CERTIFICATE

Of CE (MDD) NOTIFICATION

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/0317

Certificate No.: CMC/CE/2020/0317

Registration number: **RPS/340/2020**

PRODUCTS DETAIL IN ANNEX I (1 page)

MANUFACTURER BY COMPANY:

Sure Bio-Tech (USA) Co., Ltd

228 Park Ave S 79525 New York, NY 10003.

The Manufacturer declares that he complies with the applicable essential requirements of the Council Directive 98/79/EC and Regulation (EU) 2017/746 concerning in vitro diagnostic medical devices.

The manufacturer has provided CMC Medical Devices S.L. with all appropriate declarations as per the European Council Directive 98/79/EEC including EC Declaration of Conformity (according to Annex III) confirming that their class IVD others, as stipulated here below, are fulfilling the applicable requirements of the European council Directive 98/79/EEC.
The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above reference models, the CE Marking according to this example:

CE IVD

CMC Medical Devices has performed all notification duties and responsibilities as the European Authorized representative of Sure Bio-Tech (USA) Co., Ltd therefore may place these devices in the European community territory as long as the Manufacturer will continue complying with the hereabove mentioned requirements.

Issued on: 17/03/2020
Authorized signature

CMC Medical Devices & Drugs, S.L.

CERTIFICATE

NO. CMC/CE/2020/0317

ANNEX I:

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