

#### 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

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



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President