Declaration of Conformity

Manufacturer:	**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**
European Representative:	**Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany**
Product Name:	**SARS-CoV-2 Antigen Rapid Test Kit**
Model:	**1 Test/ Box - REF. D0101TE 5 Tests/ Box - REF. D0501EE 25 Tests/ Box - REF. D2501AT**

Classification (98/79/EC IVDD, Annex II): **Self-testing**

Conformity Assessment Route:**Annex III, section 6**

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards under our solo responsibility. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:
Medical Device Directive: COUNCIL DIRECTIVE 98/79/EC of 27 October 1998 concerning In Vitro Diagnostic Medical Devices (IVDD 98/79/EC)

Notified Body:	**POLISH CENTRE FOR TESTING AND CERTIFICATION 469 Puławska Street, 02-844 Warsaw www.pcbc.gov.pl**
NB Identification number:	**1434**
(EC) Certificate(s):	**1434-IVDD-231/2022**
Expire date of the Certificate:	**2025.05.27**
Start of CE Marking:	**2022.6**
Place. Date of Issue:	**Nantong 2022.5.25**
Signature:	Su Ling Ling
Name:	**Su Lingling**
Position:	**Management Representative**