

## 4. CE statement—reagent

 新健康成®

XC-CE-2020-001

### 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) Eiffelstrasse 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:** 

**CE**