



# CERTIFICATE

**EC Certificate No. 1434-IVDD-447/2021**

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

Polish Centre for Testing and Certification certifies  
that manufactured by:

**GETEIN Biotech, Inc.**

**Nanjing, ul. Bofu Road, Luhe District 9, China**

*in vitro* diagnostic medical devices  
for self-testing

**One Step Test for SARS-CoV-2 Antigen (Colloidal Gold)**

*Ref. codes: CG20615, CG206152, CG206153, CG206155, CG206156, CG206157, CG206158, CG206159,  
CG2061510, CG2061512, CG2061515, CG2061520, CG2061525*

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 30.07.2021 to 27.05.2024

The date of issue of the Certificate: 30.07.2021

The date of the first issue of the Certificate: 30.07.2021



Issued under the Contract No. [MD-66/2021](#)

Application No: [142/2021](#)

Certificate bears the qualified signature.

Warsaw, 30.07.2021

Module [A1](#)

**Vice-President**