CE

DECLARATION OF CONFORMITY

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

Manufacturer:	Hangzhou Laihe Biotech Co.,Ltd.
Address:	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
Notified Body:	TÜV Rheinland LGA Products GmbH
Address:	Tillystraße 2 - 90431 Nürnberg
Product Name:	Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold) for self-testing SARS-Cov-2 Antigen Rapid Tests for self-testing
Specification:	1/2/5/7/25 Tests/Box
Classification:	Self-testing (IVDD)
Conformity Assessment Procedure:	Annex IV of In Vitro Diagnostic Directive (98/79/EC) and technique documents reviewed by NB

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 14971:2019	EN ISO 18113-1:2011	EN ISO 18113-4:2011
EN 13612:2002	EN ISO 23640:2015	EN 13641:2002
EN 13532:2002	EN IEC 62366-1:2015	EN ISO 15223-1:2016

Signature: _____

Name/ Position: Yun Ouyang / GM

Date: August 20, 2021

Place: Hangzhou/China