

**CE EC Declaration of Conformity CE**

**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

**European Representative:** SUNGO Europe B.V.  
Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

**Product Name:** COVID-19 IgG/IgM Test kit (Colloidal Gold Method)  
COVID-19 Test kit (Colloidal Gold Method)  
COVID-19 IgG Test kit (Colloidal Gold Method)  
COVID-19 IgM Test kit (Colloidal Gold Method)

**Classification:** Others

We confirm our product can meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79EC) and the following harmonized standards.

EN ISO 14971:2012	EN 15223-1:2016	EN ISO 23640:2015
EN ISO 18113-1:2011	EN 13612:2002/AC:2002	EN 13641:2002
EN ISO 18113-2:2011	EN ISO 13485:2016	

Hangzhou . March . 06 . 2020  
Place and Date

Wesley Sun . General Manager  
Signature and Position  
Signed for and on behalf of the Manufacturer