

EC Certificate No. 1434-IVDD-036/2022

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

Polish Centre for Testing and Certification certifies that manufactured by:

Hangzhou 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

COVID-19 Antigen Rapid Test (Oral Fluid)

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 16.03.2022 to 27.05.2025

The date of issue of the Certificate: 16.03.2022

The date of the first issue of the Certificate: 28.05.2021

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Issued under the Contract No. MD-136/2020 Application No: 333/2020 Certificate bears the authorized person signature. Warsaw, 16/03/2022´ Module A1





ANNEX TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE No 1434-IVDD-036/2022

List of medical devices covered by the certificate:

Serial No.	Brand/Trademark	Product Name	REF. No.
1	ALLTEST	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
2	Beright	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
3	JusChek	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
4	Lambra	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
5	SCREEN CHECK TEST	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
6	Rapid Response	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
7	AllChek	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
8	RYPO	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
9	Mila	Mila Covid-19 Szybki Test Antygenowy Ze Śliny	ICOV-802H
10	Novasalus	Test Rapido per l'Antigene COVID-19 (Fluido Orale)	ICOV-802H
11	Detect	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
12	DNA DIAGNOSTIC	COVID-19 Antigen Rapid Test (Oral Fluid)	CV19OFH
13	EQL PHARMA	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-EQL1
14	INNOVA	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H
15	the one medical	COVID-19 Antigen Rapid Test (Oral Fluid)	ICOV-802H



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Application No: 333/2020

Certificate bears the authorized person signature.

Warsaw, 16/03/2022

President Aleksandra Kostrzewa