

# 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.  
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