

DECLARATION of CONFORMITY

to Council Directive 98/79/EC of the European Parliament and
of the Council of 27 October 1998 on in vitro diagnostic
medical devices



Manufacturer: Sure Bio-Tech (USA) Co., Ltd

Add : 228 Park Ave S 79525 New York, NY 10003

Medical Device: (See the list in the Annex I)

Classification: IVD Others



We **Sure Bio-Tech (USA) Co., Ltd** Herewith declare that the stated
medical devices meet the transposition into national law, the provisions of Council
Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on
in vitro diagnostic medical devices; All supporting documentation is retained at the
premises of the manufacturer.



CMC Medical Devices & Drugs S.L

Add: Horacio Lengo, 18.29006 Málaga, Spain

European Representative:

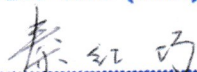
Tel: +34951214054

Place: New York

Date of Declaration: August 3rd, 2020

Signature:

For and on behalf of
Sure Bio-Tech (USA) Co., Ltd


.....
Authorized Signature(s)

Managing Director

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ANNEX I

	Product Name	Classification	Conformity assessment route
1	2019-nCoV Antigen Rapid Test (Colloidal Gold)	Non listed devices of IVDD 98/79/EC	Directive 98/79/EC, article 9, annex III: others

These products compliance with the essential requirements in accordance with Annex I of the In Vitro Diagnostic medical devices 98/79/EC.