



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

Classification: Others (IVDD)

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

On behalf of SUNGO Europe office, EU REP of the company who issues this document.



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 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

Signature: 
 Name/Position: Sun Weiqing/ GM


Date: 2020.11.10

Place: Hangzhou, China
On behalf of SUNGO Europe office, EU REP of the company who issues this document.


 Authorized Signature (S)

ANNEX

Product Name	Model	Picture
COVID-19 Antigen Test Kit (Colloidal Gold)	/	

I confirmed we are
this document.



Authorized Signature (S)

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


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