CE Konsung CE

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 (harmonizd) 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 (if consulted) Not applicable

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.

04.03.2021

SIGNATURE: 吴玉家

JIANGSU KONSUNG BIO-MEDICAL SCIENCE AND TECHNOLOGY CO.,LTD. 3211815015196

NAME: Wu Yujia

POSITION: GENERAL MANAGER