# EC Declaration of Conformity

**Manufacturer:**

**Name:** Hangzhou Immuno Biotech Co.,Ltd.

**Address:**Room401, 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, here with 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*

CE

We, the manufacturer, here 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.

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|---|---|
| **Name of General Manager** | Xiaoguang Li |
| **Signature** | Xi'aoguang Li |
| **Date** | Nov. 30, 2020 |
| **Place** | Hangzhou, China. |
| **Seal (Manufacturer)** | |

Certificate of Registration

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

UKAS MANAGEMENT SYSTEMS 015