CE

DECLARATION OF CONFORMITY

Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer:	Shenzhen Huian Biosci Technology Co., Ltd.
Address:	3F/4F Blk3, Hangcheng Hedong Industrial Park, Xixiang, Baoan District, Shenzhen, Guangdong, P.R.China
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name:	SARS-CoV-2 Antigen Test Kit (Colloidal Gold)
Specification:	REF ST-001: 1T/KIT, REF ST-002: 2T/KIT, REF ST-005: 5T/KIT, REF ST-007: 7T/KIT, REF ST-020: 20T/KIT, REF ST-025: 25T/KIT
Classification:	Self-Test
Conformity Assessment Procedure:	Annex III including Section 6

We here with declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011

Notified Body: CeCert Sp. Z o. o.

Identification Number: CE2934

Start Of CE Marking: MAY 24, 2022

Signature:

Name/ Position: Gao Xiang / GM

Date: 2022. 5. 24

Place: Shenzhen / China