



Self-test Approval of EU

CERTIFICATE

EC Certificate No. 1434-IVDD-476/2021

EC Design-examination

Directive 98/79/EC concerning

***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

New Gene (Hangzhou) Bioengineering Co., Ltd.
Room 1606, Floor 16, Building 5, 688 Bin'an Road, Changhe Street,
Binjiang District, Hangzhou City, Zhejiang Province,
P. R. China

**in vitro diagnostic medical devices
for self-testing**

The list of medical devices covered by this certificate is provided in the annex I

in terms of design documentation, comply with requirements
of Annex III (Section 6) to Directive 98/79/EC (as amended)
implemented into Polish law,

as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 01.12.2021 to 27.05.2024

The date of issue of the Certificate: 01.12.2021

The date of the first issue of the Certificate: 11.08.2021



Issued under the Contract No. MD-116/2021
Application No: 381/2021
Certificate bears the qualified signature.
Warsaw, 01.12.2021
Module A1

Anna
Małgorzata
Wyroba

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.12.01
17:43:33 +01'00'
Vice-President



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

