manufacturer / Hersteller	**XEMA LLC** **SRN: UA-MF-000032959** UKRAINE, 03179 KYIV Akademika Yefremova St. 23 qa@xema.com.ua; www.xema.in.ua
Product name / Produkt	**See annex to the Certificate** Siehe Anhang zum Zertifikat
Product Classification: Produktklassifizierung	**In Vitro Diagnostic Medical Devices** In-vitro-Diagnostikum (IVD) Medizinprodukte
Category: Kategorie	**Common/ Other IVD** Sonstige IVD-Produkte
Conformity assessment procedure: Konformitatsbewertungsverfahren:	**EC DECLARATION OF CONFORMITY** **(Annex III, except point 6, Directive 98/79/EC)** **in connection with article 110(3) IVDR** **EU- KONFORMITATSERKLARUNG** (Anhang III, außer Nummer 6, Richtlinie 98/79 / EG) in Verbindung mit Artikel 110 (3) IVDR
State Competent Authority: Staatliche Zuständige Behörde	**BfArM** Federal Institute for Drugs and Medical Devices DMIDS (German Medical Device Information and Database System) **BfArM** Das Bundesinstitut für Arzneimittel und Medizinprodukte DMIDS (Deutsches Medizinprodukte-Informations- und Datenbanksystem)

Date of issue : **2023-03-07**
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Gilt nur mit :Auszug aus der Datenbank www.dimdi.de (Deutsches Medizinprodukte-Informations- und Datenbanksystem (DMIDS))

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Vertretung und Repräsentanz

Annex to the Certificate No.:

Anhang zum Zertifikat Nr.:

AR/IVD/XEMA LLC/01/2023

The following medical devices can be placed on the market in the Federal Republic of Germany, in the member states of the European Economic Community (EEC) and in the other contract states of the agreement about the European Economic Area.

Die folgenden Medizinprodukte in der Bundesrepublik Deutschland, in den Mitgliedsstaaten der Europäischen Wirtschaftsgemeinschaft (EG) und in den Vertragsstaaten der EG in den Verkehr gebracht werden dürfen.

#	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DMIDS Registration number Registriernummer
1.	ASPERGILLUS	K021	GalMAg EIA	**DE/CA64/00115824**
2.	HSV IgG	K104	HSV 1/2 IgG EIA	**DE/CA64/00115826**
3.	HSV IgM	K104M	HSV 1, 2 IgM EIA	**DE/CA64/00115833**
4.	HSV 2 IgG	K104B	HSV 2 IgG EIA	**DE/CA64/00115836**
5.	MYCOPLASMA ANTIBODY ASSAYS	K106	Mycoplasma IgG EIA	**DE/CA64/00115837**
6.	SYPHILIS ANTIBODY ASSAYS TOTAL	K111	anti-Treponema pallidum EIA	**DE/CA64/00115839**
7.	SYPHILIS ANTIBODY IGG	K111G	Treponema pallidum IgG EIA	**DE/CA64/00115840**
8.	H. PYLORI ANTIBODY ASSAYS	K119G	Helicobacter pylori IgG EIA	**DE/CA64/00115850**
9.	OTHER OTHER BACTERIOLOGY IMMUNOASSAY	K126	Ureaplasma IgG EIA	**DE/CA64/00115851**
10.	THYROID PEROXIDASE (INCL. MICROSOMAL) ANTIBODIES	K131	aTPO EIA	**DE/CA64/00115852**
11.	THYROGLOBULIN AUTOANTIBODIES	K132	aTG EIA	**DE/CA64/00115853**
12.	MPO ANCA	K133	aMPO EIA	**DE/CA64/00115854**
13.	TISSUE TRANSGLUTAMINASE ANTIBODIES	K160 K161	anti-TGlu IgG EIA anti-TGlu IgA EIA	**DE/CA64/00115855**
14.	GIARDIA LAMBLIA	K171	anti-Giardia lamblia EIA	**DE/CA64/00115856**
15.	OTHER PARASITOLOGY	K174	Ascaris IgG EIA	**DE/CA64/00115857**
16.	ECHINOCOCCUS	K175	Echinococcus IgG EIA	**DE/CA64/00115858**
17.	DISTOMATOSIS	K176	Opisthorchis IgG EIA	**DE/CA64/00115859**
18.	GLIADIN ANTIBODIES	K180 K181	Gliadin IgG EIA Gliadin IgA EIA	**DE/CA64/00115860**
19.	IMMUNOGLOBULIN E – TOTAL	K200	Total IgE EIA	**DE/CA64/00115861**
20.	THYROID STIMULATING HORMONE	K201	TSH EIA	**DE/CA64/00115863**
21.	LUTEINISING HORMONE	K202	LH EIA	**DE/CA64/00115864**
22.	FOLLICLE STIMULATING HORMONE	K203	FSH EIA	**DE/CA64/00115865**
23.	HUMAN GROWTH HORMONE	K204	GH EIA	**DE/CA64/00115866**
24.	HUMAN CHORIONIC GONADOTROPIN TOTAL	K205	hCG EIA	**DE/CA64/00115867**
25.	PROLACTIN	K206	Prolactin EIA	**DE/CA64/00115868**

The above-mentioned medical products are marked with the CE symbol.
Die oben genannten medizinischen Produkte sind mit dem CE-Zeichen gekennzeichnet.

