CE

DECLARATION OF CONFORMITY

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

Manufacturer:	Wuhan Life Origin Biotech Joint Stock Co., Ltd
Address:	Floor 1st, 2nd and 3rd, Wuhan Hi-Tech Medical Device Park B11,No.818 Gaoxin Avenue, Donghu Hi-Tech Development Zone, Wuhan, Hubei Province, P.R. China
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name:	SARS-CoV-2 IgM/IgG Antibody Assay Kit (Immunochromatography)
Specification:	1 test/ kit ,25 tests/kit, 50 tests/kit, 100 tests/kit
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 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 13485:2016
EN ISO 15223-1:2016 EN 62366-1:2015 EN 13612:2002 EN ISO 23640:2015 EN ISO 17511:2003
EN 13641:2002 EN 13975:2003

Signature: Hua Quangao

Name/ Position: Chairman

Date: Mar. 22. 2021

Place: Wuhan, Hubei Province, P.R. China

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)