



Self-test Approval of EU

# CERTIFICATE

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

**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

## COVID-19 Antigen Detection Kit - Nasal Swab

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 11.08.2021 to 27.05.2024

The date of issue of the Certificate: 11.08.2021

The date of the first issue of the Certificate: 11.08.2021



Issued under the Contract No. MD-116  
Application No: 239/2021  
Certificate bears the qualified signature.  
Warsaw, 11.08.2021  
Module A1

  
Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.08.11  
09:14:18 +02'00'  
Vice-President