CE

# DECLARATION OF CONFORMITY

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

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|---|---|
| **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:** | COVID-19 Antigen Rapid Test Kit ( Saliva) |
| **Specification:** | 1test/kit,5tests/kit,7tests/kit,10tests/kit,25tests/kit,50tests/kit, 100tests/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

*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)*

Date: Mar. 22. 2021

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