## **EC Declaration of Conformity**

## Manufacturer:

Name: JOYSBIO (Tianjin) Biotechnology Co., Ltd.

**Address:** Tianjin International Joint Academy of Biotechnology & Medicine 9th floor, No.220, Dongting Road, TEDA 300457 Tianjin

China.

**Tel:** +86-022-65378415 **Email:** molly@joysbio.com

We, the manufacturer, here with declare that the product(s)

## Whose Authorized Representative:

Name: Lotus NL B.V.

**Address:** Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

E-mail: peter@lotusnl.com

Product Name	SARS-CoV-2 Antigen Rapid Test Kit-PRO (Colloidal Gold)	Specification	20 tests per box, 1 test per box
Intended Use	For in vitro qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasal, oropharyngeal and nasopharyngeal swab specimens directly from individuals who are suspected of COVID-19. This test is provided for use by clinical laboratories, to healthcare workers for point-of-care testing. Home-test by lay person is subject to local legislations.		
Classification	Others		

Conformity Assessment Route: IVDD98/79/EC Annex III.

## **Applicable Standards:**

ISO 13485:2016 ISO 14971:2019 EN ISO 18113-1:2011 EN ISO 18113-2:2011 EN ISO 18113-3:2011 EN 13641:2002 ISO 15223-1:2016 EN 13612:2002 ISO 23640:2015 EN 62366-1:2015



We, the manufacturer, here declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We agree to develop, implement and maintain a documented post-production monitoring process.

Name of General Manager	Sen Wang 王森	
Signature Signat	24	
Date	13/3/2021	
Place	Tianjin, China.	
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	で、正元盛邦(天津) い、生物科技有限公司	
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