



# CERTIFICATE

**EC Certificate No. 1434-IVDD-017/2022**

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

Polish Centre for Testing and Certification certifies  
that manufactured by:

**Hangzhou Clongene Biotech Co., Ltd.  
No.1 Yichuang Road, Yuhang Sub-district, Yuhang District,  
311121 Hangzhou, China.**

in vitro diagnostic medical devices  
for self-testing

## **COVID-19 Antigen Rapid Test**

*The list of medical devices covered by this certificate is provided in the annex 1*

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 11.02.2022 to 27.05.2025

The date of issue of the Certificate: 11.02.2022

The date of the first issue of the Certificate: 11.02.2022



Issued under the Contract No. MD-187/2021  
Application No: 387/2021  
Certificate bears the qualified signature.  
Warsaw, 11.02.2022  
Module A1

President

# ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-IVDD-017/2022**

*List of medical devices covered by the certificate:*

*Reference numbers: ISCOVu002-A001; ISCOVu002-A005;  
ISCOVu002-A025; ISCOVu002-B001; ISCOVu002-B005;  
ISCOVu002-B025.*



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Application No: 387/2021  
Certificate bears the qualified signature.  
Warsaw, 11.02.2022

President