CE AIKRS CE

EC DECLARATION OF CONFORMITY

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

Manufacturer	Jiangsu Accuracy Biotechnology Co., Ltd.
Address	No. 8, Shengchang West Road, Danyang Development Zone, 212300 Danyang Jiangsu Province, PEOPLE'S REPUBLIC OF CHINA.
In vitro giagnostic device(s)	**Product Name:** COVID-19 Salivary Antigen Rapid Test Kit (Colloidal Gold) **Specification:** 1 PC/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 62366-2008
EN ISO 18113-1: 2011	EN ISO 18113-4: 2011	EN ISO 18113-5:2011	
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:

Lotus NL B.V.
Koningin Juliana 10, 1e Verd, 2595AA, The Hague, Netherlands.
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Tel: +49-40-2513175 Fax: +49-40-255726

PLACE, DATE OF DECLARATION:

No. 8 Shengchang West Road, Danyang Development Zone, 212300 Danyang Jiangsu pr
PEOPLE'S REPUBLIC OF CHINA

2021-03-29

SIGNATURE: 丁超

NAME: Ding Chao

POSITION: GENERAL MANAGER

JIANGSU ACCURACY BIOTECHNOLOGY CO., LTD. 江苏爱康润斯生物科技有限公司 3211811075888

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