



## CE DECLARATION OF CONFORMITY

Distributor: JBM CAMPLLONG, S.L.U.

Address: CIM La Selva – Crta. Aeroport Km 1.6 Nave 2.2, 17185 Vilobí d’Onyar, Girona

CIF: B17419292

Product description: COVID-19 ANTIGEN TEST KIT

Factory item number: SL030101NST-1

JBM item number: 54118M

- Conformity with directive 98/79EC on in vitro medical devices

Signed:



Eduard Godoy

Purchasing department's manager

Girona, a 14th January de 2022



# CERTIFICATE

**EC Certificate No. 1434-IVDD-445/2021**

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

Polish Centre for Testing and Certification certifies  
that manufactured by:

**Anhui Deepblue Medical Technology Co., Ltd.**  
**4th Floor, D-1#Zone, Pearl Industrial Park, 106  
Innovation Avenue, High-Tech Development Zone,  
230088 Hefei, Anhui, China**

*in vitro* diagnostic medical devices  
for self-testing

## **COVID-19 (SARS-COV-2) Antigen Test Kit (Colloidal Gold)**

SL030101NST-1, SL030101NST-2, SL030101NST-3, SL030101NST-5, SL030101NST-6, SL030101NST-7, SL030101NST-8,  
SL030101NST-9, SL030101NST-10, SL030101NST-11, SL030101NST-12, SL030101NST-15, SL030101NST-16, SL030101NST-  
17, SL030101NST-18, SL030101NST-19, SL030101NST-20, SL030101NST-25

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 30.07.2021 to 27.05.2024

The date of issue of the Certificate: 30.07.2021

The date of the first issue of the Certificate: 22.07.2021



Issued under the Contract No. MD-96/2021  
Application No: 183a/2021  
Certificate bears the qualified signature.  
Warsaw, 30.07.2021  
Module A1

Anna  
Małgorzata  
Wyroba  
Vice-President  
Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.07.30  
10:31:11 +02'00'



www.dbluemedical.com

## DECLARATION OF CONFORMITY

MANUFACTURER: ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.  
4<sup>th</sup> Floor,D-1# Zone, Pearl Industrial Park, 106 Innovation Avenue,  
High-Tech Development Zone , 230088 Hefei, Anhui, People's  
Republic of China

EUROPEAN REPRESENTATIVE: Luxus Lebenswelt GmbH  
Kochstr. 1, 47877, Willich, Germany

PRODUCT: COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold)

Models: SEE ATTACHMENT

REF: SEE ATTACHMENT

CLASSIFICATION: SELF-TESTING

EDMA CODE: 15 70 90 90 00

CONFORMITY ASSESSMENT ROUTE: Following the procedure relating to the EC Declaration of Conformity set out in Annex III Article 6 of Directive 98/79/EC.

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

THE MANUFACTURER IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED: EN ISO 13485:2016  
EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:  
2002/AC:2002, EN ISO 23640:2015, EN 13641: 2002, EN ISO  
15223-1: 2016, EN 13975:2003, EN 13532:2002, EN ISO  
14971:2012.

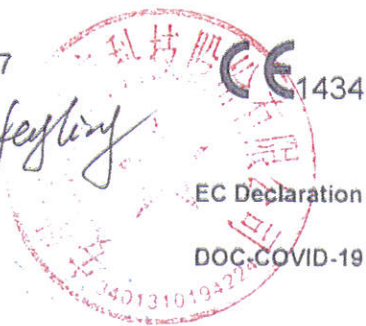
NOTIFIED BODY: Polish Center for Testing and Certification  
469 Puławska Street,02-844 Warsaw,Poland

(EN) CERTIFICATE(S): 1434-IVDD-445/2021

START OF CE-MARKING: 2021-07-30

PLACE, DATE OF ISSUE: HEFEI, 2021-10-27

SIGNATURE: CHEN FENGLING  
GENERAL MANAGER



EC Declaration of Conformity

DOC-COVID-19 Ag(P/1)



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## DECLARATION OF CONFORMITY ATTACHMENT

Specification	REF
1 piece per box	SL030101NST-1
2 pieces per box	SL030101NST-2
3 pieces per box	SL030101NST-3
5 pieces per box	SL030101NST-5
6 pieces per box	SL030101NST-6
7 pieces per box	SL030101NST-7
8 pieces per box	SL030101NST-8
9 pieces per box	SL030101NST-9
10 pieces per box	SL030101NST-10
11 pieces per box	SL030101NST-11
12 pieces per box	SL030101NST-12
15 pieces per box	SL030101NST-15
16 pieces per box	SL030101NST-16
17 pieces per box	SL030101NST-17
18 pieces per box	SL030101NST-18
19 pieces per box	SL030101NST-19
20 pieces per box	SL030101NST-20
25 pieces per box	SL030101NST-25





# Certificate

No. Q5 003706 0001 Rev. 01

**Holder of Certificate:** **ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.**  
4th Floor, D-1# Zone  
Pearl Industrial Park  
106 Innovation Avenue, High-Tech Development Zone  
230088 Hefei, Anhui  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of In Vitro Diagnostic Reagents by Colloidal Gold and Enzyme Chemical Reaction Method, Medical Ultrasonic Couplant, Acetowhite Solution, Epithelial Tissue Staining Solution, Rapid Test for Vaginitis(Polyamines) and Cell Preservation Solution**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 003706 0001 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 003706 0001 Rev. 01)

**Report No.:** SH21130301

**Valid from:** 2021-06-22  
**Valid until:** 2024-06-21

**Date,** 2021-06-16

Christoph Dicks  
Head of Certification/Notified Body

# Certificate

No. Q5 003706 0001 Rev. 01

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** ANHUI DEEPBLUE MEDICAL TECHNOLOGY CO.,LTD.  
4th Floor, D-1# Zone, Pearl Industrial Park, 106 Innovation  
Avenue, High-Tech Development Zone, 230088 Hefei, Anhui,  
PEOPLE'S REPUBLIC OF CHINA

See Scope of Certificate