CE

DECLARATION OF CONFORMITY

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

Manufacturer:	Shenzhen Homed Medical Device Co., Ltd.
Address:	3rd Floor, Block F, Longquan Industrial Zone, Huarong Road, Dalang Street, Longhua New District, Shenzhen 518109, People's Republic of China
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name:	COVID-19 Nucleocapsid Antigen Test Kit (Colloidal Gold)
Model:	2019N1
Classification:	Others (IVDD)
Conformity Assessment Procedure:	Annex III of In Vitro Diagnostic Directive (98/79/EC)

We here with 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 18113-1:2011 EN ISO 18113-2:2011

EN 13612:2002+AC:2002 EN ISO 23640:2015 EN 13641:2002

[redacted]

5.1.2e

Date: 2021/3/30

Place: Shenzhen / China