



DECLARATION OF CONFORMITY

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

Manufacturer: Hangzhou Singclean Medical Products Co., Ltd.
Address: No. 125 (E), 10th Street, Hangzhou Economic and Technological Development Zone, Zhejiang, China 310018

EC Representative: SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

Product Category: See Annex

Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith 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 15223-1:2016	EN ISO 23640:2015
EN ISO 18113-1:2011	EN 13612:2002	EN 13641:2002
EN ISO 18113-2:2011	EN ISO 13485:2016+A11:2021	ISO 20916:2019

Signature: 

Date: 2022-04-22

Name/ Position: Sun Weiqing/ General Manager

Place: Hangzhou/ China

ANNEX

Product Name	Model	Picture
COVID-19 & FLU A/B Antigen Test Kit (Colloidal Gold)	1 test/box	
	20 tests/box	