

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 Neutralizing antibody Rapid Test Kit				
Intended Use	This SARS-CoV-2 Neutralizing antibody Rapid Test Kit is only used for rapid in vitro qualitative assessment of SARS-CoV-2 neutralizing antibody in human serum/plasma/whole blood(Venipuncture and Fingerstick). For professional In Vitro Diagnostic Use Only.				
PackSize/REF/ Barcodes	<i>PackSize:</i> <i>REF:</i> <i>Barcodes:</i>	1 test/kit C011911 6950917930171	5 tests/kit C011912 6950917930188	10 tests/kit C011913 6950917930195	25 tests/ kit C011914 6950917930201
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



Valid until: May 24, 2022

Name Of Authorized Signatory	Jin Li (李劲)
Position Held In The Company	General Manager
Signature	
Date	July 5, 2021
Place	Xiamen, China.
Seal (Manufacturer)	