



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 EC-REP GmbH

Address: Borkstrasse 10, 48163 Muenster, Germany.

Product Name: See Attachment

Cat. No.: See Attachment

Brand/Trademark: See Attachment

Kit Size: See Attachment

Analyte: Qualitative detection of SARS-CoV-2 Nucleocapsid antigens in saliva specimen

Model: Midstream

Classification: Self-testing of IVDD 98/79/EC

Conformity Assessment Route: IVDD 98/79/EC Annex III, Article 6

GMDN Code: 65454

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.

DIRECTIVES

General applicable directives:

DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro 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 13532:2002, EN ISO 15223-1:2016.

Notified Body: Polish Center for Testing and Certification (CE1434)

Address: 469, Pulawska Street, 02-844 Warsaw, Poland

EC Certificate Number: 1434-IVDD-216/2022

Expire date of the Certificate: 2025-05-27

Start of CE Marking: 2022-05-24

Place, Date of First Issue of DOC: in Hangzhou on 2022-05-24

The Date of Issue of DOC on 2022-08-25

Signature: 

Name: Gao Fei (Position: General Manager)

Hangzhou AllTest Biotech Co., Ltd.
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Attachment:

Serial No.	Brand/Trademark	REF. No.	Kit Size	Product Name
1	ALLTEST	ICOV-803H	1T, 2T, 5T, 7T, 10T, 15T, 20T 25T	SARS-COV-2(COVID-19) Antigen Rapid Test (Saliva)
2	Beright	ICOV-803H	1T	SARS-COV-2(COVID-19) Antigen Rapid Test (Saliva)
3	JusChek	ICOV-803H	1T	SARS-COV-2(COVID-19) Antigen Rapid Test (Saliva)
4	AllChek	ICOV-803H	1T	SARS-COV-2(COVID-19) Antigen Rapid Test (Saliva)

Signature: 
Name: Gao Fei (Position: General Manager)



Issue Date: 2022-08-25