CE 1011

DECLARATION OF CONFORMITY

Manufacturer: Joinstar Biomedical Technology Co.,Ltd.

Address: 10th Floor, Administration Building, NO.519, XingGuo RD., Yuhang Economic and Technological Development Zone,Hangzhou, Zhejiang,China,311188

EC Representative's Name: Lotus NL B.V.

EC Representative's Address: Koningin Julianaplein 10,1e Verd, 2595AA,The Hague,Netherlands.

Declares, that the product

Product Name and Model:

COVID-19 Antigen Rapid Test (Colloidal Gold)anterior nasal-self testing device

FGCOVG7100 1 test /kit; FGCOVG7200 5 tests /kit;

FGCOVG7300 10 tests/kit; FGCOVG7400 25 tests/kit

as described above are in conformity with the requirements as defined in IVDD98/79/EC Annex III（6）.

Additional information:

Conformity assessment route: Directive 98/79/EC, Annex III（6）

Classification: self testing

NEOEMKI National Medical Device Conformity Assessment and Certification LLC

H-1097 Budapest, Albert Florian ut 3 / A

Registry number of the report on the examination of the design dossier: NE/195/2021

Validity of the certificate: from 10/19/2021 to 05/26/2024

Applied Standards:

EN ISO 13485:2016; EN ISO 14971:2012; EN ISO 23640:2015; EN ISO 17511:2003; EN 13612:2002; EN ISO 18113-1:2011; EN ISO 18113-4:2011; EN ISO 15223-1:2016; EN 62366-1:2015; EN 13641:2002; EN 13532:2002

I, the undersigned, hereby declare that the medical devices specified above conform with the Directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements.

2021-11-16

Zhong WANG: Date Signed

Management Representative

Joinstar Biomedical Technology Co.,Ltd.

Version:0.0