



## 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  
**EC Certificate No.:** 1434-IVDD-449/2021

**Product Name:** COVID-19 Antigen Detection Kit – Nasal Swab  
**Specification:** 1Test/Box, 5Tests/Box, 25Tests/Box  
**Classification:** Self Test (IVDD)  
**Conformity Assessment Procedure:** Annex III (Section 6) to 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 13612:2002	EN 13641:2002
EN ISO 14971:2019	EN ISO 18113-1 2011

Signature: 

Name/ Position: Mingfu Li / General Manager

Date: 11/08/2021

Place: Hangzhou, Zhejiang, China

