



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: Su Lingling 苏玲玲

Name: Su Lingling

Position: Management Representative

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EGENS/CE-01, A/1

Date: August 27,2020

