

EC Certificate No. 1434-IVDD-429/2021

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

Polish Centre for Testing and Certification certifies that manufactured by:

Hangzhou AllTest Biotech Co., Ltd,

#550, Yinhai Street Hangzhou Economic & Technological Development Area, Hangzhou, 310018, P.R. China

> in vitro diagnostic medical devices for self-testing

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 07.06.2021 to 27.05.2024

The date of issue of the Certificate: 07.06.2021 The date of the first issue of the Certificate: 28.05.2021

Issued under the Contract No. MD-136/2020 Application No: 333/2020a Certificate bears the qualified signature. Warsaw, 07.06.2021 Module A1

Anna Małgorzata Małgorzata Wyroba Wyroba

Elektronicznie podpisany przez Anna Data: 2021.06.08 16:53:30 +02'00'

Vice-President



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE No 1434-IVDD-429/2021

List of medical devices covered by the certificate:

| Product | REF Number | Brand |
|--|------------|-------------------|
| COVID-19 Antigen Rapid Test (Oral Fluid) | ICOV-802H | ALLTEST |
| COVID-19 Antigen Rapid Test (Oral Fluid) | ICOV-802H | Beright |
| COVID-19 Antigen Rapid Test (Oral Fluid) | ICOV-802H | JusChek |
| COVID-19 Antigen Rapid Test (Oral Fluid) | ICOV-802H | Lambra |
| COVID-19 Antigen Rapid Test (Oral Fluid) | ICOV-802H | SCREEN CHECK TEST |
| COVID-19 Antigen Rapid Test (Oral Fluid) | ICOV-802H | Rapid Response |



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