CERTIFICATE

EC Certificate No. 1434-IVDD-157/2022

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Shenzhen Lvshiyuan Biotechnology Co., Ltd

101, 201, 301 D Building, No. 2 Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen 518120, China

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

Ref. No.: GF102BS1, GF102BS5, GF102BS10, GF102BS25

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 16.05.2022 to 27.05.2025

The date of issue of the Certificate: 16.05.2022

The date of the first issue of the Certificate: 16.05.2022

CE 1434

Issued under the Contract No. MD-43/2021
Application No: 94/2021
Certificate bears the qualified signature.
Warsaw, 16/05/2022
Module A1

Aleksandra Kostrzewa
Digitally signed by Aleksandra Kostrzewa
President

Declaration of Conformity

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

Company Name: Shenzhen Lvshiyuan Biotechnology Co., Ltd.
Address: 101, 201, 301, D Building, No. 2 Industrial Avenue, Buxin Village, Buxin Community, Dapeng Subdistrict Office, Dapeng New District, Shenzhen 518120 China

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

List of Products:

1. SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

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 6 of Directive 98/79/EC.***

Our current Quality System is formatted to international standards:

ISO 9001: 2015

Notify body: POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.
Notified body number:1434

Corporate Contact Information

COMPANY NAME: Shenzhen Lvshiyuan Biotechnology Co., Ltd.
COMPANY ADDRESS: 101, 201, 301, D Building, No. 2 Industrial Avenue, Buxin Village, Buxin Community Dapeng Subdistrict Office, Dapeng New District, Shenzhen 518120 China
COMPANY PHONE: +86 755 28438788
COMPANY FAX: +86 755 28938800
COMPANY EMAIL: sales@lsybt.com
RESPONSIBLE PERSON'S name: Jiang Yongqing
Position: Vice General Manager
SIGNATURE : Jiang Yongqing
Date : 2020/11/09
Stamp

European Authorized Representative:
Registered Address:
Obelis s.a.
Bd. Général Wahis 53
B-1030 Brussels, Belgium
Phone: 32.2.732.59.54
Fax: 32.2.732.60.03
E-mail: mail@obelis.net
Representative: Mr. Gideon ELKAYAM (CEO)

The Statement on Detection of Mutant Viruses

Date： 31th October, 2022

Product：Green Spring® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

We, Shenzhen Lvshiyuan Biotechnology Co., Ltd., as the manufacturer, hereby declare that Green Springs SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) can detect the following SARS-CoV-2 Virus variants which is listed as 'variants of concern (VOC)'& 'variants of interest (VOI) & Variants under monitoring (VUMs)'by the World Health Organization. VOC refers to the large number and wide range of cases caused worldwide, and data confirms its transmission ability, strong toxicity, or reduced effectiveness of vaccines and clinical treatments. VOI refers to a confirmed case of community transmission, or has been found in multiple countries, but has not yet formed a large-scale infection. VUM refers to a SARS-CoV-2 variant with genetic changes that are suspected to affect virus characteristics with some indication that it may pose a future risk, but evidence of phenotypic or epidemiological impact is currently unclear, requiring enhanced monitoring and repeat assessment pending new evidence.

WHO Categories	WHO Label	Pango Lineage	Date of Designation
Variants Of Concern (VOC)	Alpha	B.1.1.7	September, 2020
	Beta	B.1.351	May 2020
	Gamma	P.1	November 2020
	Delta	B.1.617.2	October 2020
	Omicron	B.1.1.529	November 2021
Variants Of Interest (VOI)	Epsilon	B.1.427	February, 2021
		B.1.429	June 2021
	Eta	B.1.525	February 2021
	Iota	B.1.526	February 2021
	Kappa	B.1.617.1	May, 2021
	N/A	B.1.617.3	May, 2021
	Zeta	P.2	February 2021
	Mu	B.1.621, B.1.621.1	September, 2021
	IHU	B.1.640.2	September, 2021
Variants under monitoring (VUMs)		BA.1 x AY.4 recombinant	09-Mar-2022

		B.1.640	22-Nov-2021
		BA.1	Nov-2021
		BA.2	Feb-2022
		BA.2.12.1	Feb-2022
		BA.3	Feb-2022
		BA.4	Jan-2022
		BA.5	Jan-2022
		BF.7	Mar-2022
		BA.2.75	May-2022
		BQ.1.1	Aug-2022
		XBB	Sep-2022
		BQ.1	Sep-2022

The new coronavirus (SARS-CoV-2 or 2019-nCoV) is a non-segmented forward RNA virus. This is the cause of the new type of coronavirus pneumonia (COVID-19), which is highly contagious in humans. The SARS-CoV-2 virus has several structural proteins, including spikes (S), envelope (E), membrane (M) and nucleocapsid (N).

The SARS-CoV-2 virus has the characteristics of strong nucleocapsid (N) protein stability. The mutant virus strains that have been found worldwide are derived from the SARS-CoV-2 20B/GR evolutionary strain (lineage B.1.1.7), including many mutation, the mutation location is the spike (S) protein of the new coronavirus, which is the location where the SARS-CoV-2 virus uses to bind to the cell's ACE2 receptor.

The SARS-CoV-2 Antigen Rapid Test Kit produced by Shenzhen Lvshiyuan Biotechnology Co., Ltd. is used for in vitro qualitative detection of SARS-CoV-2 virus nucleocapsid (N) protein in human nasopharyngeal , oropharyngeal , anterior -nasal or saliva samples.

It can be seen that the mutation sites of mutated virus strains including BQ.1.1 strain have no effect on the detection rate of the kits produced by our company. The kit is suitable for assay of the SARS-CoV-2 variant virus as listed in the table above.

Shenzhen Lvshiyuan Biotechnology .Co., Ltd.

Chief Executive Officer Fangxiu Wang

Signature : Fangxiu Wang