

## DECLARATION OF CONFORMITY

**MANUFACTURER:**

Sichuan Xincheng Biological Co., LTD  
101 Tianxin Road, High-tech west zone, Chengdu, Sichuan, China

**EUROPEAN REPRESENTATIVE:**

Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537  
Hamburg, Germany

**PRODUCT:** SARS-Cov-2 IgG/M Antibody Assay Kit by Immunofluorescence  
Chromatography Method

**CLASSIFICATION:** Others

## CONFORMITY ASSESSMENT

**ROUTE:** Annex III except section 6

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS  
MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN  
VITRO DIAGNOSTIC MEDICAL DEVICES. ALL SUPPORTING  
DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE  
MANUFACTURER

**START OF CE-MARKING:** 2020-03-03

**PLACE, DATE OF ISSUE:** Chengdu . 2020-03-03

**SIGNATURE OF PRESIDENT:**





SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION Co., Ltd.

## Test Verification of Conformity

Certificate No.: CTS17110159

R/C: 45197

Issued Date: Dec 1, 2017

The equipment, as described herewith, was tested pursuant to applicable test procedure and complies with the requirements of:

IEC 61010-1:2010  
IEC 61010-2-081:2015  
IEC 61010-2-101:2015

The test results are traceable to the international or national standards.

**Applicant:** Guangzhou Labsim Biotech Co., Ltd

G4-402, No.31 Kefeng Road, High-tech Industrial Zone, 510670 Guangzhou, Guangdong Province,  
P.R. China

**Manufacturer:** Guangzhou Labsim Biotech Co., Ltd

G4-402, No.31 Kefeng Road, High-tech Industrial Zone, 510670 Guangzhou, Guangdong Province,  
P.R. China

**EUT Name:** Fluorescent Immunoanalyzer

**Model number:** AFS-1000

**Listed Model(s):** --

**Laboratory:** Shenzhen Huatongwei International Inspection Co., Ltd.

Hongfa Hi-tech Industrial Park, Genyu Road, Tianliao, Gongming, Shenzhen, Guangdong, China  
Tel: 86-755-26748078 Fax: 86-755-26748089  
Http: //www.szhtw.com.cn E-mail: cs@szhtw.com.cn

**Note:**

The certification is only valid for the equipment and configuration described, in conjunction with the test data detailed above.

For and on behalf of  
Shenzhen Huatongwei International Inspection Co., Ltd.

Authorized by:

*Caroline Li*





SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION Co., Ltd.

## Test Verification of Conformity

Certificate No.: CTC17110120

R/C: 31449

Issued Date: Dec 15, 2017

The sample, as described herewith, was tested pursuant to the testing standard :

IEC62321-3-1-2013, IEC62321-5-2013, IEC62321-7-1-2015, IEC62321-6-2015

and all the test results comply with the requirements of :

RoHS Directive 2011/65/EU

Restriction of the use of certain Hazardous Substance  
in electrical and electronic equipment

**Applicant:** Guangzhou Labsim Biotech Co.,Ltd

G4-402, No.31Kefeng Road, High-tech Industrial Zone, 510670 Guangzhou, Guangdong Province,  
P.R. China

**Manufacturer:** Guangzhou Labsim Biotech Co.,Ltd

G4-402, No.31Kefeng Road, High-tech Industrial Zone, 510670 Guangzhou, Guangdong Province,  
P.R. China

**Sample Name:** Fluorescent immunoanalyzer

**Sample Model(s):** AFS-1000

**Laboratory:** Shenzhen Huatongwei International Inspection Co., Ltd.

6/F East, Heping Building, Heping Road, Luohu, Shenzhen, China

Tel: 86-755-26748019 Fax: 86-755-26748089

Http: //www.szhtw.com.cn E-mail: cs@szhtw.com.cn

# RoHS

**Note:**

The certification is only valid for the submitted sample(s), in conjunction with the test data detailed in test report.

For and on behalf of  
Shenzhen Huatongwei International Inspection Co., Ltd.

Authorized by:

