



CERTIFICATE

EC Certificate No. 1434-IVDD-057/2022

**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 30.03.2022 to 27.05.2025

The date of issue of the Certificate: 30.03.2022

The date of the first issue of the Certificate: 10.11.2021



Issued under the Contract No. MD-113/2021
Application No: 230/2021
Certificate bears the qualified signature.
Warsaw, 30/03/2022
Module A1

Aleksandra Digitally signed
Kostrzewska by Aleksandra
Kostrzewska
President



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-057/2022

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



Issued under the Contract No. MD-113/2021
Application No: 230/2021
Certificate bears the qualified signature.
Warsaw, 30/03/2022

Aleksandra Kostrzewa
Digitally signed
by Aleksandra
Kostrzewa
President



POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

BM.433.0230.2021/KW/MV/2024/0490

Warsaw, 29.08.2024

Fenglin Chen
Anhui Deepblue Medical Technology, No. 777
Jimingshan Road, High-Tech Development
Zone, 230088, Hefei, Anhui, PEOPLE'S
REPUBLIC OF CHINA.

Dear Fengling Chen,

Basing on the Contract No. MD-113/2021 of 27.05.2021, following the submission of a manufacturer change notification form on 15.08.2024 for in vitro diagnostic medical device for self-testing: COVID-19 (SARS-CoV-2) Antigen Test Kit (Colloidal Gold) – Saliva regarding changes of the address of the company's registered office, addition of supplier of swab and device shelf-life extension from 24 months to 36 months, we inform you that the documentation evaluation process has been completed.

Implementation of the change does not represent a significant change in design or intended purpose under IVDR 2017/746 Article 110(3) and the related IVDD Certificate no. 1434-IVDD-057/2022 issued 30.03.2021 remains valid.

Please also remember that any significant changes to the design, instruction for use, labels must be report to PCBC.

Yours Sincerely,

Deputy Head of Medical Device Certification Department



CERTIFICATION.
TESTING.
TRAINING.

Polish Centre for Testing and Certification
469 Puławska Street, 02-844 Warsaw
Tel.: +48 22 46 45 200
pcbc@pcbc.gov.pl

NIP 9512063356
REGON 015276609
KRS 0000144813

Initial capital
16.000.000 PLN
(fully paid)

Bank account: Bank Pekao S.A.
PL 90 1240 6003 1111 0000 4946 7594

The company registered in the District Court for
the Capital City of Warsaw, XIIIth Commercial Division