

EC Certificate No. 1434-IVDD-516/2021

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 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood)

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 06.12.2021 to 27.05.2024

The date of issue of the Certificate: 06.12.2021

The date of the first issue of the Certificate: 06.12.2021

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Issued under the Contract No. MD-98/2021 Application No: 042/2021

Certificate bears the qualified signature.

Warsaw, 06.12.2021

Module A1

Anna Małgorzata Wyroba Elektronicznie podpisany przez Anna Małgorzata Wyroba Data: 2021.12.06 15:34:13 +01'00'

Vice-President



ANNEX 1 TO THE CERTIFICATE

VALID ONLY WITH CERTIFICATE No 1434-IVDD-516/2021

List of medical devices covered by the certificate:

Serial No.	Brand/Trademark	REF. No.	Product Name
1	ALLTEST	ICSG-402H	SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood)
2	Beright	ICSG-402H	SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood)
3	JusChek	ICSG-402H	SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood)
4	SCREEN CHECK TEST	ICSG-402H	SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood)
5	AllChek	ICSG-402H	SARS-CoV-2 S-RBD IgG Antibody RapidTest (Fingerstick Whole Blood)



Issued under the Contract No. MD-98/2021 Application No: 042/2021 Certificate bears the qualified signature. Warsaw, 06/12/2021

Anna Małgorzata Małgorzata Wyroba Wyroba

Elektronicznie podpisany przez Anna Data: 2021.12.06 15:33:30 +01'00'

Vice - President