

EC DESIGN-EXAMINATION CERTIFICATE
Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex III (6)

No. 7-038-306-2110

The NEOEMKI National Medical Device Conformity Assessment and Certification LLC.
certifies that the following manufacturer's

Joinstar Biomedical Technology Co. Ltd.
NO. 519 XingGuo RD, Yuhang Economic and Technological Development Zone
Hangzhou
China

with authorized representative in EU:

Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd
2595AA The Hague, Netherlands

product's **COVID-19 Antigen Rapid Test (Colloidal Gold) anterior nasal - self testing device**
following model's

FGCOVG7100 1 test / kit
FGCOVG7200 5 tests / kit
FGCOVG7300 10 tests / kit
FGCOVG7400 25 tests / kit

design dossier conforms to the requirements of Directive 98/79/EC on in vitro diagnostic
medical devices.

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

This certificate is valid until: **2024-05-26**

Issued by NEOEMKI LLC. as a Notified Body with identification number 1011.

Budapest, 2021-10-19


László Imre
Managing Director



EMKI 2785

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.
neoEMKI National Medical Device Conformity Assessment and Certification LLC.

H-1097 Budapest, Albert Flórián út 3/A, tel: +36 20 268 75 95, e-mail: cert@emki.hu
www.emki.hu

NEOEMKI