



EC 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

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

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

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