

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

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Issued under the Contract No. MD-113/2021 Application No: 230/2021 Certificate bears the qualified signature. Warsaw, 10.11.2021 Module A1 Anna Elektron podpisa Anna Małgorzata Wyroba Data: 20 16:15:24

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

Vice-President



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



Issued under the Contract No. MD-113/2021 Application No: 230/2021 Certificate bears the qualified signature. Warsaw, 10/11/2021 Anna Elektronicznie podpisany przez Anna Małgorzata Wyroba Data: 2021,11.10 16:16:26 +01'00' Vice-President