



# CERTIFICATE

**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  
Wyroba  
Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
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    |
| COVID-19 Antigen Rapid Test (Oral Fluid)           | ICOV-802H  | AllChek           |
| COVID-19 Antigen Rapid Test (Oral Fluid)           | ICOV-802H  | RYPO              |
| Mila Covid-19 Szybki Test Antygenowy Ze Śliny      | ICOV-802H  | Mila              |
| Test Rapido per l'Antigene COVID-19 (FluidO Orale) | ICOV-802H  | Novasalus         |



Issued under the Contract No. **MD-136/2021**  
Application No: **333/2020a**  
Certificate bears the qualified signature.  
Warsaw, 06/10/2021

Anna  
Małgorzata  
Wyroba  
Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.10.06  
10:09:19 +02'00'  
**Vice-President**