EC Declaration of Conformity

Manufacturer:

Name: Wenzhou OJA Biotechnology Co., Ltd.

Address: China Eye Valley, Room 228, Building A, No. 100 Northeast Street, Yongzhong Street, Longwan District, Wenzhou, Zhejiang, China.

Tel: +86 0571-82668662

Email: ojaservice@163.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 Detection Kit (Colloidal Gold Method)	**Specification**	20 Tests/Kit
Intended Use	The kit is used to qualitatively determine the presence of the Noval Coronavirus SARS-CoV-2 N antigen in human throat swabs,nasal swabs in vitro.It is mainly used for infection screening and auxiliary diagnosis.		
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 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	Jingu Wang
Signature	
Date	10.09.2021
Place	Wenzhou, China.
Seal (Manufacturer)	