



CERTIFICATE

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

Anna
Małgorzata
Wyroba

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.10.01
09:32:52 +02'00'
Vice-President