

# EC Declaration of Conformity

**Manufacturer:**

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

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**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)

<b>Product Name</b>	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	<b>Specification</b>	20Tests/box (1Test/bag ×20 Bags) , 40 Tests /box (1Test / bag ×40 Bags)
<b>Intended Use</b>	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.		
<b>Classification</b>	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.

<b>Name of General Manager</b>	王森
<b>Signature</b>	
<b>Date</b>	2020.08.28
<b>Place</b>	Tianjin, China.
<b>Seal (Manufacturer)</b>	