## POCT EGENS DIAGNOSTICS

## Nantong Egens Biotechnology Co., Ltd

Building 15 & building 12(west) No.1692 xinghu avenue, Nantong Economy & Technology Dev. Zone, Jiangsu Province, 226010, P.R. China

## **DECLARATION OF CONFORMITY**

**Manufacturer**: NANTONG EGENS BIOTECHNOLOGY Co. Ltd. Building 15, Building 12 (west), No. 1692 Xinghu Avenue, Namtong Exonomy&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: LINKCARE BIOSCREENING
Model: SARS-CoV-2 ANTIGEN KIT (SALIVA)

Classification (IVDD, Annex II): Others

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

All the supporting documentations are retained under the premises of the manufacturer and will be available for the competent national authorities upon request.

Signature:

Name: Wang Min

Position: Directo

Date:2020/12