

## *EC Declaration of Conformity*

**Manufacturer:**

Name: HANGZHOU ALLTEST BIOTECH CO., LTD.

Address: #550, Yin Hai Street, Hangzhou Economic & Technological Development Area,  
Hangzhou -310018, P.R. China

**European Representative:**

Name: MedNet GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany

Product Name: SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood)

Analyte: IgG antibodies to SARS-CoV-2 anti-spike protein receptor-binding domain

Model: Cassette

Catalogue No.: See Attachment

Brand/Trademark: See Attachment

Classification: Self-testing, not listed in Annex II of IVDD 98/79/EC

Conformity Assessment Route: Annex III, section 6, IVDD 98/79/EEC

GMDN: 65586

We, HANGZHOU ALLTEST BIOTECH CO., LTD., herewith declare that we are exclusively responsible for this declaration of conformity. We herewith declare that the above mentioned products meet the corresponding national laws, the provisions of the following EC Council Directives, Standards and Common Technical Specifications. All supporting documentations are retained at the premises of the manufacturer.

**General applicable directives:**

OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on invitro diagnostic medical devices

Standard Applied: EN ISO 13485:2016, EN ISO 14971:2012, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-4:2011, EN 13612:2002/AC:2002, EN ISO 17511:2003, EN ISO 23640:2015, EN 13641:2002, EN ISO 15223-1:2016, EN 13532:2002

Notified body: Polish Center for Testing and certification (ID: 1434)

(EC) Certificate(s): 1434-IVDD-516/2021

Expire date of the Certificate: 2024-05-27

Start of CE Marking: 2021-12-06

Place, Date of first Issue of DOC: in Hangzhou on 2021-12-06

Signature: 

Name: Gao Fei (Position: General Manager)



Attachment:

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 Rapid Test (Fingerstick Whole Blood)

Issue Date: 2021-12-06