EC Declaration of Conformity

Manufacturer:

Name: Zhejiang Jilong Biotechnology Co., Ltd.

Address: Room 303, Building 4, No. 1 Nangonghe Road, Yuhang Economic and technological Development Zone, Linping District, 311100 Hangzhou, Zhejiang, China.

Tel: +86-571-85179852

Email: jilong@jilongbio.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	Fast SARS-CoV-2 Detection Kit (RT-PCR)	**Model/ Specification**	16 Tests / Box, 32Tests / Box, 48 Tests / Box, 96 Tests / Box
Intended Use	This product is used to qualitatively detect suspected cases of pneumonia with novel coronavirus infections, suspected cluster cases, and other pharynx swabs and nasal swabs samples that require diagnosis or differential diagnosis of novel coronavirus infections in novel coronavirus (SARS-CoV-2) RdRp genes and N genes.		
Classification	Others		

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

Applicable Standards:

EN ISO 13485:2016
EN ISO 14971:2012
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 18113-3:2011
EN 13641:2002
EN ISO 15223-1:2016
EN 13612:2002
EN ISO 23640:2015
EN 62366-1:2008

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	Xiaoli Zhang
Signature	
Date	2021.10.10
Place	Hangzhou, China
Seal (Manufacturer)	