CE

DECLARATION OF CONFORMITY

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

Manufacturer:	Hangzhou Laihe Biotech Co.,Ltd.
Address:	1st Floor, Room 505-512, 5th Floor, No.2B Building, No.688 Bin'an Road, Changhe Jiedao, Binjiang District, Hangzhou, Zhejiang, People's Republic of China
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name:	Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)
Specification:	1/5/25/40 Tests/Box
Classification:	Others (IVDD)
Conformity Assessment Procedure:	Annex III of In Vitro Diagnostic Directive (98/79/EC)

We herewith declare that the above-mentioned products meet the requirements of In Vitro Diagnostic Directive (98/79/EC) and the following harmonized standards.

EN ISO 14971:2012	EN ISO 18113-2:2011	EN ISO 23640:2015
EN ISO 18113-1:2011	EN 13612:2002+AC:2002	EN 13641:2002

Signature: 5.1.2e

Name/ Position: 5.1.2e

Date: Jan 21, 2021

Place: Hangzhou/ China

On behalf of SUNGO Europe office. I confirm/ we are EU REP of the company who issue this document.

Sungo

5.1.2e