CE

DECLARATION OF CONFORMITY

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

Manufacturer:	Xiamen Hopegen Medical Technology Co., Ltd.
Address:	Room 905, 253 Duiying Nan Road, Houxi Town, Jimei District, Xiamen, Fujian, China
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Catalogue number:	XJ-ZC-411, XJ-ZC-412, XJ-ZC-413, XJ-ZC-414
Product Name:	COVID-19 Antigen Rapid Test Kit (Colloidal Gold)
Specification:	1 Test/kit, 2 Tests/kit, 5 Tests/kit, 25 Tests/kit
Classification:	Self-Test
Conformity Assessment Procedure:	Annex III including Section 6

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

EN ISO 20417: 2021

Notified Body: CeCert Sp. Z o. o.

Identification Number: CE2934

Start Of CE Marking: February 14, 2022

Signature: Wu Feng

Position: General Manager

Date: February 14, 2022

Place: Xiamen / China