



EC Declaration of Conformity



Regarding In Vitro Diagnostic Directive (98/79/EC)

Manufacturer: Hangzhou Singlean 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 (98/79/EC) 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

Distributor pro ČR:
Servatech s.r.o.
W: www.servatech.cz
E: obchod@servatech.cz
T: +420 277 279 330