CERTIFICATE

EC Certificate No. 1434-IVDD-485/2021

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

武汉明德生物科技股份有限公司
2021-11-10
Wuhan EasyDiagnosis Biomedicine Co., Ltd

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-02S, W-AgH-02, 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 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-81/2021
Application No: 157b/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 16:17:43 +01'00'
Vice-President

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