



## 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**

Model: Strip, Cassette

Classification (IVDD, Annex II): Others

Conformity Assessment Route: **Annex III**

We here with declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives 98/79/EC and Standards EN ISO13485:2016, under our sole responsibility.

All supporting documentations are retained under the premises of the manufacturer.

Signature: 

Name: Su Lingling

Position: Management Representative

Date: August 27,2020



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