

## 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

European Representative:

Add: Horacio Lengo, 18.29006 Málaga, Spain

Tel: +34951214054

Place:

New York

Date of Declaration:

March 13, 2020

Signature:

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

.....  
*Authorized Signature(s)*

Managing Director

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### ANNEX I

	<b>Product Name</b>	<b>Classification</b>	<b>Conformity assessment route</b>
<b>1</b>	<b>SARS-CoV-2 IgM Ab Rapid Test</b>	Non listed devices of IVDD 98/79/EC	Directive 98/79/EC, article 9, annex III: others
<b>2</b>	<b>SARS-CoV-2 IgG Ab Rapid Test</b>	Non listed devices of IVDD 98/79/EC	Directive 98/79/EC, article 9, annex III: others
<b>3</b>	<b>SARS-CoV-2 IgM/IgG Ab Rapid Test</b>	Non listed devices of IVDD 98/79/EC	Directive 98/79/EC, article 9, annex III: others