CERTIFICATE

EC Certificate No. 1434-IVDD-484/2021

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) – Saliva

The list of medical devices covered by this certificate is provided in the annex 1

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 10.11.2021 to 27.05.2024

The date of issue of the Certificate: 10.11.2021

The date of the first issue of the Certificate: 10.11.2021

CE 1434

Issued under the Contract No. MD-113/2021
Application No: 230/2021
Certificate bears the qualified signature.
Warsaw, 10.11.2021
Module A1

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.11.10 16:15:24 +01'00'

Vice-President

POLISH CENTRE FOR TESTING AND CERTIFICATION 02-844 Warsaw, 469 Puławska Street, tel. +48 22 46 45 200, e-mail:pcbc@pcbc.gov.pl

ANNEX TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-484/2021

List of medical devices covered by the certificate:

DEEPBLUE, ShenLanTest, Highbluetest, NewBluetest, Quicklyblue

REF: SL030101SST-1, SL030101SST-2, SL030101SST-3, SL030101SST-4, SL030101SST-5, SL030101SST-6, SL030101SST-7, SL030101SST-8, SL030101SST-9, SL030101SST-10, SL030101SST-11, SL030101SST-12, SL030101SST-13, SL030101SST-14, SL030101SST-15, SL030101SST-16, SL030101SST-17, SL030101SST-18, SL030101SST-19, SL030101SST-20, SL030101SST-21, SL030101SST-22, SL030101SST-23, SL030101SST-24, SL030101SST-25

CE 1434

Issued under the Contract No. MD-113/2021
Application No: 230/2021
Certificate bears the qualified signature.
Warsaw, 10/11/2021

Anna Małgorzata Wyroba

Elektronicznie podpisany przez Anna Małgorzata Wyroba
Data: 2021.11.10 16:16:26 +01'00'

Vice-President

www.dbluemedical.com

DECLARATION OF CONFORMITY

MANUFACTURER:	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
EUROPEAN REPRESENTATIVE:	Luxus Lebenswelt GmbH Kochstr. 1, 47877, Willich, Germany
PRODUCT:	COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) -Saliva
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 Section 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-484/2021
START OF CE-MARKING:	2021-11-10
PLACE, DATE OF ISSUE:	HEFEI, 2021-11-12

CE 1434

SIGNATURE: **CHEN FENGLING**

GENERAL MANAGER

www.dbluemedical.com

DECLARATION OF CONFORMITY
ATTACHMENT

DEEPBLUE, ShenLanTest, Highbluetest, NewBluetest, Quicklyblue

Specification	REF
1 piece per box	SL030101SST-1
2 pieces per box	SL030101SST-2
3 pieces per box	SL030101SST-3
4 pieces per box	SL030101SST-4
5 pieces per box	SL030101SST-5
6 pieces per box	SL030101SST-6
7 pieces per box	SL030101SST-7
8 pieces per box	SL030101SST-8
9 pieces per box	SL030101SST-9
10 pieces per box	SL030101SST-10
11 pieces per box	SL030101SST-11
12 pieces per box	SL030101SST-12
13 pieces per box	SL030101SST-13
14 pieces per box	SL030101SST-14
15 pieces per box	SL030101SST-15
16 pieces per box	SL030101SST-16
17 pieces per box	SL030101SST-17
18 pieces per box	SL030101SST-18
19 pieces per box	SL030101SST-19
20 pieces per box	SL030101SST-20
21 pieces per box	SL030101SST-21
22 pieces per box	SL030101SST-22
23 pieces per box	SL030101SST-23
24 pieces per box	SL030101SST-24
25 pieces per box	SL030101SST-25

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

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:

TÜV SÜD EN ISO 13485 tuv-sud.com/ps-cert

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

Report No.: SH21130301

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

Date, 2021-06-16

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

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

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