

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

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

Vice-President



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)



Issued under the Contract No. MD-34/2021 Application No: 048/2021 Certificate bears the qualified signature. Warsaw, 05/07/2021

Anna Małgorzata Małgorzata Wyroba Wyroba /

Elektronicznie podpisany przez Anna Data: 2021.07.05 20:00:44 +02'00'

Vice - President