



DECLARATION OF CONFORMITY

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

Manufacturer: Xiamen Zhongsheng Langjie Biotechnology Co.,Ltd
Address: 2012 Wengjiao West Road,Xinyang Street,Haicang District,Xiamen

EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: COVID-19 Antigen Test Cassette(hypersensitive colloidal gold)
Specification: One test per bag for one person, 6 tests/kit

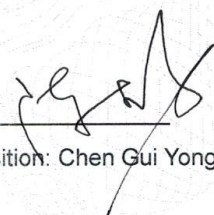
Classification: Others (IVDD)
Conformity Assessment Procedure: Annex III of In Vitro Diagnostic Directive (98/79/EC)

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 14971:2012

EN ISO 18113-2:2011

EN ISO 18113-1:2011

Signature: 

Name/ Position: Chen Gui Yong/ GM

Date: 2020.8.3

Place: xiamen/ China



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





Authorized Signature (S)