



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: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Category: See Annex
COVID-19 Antigen Test Kit (Colloidal Gold)
Nasopharyngeal Swab
COVID-19 Antigen Test Kit (Colloidal Gold)
Saliva Swab

Classification: Others (IVDD)

Conformity

Assessment Annex III of In Vitro Diagnostic Directive (98/79/EC)

Procedure:

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	ISO 20916:2019
EN 62366-1:2015+A1:2020	EN 13975:2003	EN ISO 17511:2003

Signature: 
Name/ Position: Sun Weiqing/ GM

Date: 2021.07.28

Place: Hangzhou/ China

ANNEX

Product Name	Model	Picture
COVID-19 Antigen Test Kit (Colloidal Gold)	Nasopharyngeal Swab	
COVID-19 Antigen Test Kit (Colloidal Gold)	Saliva Swab	