



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, I confirm that I am the 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 |


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Signature:  Date: 2020.11.10

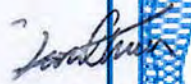
Name/Position: Sun Weiqing/ GM Place: Hangzhou, China
 On behalf of SUNGO Europe office, I confirm that I am the EU REP of the company who issues this document.



ANNEX

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

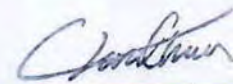
I confirmed we are
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Authorized Signature (S)

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

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