



# CERTIFICATE

**EC Certificate No. 1434-IVDD-519/2021**

**EC Design-examination**

**Directive 98/79/EC concerning  
*in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies  
that manufactured by:

**SHENZHEN YHLO BIOTECH CO., LTD.**

**Building 1, YHLO Biopark, Baolong 2nd Road, Baolong  
Subdistrict, Longgang District, 518116 Shenzhen, PEOPLE'S  
REPUBLIC OF 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 16.12.2021 to 27.05.2024

The date of issue of the Certificate: 16.12.2021

The date of the first issue of the Certificate: 16.12.2021



Issued under the Contract No. MD-146/2021

Application No: 556/2021

Certificate bears the qualified signature.

Warsaw, 16.12.2021

Module A1

FBM-30-E\_10

**Director  
Medical Device Certification  
Department**

# **ANNEX 1 TO THE CERTIFICATE VALID ONLY WITH CERTIFICATE**

**No 1434-IVDD-519/2021**

**List of medical devices covered by the certificate:**

Product	REF number	variant
GLINE-2019-nCoV Ag	G86256	1 test/kit
GLINE-2019-nCoV Ag	G86257	5 tests/kit
GLINE-2019-nCoV Ag	G86278	7 tests/kit
GLINE-2019-nCoV Ag	G86279	10 tests/kit
GLINE-2019-nCoV Ag	G86280	15 tests/kit
GLINE-2019-nCoV Ag	G86273	20 tests/kit
GLINE-2019-nCoV Ag	G86281	25 tests/kit



Director

Medical Device Certification Department

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Application No: [556/2021](#)  
Certificate bears the qualified signature.  
Warsaw, [16.12.2021](#)