



# 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)

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

**Signature:**   
**Name/ Position:** Sun Weidong/ GM

**Date:** 2020. 11. 20  
**Place:** Hangzhou/ China

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

## ANNEX

Product Name	Model	Picture
COVID-19 & FLU A/B Antigen Test Kit (Colloidal Gold)	/	
FLU A/B Antigen Test Kit (Colloidal Gold)	/	



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**Sungo**  
gold service

*Authorized Signature (S)*