CERTIFICATE

DIRECTIVE 98/79/EC
EC DESIGN-EXAMINATION

CeCert Sp. z o.o. hereby confirms that manufactured by

Suny (Xiamen) Biotechnology Co., Ltd.
Floor 3 to 8, Building 24, No. 71 Houxiang Road,
Haicang District, 361026 Xiamen, Fujian, P.R. China

in vitro diagnostic medical device for self-testing

The list of devices covered by the scope of this Certificate is included in Annex 1

in term of the design conforms to the requirements of Annex III section 6 to Directive 98/79/EC (as amended) implemented into Polish Law, as evidenced by the assessment conducted by CeCert Sp. z o.o.

CE 2934

Validity date: 06.05.2022 – 26.05.2025

Edition issue date: 25.05.2022

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device
Certification Department

CeCert Sp. z o.o.
ul. Żurawia 32/34
00-515 Warszawa

www.cecert.pl
e-mail: biuro@cecert.pl

Certificate no: CeCert/073/W/E.2

ANNEX 1

TO THE CERTIFICATE NO. CECERT/073/W/E.2

List of *in vitro* diagnostic medical devices covered by the scope of the Certificate No. CeCert/073/W/E.2:

Brand/Trademark	Catalogue Number	Device Name
SunyBio	S6061701	Rapid SARS-CoV-2&Flu A&Flu B Antigen Test (Colloidal Gold) / Nasal Swab
	S6061702	
	S6061703	
	S6061704	
SAYEE BIOONE	B6061701	Rapid SARS-CoV-2&Flu A&Flu B Antigen Test (Colloidal Gold) / Nasal Swab
	B6061702	
	B6061703	
	B6061704	
BOIRON TEST & CARE	F6061701	TEST 2 EN 1 COVID-19 / GRIPPE - AUTOTEST NASAL 2 IN 1 TEST COVID-19 / FLU NASAL SELF TEST
	F6061702	
	F6061703	
	F6061704	
MedRhein	M6061701	SARS-CoV-2 & FluA & FluB Antigen-Schnelltest (Kolloidales Gold) / Nasenabstrich Rapid SARS-CoV-2&Flu A&Flu B Antigen Test (Colloidal Gold) / Nasal swab
	M6061702	
	M6061703	
	M6061704	
Anbio Biotech	A6061701	Rapid SARS-CoV-2 & Flu A & Flu B Antigen Test (Colloidal Gold) / Nasal Swab
	A6061702	
	A6061703	
	A6061704	

Check it

Kamil Szczurowski
Director of *in Vitro* Diagnostic Medical Device Certification Department

Suny CE 2934

DECLARATION OF CONFORMITY

English

Statement:

According Directive 98/79/EC on *In Vitro Diagnostic Medical Devices*, Annex III. This declaration of conformity is issued under the sole responsibility of Suny (Xiamen) Biotechnology Co., Ltd.

Manufacturer Information:

Manufacturer Name:	Suny (Xiamen) Biotechnology Co., Ltd.
Postal Address:	Building 24, No. 71, Houxiang Road, Haicang District
Postcode:	361026
City & Country:	Xiamen, Fujian, China
Telephone Number:	+86 0592-6312399
Web-site:	www.sunybio.cn

European Representative:

ECRP Name:	Lotus NL B.V.
Postal Address:	Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
Postcode:	2595AA
City & Country:	Netherlands.
Telephone Number:	+31 64 41 68 999
E-Mail Address:	peter@lotusnl.com

In Vitro Diagnostic Directive:

Product Name:	Rapid SARS-CoV-2&FluA/B Antigen Test (Colloidal Gold)
Model:	S6061701, S6061702, S6061703, S6061704, S6061705
Packing Specification:	1 Test/ Kit, 5 Tests/ Kit, 10 Tests/ Kit, 20 Test/ Kit, Other specifications
GMDN Code:	65454
Category:	For Self-Test
Conformity assessment route:	Declaration of Conformity *98/79/EC* Annex III section 6

Statement of Responsibility:

We, Suny (Xiamen) Biotechnology Co., Ltd. here with declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive *98/79/EC* of the European Parliament and of the Council on *In Vitro Diagnostic Medical Devices*. We agree to develop, implement and maintain a documented post-production monitoring process.

Supplementary Information (If Applicable):

We hereby declare that the product described above, to which this declaration of conformity refers to, is in conformity with the essential requirements of the following international standards:

EN ISO 13485:2016;	EN ISO 18113-1:2011;	EN 13612:2002;	EN ISO 15223-1:2016;
EN ISO 14971:2019;	EN ISO 18113-2:2011;	EN 13641:2002;	EN ISO 23640:2015;
EN 62366-1:2015;	EN ISO 18113-3:2011;	EN 13532:2002;	

Signature and Stamp:

Tieli Zhang

General Manager

For and on Behalf of M/s. Suny (Xiamen) Biotechnology Co., Ltd.

Place: Xiamen, China

Date : 2022.04.15

SunyBio

Suny (Xiamen) Biotechnology Co.,Ltd.

To whom it may concern,

We, Suny (Xiamen) Biotechnology Co.,Ltd,as the manufacturer of Rapid SARS-CoV-2&Flu A&Flu B Antigen Test (Colloidal Gold) ,here by declare that our test is effective for， but not limited to,the mutant strain and the following variants;SARS-CoV-2 of Alpha (B1.1.7), Beta (B.1.351), Gamma (P.1), Delta (B.1.617.2), Epsilon (B.1.427/B.1.429), Zeta (P.2), Eta (B.1.525), Theta (P.3), Iota (B.1.526), Kappa (B.1.617.1), Lambda (C.37), Mu(B.1.621), Delta plus (AY.4.2), Omicron(B.1.1.529) , Omicron(BA.5)， Omicron(BQ.1),Omicron(BQ.1.1),Omicron(XBB.1.5).

The aforementioned variants have several mutations in the spike protein and minimal mutations in the nucleocapsid protein.

There is no obvious difference when testing with different recombinant nucleocapsid protein antigens (Alpha, Beta, Gamma, Delta, Epsilon, Zeta, Eta, Theta, Iota, Kappa, Lambda, Mu and Delta plus), based on these different variants of SARS-CoV-2.

The theoretical analysis of the mutations in the nucleocapsid protein suggests no apparent interference for the Rapid SARS-CoV-2&Flu A&Flu B Antigen Test (Colloidal Gold) with detecting the Omicron variant of COVID-19(Includes Omicron BA.1 ,Omicron BA.2 Omicron BA.5, Omicron BQ.1， Omicron BQ1.1,Omicron(XBB.1.5)and all related variants).
We anticipate our test will be ableto detect these variants.

Sincerely

Suny (Xiamen) Biotechnology Co.,Ltd.