

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