



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-476/2021

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: 01/12/2021
Place: Hangzhou, Zhejiang, China

