



CERTIFICATE

EC Certificate No. 1434-IVDD-035/2022

**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#, Yin Hai Street, Hangzhou Economic & Technological
Development Area, Hangzhou, 310018, P.R. China**

**in vitro diagnostic medical devices
for self-testing**

SARS-COV-2 Antigen Rapid Test (Nasal Swab)

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: **05.07.2021**

CE 1434

Issued under the Contract No. MD-34/2021
Application No: 048/2021
Certificate bears the authorized person signature.
Warsaw, 16/03/2022
Module **A1**


President
Aleksandra Kostrzewa



ANNEX TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-IVDD-035/2022

List of medical devices covered by the certificate:

Serial No.	Brand/Trademark	Product Name	REF. No.
1	ALLTEST	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	INCP-502H
2	Beright	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	INCP-502H
3	JusChek	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	INCP-502H
4	Lambra	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	INCP-502H
5	SCREEN CHECK TEST	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	INCP-502H
6	Rapid Response	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	INCP-502H
7	gruppo Si.Gi.	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	INCP-502H
8	AllChek	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	INCP-502H
9	NovaTec Immundiagnostica GmbH	GSD NovaGen SARS-CoV-2 Ag Rapid Test (Nasal Swab)	CVAG502H 05
10	Mila	Mila SARS-CoV-2 SZYBKI TEST ANTYGENOWY (Wymaz z nosa)	INCP-502H
11	DNA DIAGNOSTIC	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	CV19AGH
12	BIOGNOST	CoviGnost AG Nasal HOME SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	INCP-502H
13	INNOVA	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	INCP-502H
14	the one medical	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)	INCP-502H



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