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 Antigen Rapid Test Kit					
Intended Purpose	This SARS-CoV-2 Antigen Rapid Test Kit is only used for rapid in vitro qualitative detection of nucleocapsid protein (N protein) from SARS-CoV-2 antigen in human nasopharyngeal swabs, anterior nasal swab, posterior oropharyngeal saliva or saliva.					
PackSize/REF/ Barcodes	***PackSize:*** 1 test/kit	2 tests/kit	5 tests/kit	10 tests/kit	25 tests/ kit	50 tests/ kit
	REF: C011907	C011908	C011909	C011910	C011906	C011905
	Barcodes: 6950917930065	6950917930072	6950917930089	6950917930096	6950917930102	6950917930119
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	March 22, 2021
Place	Xiamen, China
Seal (Manufacturer)	

INTERNATIONAL BIOSCIENCES (CHINA) CO., LTD. 泰普生物科学（中国）有限公司

Digitally signed by Chirtoacă Iurie
Date: 2021.10.15 18:26:55 EEST
Reason: MoldSign Signature
Location: Moldova