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 203-001: 1T/Kit, REF 203-020: 20T/Kit
Classification:	Others (IVDD)
Conformity Assessment Procedure:	Annex III of In Vitro Diagnostic Directive (98/79/EC)

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 14971:2012 EN ISO 18113-2:2011

EN ISO 18113-1:2011

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.

Signature:

Name/ Position: Gao Xiang / GM

Sungo global service

Authorized Signature (S)

Date: 2020.09.18

Place: Shenzhen / China