EC Declaration of Conformity

Manufacturer:

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

Address: Unit 101,201,and 301,No.2041,Unit 101,201,and 501,No.2045, Xizhou Road, Tongan District, 361100 Xiamen, PEOPLE' S REPUBLIC OF CHINA.

Tel: +86-592-3737666

Web: http://www.tibchina.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,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 (TRFIA)				
Intended Use	This SARS-CoV-2 Neutralizing antibody Rapid Test Kit (TRFIA) 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	***PackSize:***	1 test/kit	5 tests/kit	10 tests/kit	25 tests/ kit
	REF:	C011915	C011916	C011917	C011918
	Barcodes:	6950917930133	6950917930140	6950917930157	6950917930164
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 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)	