



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

Vice-President