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-PLUS (Colloidal Gold)	**Specification**	1Test/box (1Test/pouch×1pouch),5Tests/box (1Test/pouch ×5 pouches), 15Tests/box(1Test/pouch ×15 pouches), 20 Tests/box (1Test/pouch ×20 pouches)
Intended Use	For in vitro qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasal, oropharyngeal, and nasopharyngeal swab specimen directly from individuals who are suspected of COVID-19 after onset of symptoms. This test is compatible with SARS-COV-2 variants which have mutation on spike protein, such as 20I/501Y.V1 and 20H/501Y.V2. This test is provided for use by clinical laboratories or to healthcare workers for point-of-care testing. The use of self-test by lay person is subject to local legislations. Not for children under the age of 3.		
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	March 24, 2021
Place	Tianjin, China
Seal (Manufacturer)	