

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 Qiantang Area, Zhejiang, China 310018

EC Representative: SUNGO Europe B.V.

Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

Product: Respiratory Multiple Rapid Test Kit (Immunochromatography)

Classification: IVDD Others

Conformity Assessment Route: Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the manufacturer is responsible for the EU declaration of conformity. We confirm the product mentioned above can meet the requirement of In Vitro Diagnostic Medical Devices Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2019+A11:2021 EN ISO 15223-1:2021 EN ISO 23640:2015


EN ISO 18113-1:2011 EN 13612:2002 EN 13641:2002

EN ISO 18113-2:2011 EN ISO 13485:2016+ A11:2021 ISO 20916:2019

Place of issue: Hangzhou, China

Name: Weiqing Sun on behalf of Hangzhou Singclean Medical Products Co., Ltd.

Position: General Manager

Signature:  Date: 2024.05.21