CERTIFICATE

EC Certificate No. 1434-IVDD-231/2022

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

Polish Centre for Testing and Certification certifies
that manufactured by:

Nantong Egens Biotechnology Co., Ltd.
Building 15, Building 12 (west), No. 1692 Xinghu Avenue, Nantong Economy &Technology Development Zone, 226010 Nantong, PEOPLE'S REPUBLIC OF CHINA.

in vitro diagnostic medical devices
for self-testing

SARS-CoV-2 Antigen Rapid Test Kit

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 25.05.2022 to 27.05.2025

The date of issue of the Certificate: 25.05.2022

The date of the first issue of the Certificate: 25.05.2022

CE 1434

Issued under the Contract No. MD-171/2021
Application No: 332/2021
Certificate bears the qualified signature.
Warsaw, 25/05/2022
Module A1

Tomasz Koeber
Elektronicznie podpisany przez Tomasz Artur Koeber
Data: 2022.05.25 09:29:01 +02'00'

Director
Medical Device Certification Department

ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No. 1434-IVDD-231/2022

List of medical devices covered by the certificate:

1 Test/ Box – REF. D0101TE

5 Tests/ Box – REF. D0501EE

25 Tests/ Box – REF. D2501AT

CE 1434

Issued under the Contract No. MD-171/2021
Application No: 332/2021
Certificate bears the qualified signature.
Warsaw, 24/05/2022

Tomasz Koeber

Elektronicznie podpisany przez Tomasz Artur Koeber
Data: 2022.05.24 19:00:58 +02'00'

Director
Medical Device
Certification Department