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 CE IVD

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.

EC REP European Representative:	CMC Medical Devices & Drugs S.L Add: Horacio Lengo, 18.29006 Málaga, Spain 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.