EC Declaration of Conformity

Manufacturer:

Name: Triplex International Biosciences (China) Co., LTD.

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Whose Authorized Representative:

Name: Lotus NL B.V.

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

E-mail: peter@lotusnl.com

We,Triplex International Biosciences (China) Co., LTD.(Manufacturer), here declare that the below mentioned medical device meets the provisions of Directive 98/79/EC which apply to them.The declaration of conformity is exclusively under the responsibility of Triplex International Biosciences (China) Co., LTD.(Manufacturer).

Product Name	SARS-CoV-2 & Flu A+B Antigen Combo Rapid Test Kit
Intended Use	This SARS-CoV-2 & Flu A+B Antigen Combo Rapid Test Kit is only used for rapid in vitro qualitative detection of SARS-CoV-2, influenza A and influenza B nucleoprotein antigens in nasopharyngeal swab, nasal swab, oropharyngeal swab or saliva specimens. It is intended to aid in the rapid differential diagnosis of SARS-CoV-2, influenza A and influenza B viral infections. Negative test results do not preclude SARS-CoV-2 or influenza infections and should not be used as the sole basis for treatment or other patient management decisions.
Classification	Others

Conformity Assessment Route:IVDD 98/79/EC Annex III(excluding Annex III.6).

Applicable Standards:

QMS:

EN ISO 13485:2016

Risk Management:

ISO 14971:2019

Product Standards:

EN ISO 18113-1:2011 *EN ISO 18113-2:2011*

EN 13612:2002 *EN 13641:2002* *EN 62366-1:2015*

ISO 15223-1:2016 *ISO 23640:2015* *ISO 10993*

CE

Valid until: May 26, 2025

Name Of Authorized Signatory	Jin Li（李劲）
Position Held In The Company	General Manager
Signature	
Date	January 20, 2022
Place	Xiamen, China.
Seal (Manufacturer)	