

Declaration of Conformity

Manufacturer:

Hangzhou Singclean Medical Products Co., Ltd.

No. 125 (E), 10th Street, Hangzhou Qiantang New Area, Zhejiang, China 310018

European Representative:

SUNGO Europe B.V.

Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

Product: COVID-19 Test Kit (Colloidal Gold Method)

Classification: Self-testing

Conformity assessment Route: Annex III, section 6, IVDD 98/79/EC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 98/79/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Standards applied:

EN ISO14971:2019

EN ISO15223-1:2016

EN ISO23640:2015

EN ISO18113-1:2011

EN ISO 18113-4: 2011

EN 13612:2002

EN 13641:2002

ISO 20916:2019

EN ISO 13485:2016

EN 62366-1:2015+A1:2020

EN 13975:2003

EN ISO 17511:2003

EN 13532:2002

Notified Body: Polish Centre for Testing and Certification (NB. No.: 1434)

469 Puławska Street, 02-844 Warsaw

EC Certificate: 1434-IVDD-459/2021

Valid date: 26.05.2025

Signature: _____



Name: Sun Weiqing

Position: General Manager

Place, Date of Issue: Hangzhou, Zhejiang, China 2024-04-17