



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

Signature:   
Name/ Position: Sun Weiqing/ GM

Date: 2021.09.26  
Place: Hangzhou/ China

# ANNEX

Product Name	Model	Picture
COVID-19 Antigen Test Kit (Colloidal Gold)	Nasopharyngeal Swab	 <p>The image shows the packaging for the Singleclean COVID-19 Antigen Test Kit (Colloidal Gold) for nasopharyngeal swabs. It includes a box with the product name and 'IVD' (In Vitro Diagnostic) label, a blister pack of swabs, and a test card with a red window for results.</p>
	Saliva Swab	 <p>The image shows the packaging for the Singleclean COVID-19 Antigen Test Kit (Colloidal Gold) for saliva swabs. It includes a box with the product name and 'IVD' label, a blister pack of swabs, and a test card with a red window for results. A red star-shaped stamp is overlaid on the left side of the image.</p>