



# EC DECLARATION OF CONFORMITY

According to In Vitro Diagnostic Medical Device Directive 98/79/EC

**Manufacturer**      Jiangsu Konsung Bio-Medical Science And Technology Co., Ltd.

**Address**             NO.8, Shengchang West Road, Danyang Development Zone,  
Jiangsu Province, 212300, P.R.China.

**In vitro giagnostic device(s)**    **Product Name:** COVID-19 Antigen Rapid Test Kit (Colloidal Gold)  
**Specification:** 1 PCS/box, 20 PCS/box  
**IVDD Classification:** Other, for professional use  
**EDMA:** 15-04-80-90-00

This declaration of conformity is issued under the sole responsibility of manufacturer that the above product(s) meet(s) the provisions of the European Directive 98/79/EC for in vitro Diagnostic Medical Devices.

### The following (harmonized) standards have been applied

EN ISO 13485:2016	EN ISO 14971: 2012	EN ISO 15223-1:2016
EN ISO 18113-1: 2011	EN ISO 18113-2: 2011	EN ISO 18113-3:2011
EN 13641:2002	EN ISO 23640 :2015	EN 13612:2002

The conformity with the requirements of the Directive has been assessed following the procedure(s) outlined in the following annexes of the Directive: Annex III, **excluding 6**

**Notified Body**      Not applicable  
**(if consulted)**

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe:

Shanghai International Holding Corp GmbH (Europe)  
Eiffestrasse 80, 20537 Hamburg Germany  
Tel: +49-40-2513175 Fax: +49-40-255726

PLACE, DATE OF DECLARATION:

*No.8 Shengchang West Road, Danyang Economic Development  
Zone, Jiangsu Province, 212300, P.R. China.*

SIGNATURE:

04, 03, 2021  
NAME: Wu Yujia

POSITION: GENERAL MANAGER

