

EC Declaration of Conformity

Manufacturer:

Name: Hangzhou Immuno Biotech Co.,Ltd.

Address: Room 401, 4F, Building 2, No.28, No.3 Street, Hangzhou Economic and Technological Development Zone, Hangzhou City, Zhejiang Province, China.

Tel: 0571-85368996

Email: info@jgbiotech.com

Whose Authorized Representative:

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

E-mail: peter@lotusnl.com

We, the manufacturer, hereby declare that the product(s)

Product Name	SARS-CoV-2 Antigen Rapid Test (COVID-19 Ag)	Specification	40 T/kit, 20 T/kit, 10 T/kit, 1 T/kit.
Intended Use	The SARS-CoV-2 Antigen Rapid Test (COVID-19 Ag) is a rapid chromatographic immunoassay for the qualitative detection of novel coronavirus SARS-CoV-2 in human throat secretions, nasal secretions and saliva specimen.		
Classification	Others		

Conformity Assessment Route : IVDD98/79/EC Annex III.

Applicable Standards:

ISO 13485:2016

ISO 14971:2019

EN ISO 18113-1:2011

EN ISO 18113-2:2011

EN ISO 18113-3:2011

EN 13641:2002

ISO 15223-1:2016

EN 13612:2002

ISO 23640:2015

EN 62366-1:2015



We, the manufacturer, hereby declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We agree to develop, implement and maintain a documented post-production monitoring process.

Name of General Manager	Xiaoguang Li
Signature	
Date	Nov 30, 2020
Place	Hangzhou, China.
Seal (Manufacturer)	



This is to certify that the Quality Management System of

Hangzhou Immuno Biotech Co., Ltd.

Unified Social Credit Code: 91330101092042370C

Operation Address: Room 401, 4F, Building 2, No.28, No.3 Street, Hangzhou Economic and Technological Development Zone, Hangzhou City, Zhejiang Province, China

Registered Address: Room 401, 4F, Building 2, No.28, No.3 Street, Hangzhou Economic and Technological Development Zone, Hangzhou City, Zhejiang Province, China

applicable to

R&D, Production and Sales of Coronavirus COVID-19 IgG/IgM Antibody Rapid Test, SARS-CoV-2 Antigen Rapid Test (COVID-19 Ag), SARS-CoV-2 Neutralizing Antibody Rapid Test (COVID-19 Ab)(Export to EU)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

Managing Director

Certificate Number

47938

Date:

27 July 2020

Reissue Date:

13 January 2021

Valid Until:

27 July 2023



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