



# CERTIFICATE

**EC Certificate No. 1434-IVDD-438/2021**

**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**

**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 **05.07.2021** to **27.05.2024**

The date of issue of the Certificate: **05.07.2021**

The date of the first issue of the Certificate: **05.07.2021**



Issued under the Contract No. **MD-34/2021**  
Application No: **048/2021**  
Certificate bears the qualified signature.  
Warsaw, 05.07.2021  
Module A1

Anna  
Małgorzata  
Wyroba  
Vice-President

Elektronicznie  
podpisany przez Anna  
Małgorzata Wyroba  
Data: 2021.07.05  
20:01:31 +02'00'



# ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE

**No 1434-IVDD-438/2021**

*List of medical devices covered by the certificate:*

Serial No.	Brand/Trademark	REF. No.	Product Name
1	ALLTEST	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
2	Beright	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
3	JusChek	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
4	Lambra	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
5	SCREEN CHECK TEST	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
6	Rapid Response	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
7	gruppo Si.Gi.	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
8	AllChek	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
9	NovaTec Immundiagnostica GmbH	CVAG502H05	GSD NovaGen SARS-CoV-2 Ag Rapid Test (Nasal Swab)
10	Mila	INCP-502H	Mila SARS-CoV-2 SZYBKI TEST ANTYGENOWY (Wymaz z nosa)
11	DNA DIAGNOSTIC	CV19AGH	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
12	BIOGNOST	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
13	INNOVA	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
14	the one medical	INCP-502H	SARS-CoV-2 Antigen Rapid Test (Nasal Swab)



Issued under the Contract No. **MD-34/2021**  
Application No: **048/2021**  
Certificate bears the qualified signature.  
Warsaw, 16/12/2021

*Tomasz Koeber*  
Elektronicznie podpisany  
przez Tomasz Artur Koeber  
Data: 2021.12.16 14:45:13  
+01'00'

**Director of Medical Devices  
Certification Department**