



# CERTIFICATE



**EC Certificate No. 1434-IVDD-444/2021**

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

Polish Centre for Testing and Certification certifies  
that manufactured by:

**Wuhan EasyDiagnosis Biomedicine Co., Ltd.  
Room 3 & 4, 2nd Floor, Bldg 25, Phase 3.1,  
Wuhan Optics Valley International Biopharmaceutical Enterprise Accelerator,  
No. 388, Gaoxin 2nd Road, East Lake Hi-Tech Development Zone, Wuhan,  
430074, Hubei, P.R. China**

*in vitro* diagnostic medical devices  
for self-testing

## **COVID-19(SARS-CoV-2) Antigen Test Kit**

**REF: W-AgH-01S, W-AgH-01, W-AgH-05S, W-AgH-05, W-AgH-07, W-AgH-07S, W-AgH-08S, W-AgH-08, W-AgH-10S, W-AgH-10, W-AgH-15S, W-AgH-15, W-AgH-20S, W-AgH-20, W-AgH-25S, W-AgH-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 28.07.2021 to 27.05.2024

The date of issue of the Certificate: 28.07.2021

The date of the first issue of the Certificate: 13.07.2021



Issued under the Contract No. MD-81/2021  
Application No: 157a/2021  
Certificate bears the qualified signature.  
Warsaw, 28/07/2021  
Module A1

Anna  
Małgorzata  
Wyroba  
Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.07.27  
14:48:51 +02'00'  
**Vice-President  
Mgr Anna Wyroba**