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#	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DMIDS Registration number Registriernummer
26.	PROGESTERONE	K207	Progesterone EIA	**DE/CA64/00115869**
27.	ESTRADIOL	K208	Estradiol EIA	**DE/CA64/00115870**
28.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K209	Testosterone EIA	**DE/CA64/00115871**
29.	CORTISOL	K210	Cortisol EIA	**DE/CA64/00115872**
30.	TRIIODOTHYRONINE	K211	T3 EIA	**DE/CA64/00115873**
31.	THYROXINE	K212	T4 EIA	**DE/CA64/00115874**
32.	FREE TRIIODOTHYRONINE	K213	fT3 EIA	**DE/CA64/00115875**
33.	FREE THYROXINE	K214	fT4 EIA	**DE/CA64/00115876**
34.	DEHYDRO-EPIANDROSTERONE SULPHATE (INCL. DHEA)	K215	DHEAS EIA	**DE/CA64/00115877**
35.	17 OH PROGESTERONE	K217	17-OH-progesterone EIA	**DE/CA64/00115878**
36.	ESTRIOL	K218	free Estriol EIA	**DE/CA64/00115880**
37.	TESTOSTERONE (WITH DEHYDRO AND FREE TESTOSTERONE)	K219	free Testosterone EIA	**DE/CA64/00115881**
38.	CANCER ANTIGEN 125	K222	CA 125 EIA	**DE/CA64/00115882**
39.	CANCER ANTIGEN 19-9	K223	CA 19-9 EIA	**DE/CA64/00115883**
40.	CARCINOEMBRYONIC ANTIGEN	K224	CEA EIA	**DE/CA64/00115884**
41.	ALPHAFETOPROTEIN	K225	AFP EIA	**DE/CA64/00115885**
42.	CANCER ANTIGEN 15-3	K226	CA 15-3 (M12) EIA	**DE/CA64/00115886**
43.	OTHER OTHER TUMOUR MARKERS	K232	Thyroglobulin EIA	**DE/CA64/00115887**
44.	ß HUMAN CHORIONIC GONADOTROPIN (INCL. SUBUNIT)	K235	free β-HCG EIA	**DE/CA64/00115888**
45.	CYFRA 21-1	K236	CYFRA 21-1 EIA	**DE/CA64/00115889**
46.	SQUAMOUS CELL CARCINOMA ANTIGEN	K237	SCC (A) EIA	**DE/CA64/00115890**
47.	PREGNANCY ASSOCIATED PLASMA PROTEIN - A (DOWNS)	K238	PAPP-A EIA	**DE/CA64/00115892**
48.	OTHER OTHER TUMOUR MARKERS	K239	HE4 EIA	**DE/CA64/00115893**
49.	CANCER ANTIGEN 242	K243	CA242 EIA	**DE/CA64/00115894**
50.	OTHER PREGNANCY TESTING HORMONES	K245	AMH EIA	**DE/CA64/00115896**

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#	Nomenclature term Nomenklaturbezeichnung	Catalog No. Katalog-Nr.	Name of device Produktbezeichnung	DMIDS Registration number Registriernummer
51.	HUMAN PLACENTAL LACTOGEN HPL	K246	Placental lactogen EIA	DE/CA64/00115897
52.	C-REACTIVE PROTEIN	K250	CRP EIA	DE/CA64/00115898
53.	C-PEPTIDE	K267C	C-peptide EIA	DE/CA64/00115900
54.	INSULIN	K267N	Insulin EIA	DE/CA64/00115901
55.	SEX HORMONE BINDING GLOBULIN	K268	SHBG EIA	DE/CA64/00115902
56.	TROPONIN (T + I)	K291	Troponin I EIA	DE/CA64/00115903
57.	LYME ANTIBODY IGG	K118G	Borelia burgdorferi IgG EIA	DE/CA64/00115904
58.	LYME ANTIBODY IGM	K118M	Borelia burgdorferi IgM EIA	DE/CA64/00115905
59.	EBV ANTIBODIES	K108V K108VM K108N	Epstein-Barr virus VCA IgG EIA Epstein-Barr virus VCA IgM EIA Epstein-Barr virus EBNA IgG EIA	DE/CA64/00115906

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Date: **March 07, 2023**

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