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

CE 1434

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.

CE 1434

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

President