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

Whose Authorized Representative:

Name: Lotus NL B.V.

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

E-mail: peter@lotusnl.com

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

Product Name	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	**Specification**	20Tests/box (1Test/bag ×20 Bags) , 40 Tests /box (1Test / bag ×40 Bags)
Intended Use	For in vitro qualitative detect of SARS-CoV-2 nucleocapsid antigen in nasal(NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days of the onset of the symptoms. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, and not for at home testing.		
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

CE

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	王森
Signature	
Date	2020.08.28
Place	Tianjin, China.
Seal (Manufacturer)	JOYSBIO (Tianjin) Biotechnology Co., Ltd. 正元盛邦(天津)生物科技有限公司 120116007903