CE

DECLARATION OF CONFORMITY

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

Manufacturer: New Gene (Hangzhou) Bioengineering Co., Ltd.

Address: Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street, Binjiang District, Hangzhou City, Zhejiang Province, P. R. China

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: **COVID-19 Antigen Detection Kit**

Product Code: **COVID-19-NG08**

Specification: 25Tests/Box 1Test/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 23640-2015	EN 13640:2002
EN 980:2016	EN 13641:2002
EN ISO 14971:2019	EN ISO 18113-1 2011
EN 13612:2002	EN ISO 18113-4 2011

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

Sungo global service

Signature: Mingfu Li

Name/ Position: Mingfu Li / General Manager

Date: 29/09/2020

Place: Hangzhou, Zhejiang, China

Authorized Signature (S)