



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