



# CERTIFICATE

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**EC Certificate No. 1434-IVDD-463/2021**

**EC Design-examination**

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

Polish Centre for Testing and Certification certifies  
that manufactured by:

**Nanjing Vazyme Medical Technology Co., Ltd**  
**Floor 1-3, Building C2, Red Maple Park of Technological  
Industry, Kechuang Road, Economy & Technology Development  
Zone, Nanjing, China.**

in vitro diagnostic medical devices  
for self-testing

**Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)  
Antigen Detection Kit (Colloidal Gold-Based)**

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 30.09.2021 to 27.05.2024

The date of issue of the Certificate: 30.09.2021

The date of the first issue of the Certificate: 30.09.2021



Issued under the Contract No. MD-56/2021  
Application No: 563/2021  
Certificate bears the qualified signature.  
Warsaw, 30.09.2021  
Module A1  
FBM-30-E\_10

**Vice-President**