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: 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 15223-1:2016

EN ISO 18113-1:2011 EN ISO 18113-3:2011

Signature:

Name/ Position: Yun Ouyang / GM

Date: Sept. 7 2020

Place: Zhejiang / China

Hangzhou Laihe Biotech Co.,Ltd.

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

Sungo global service

Authorized Signature (S)