

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 Antigen Rapid Test (Nasal Swab)

Catalogue No.: INCP-502H

Model: Cassette

Brand/Trademark: See Attachment

Classification: Self-testing, Annex III, Section 6, IVDD 98/79/EC

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

GMDN: 64787

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 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 ISO 15223-1:2016, EN 13532:2002

Notified body: Polish Center for Testing and certification

ID: 1434

(EC) Certificate(s): 1434-IVDD-438/2021

Expire date of the Certificate: 27/05/2024

Start of CE Marking: 05/07/2021

Place, Date of Issue: in Hangzhou on 05/07/2021

Signature:



Name: Gao Fei (Position: General Manager)



Attachment

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)

Date: July. 05. 2021