



CERTIFICATE
ECREP20220128.2



Ver: CERT-202110.V1

CMC MEDICAL DEVICES & DRUGS S.L.

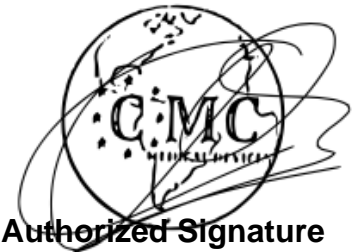
CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

WUHAN HEALTHCARE BIOTECHNOLOGY CO., LTD
Floor 1-4, Building #8, Optics Valley Precision Medicine
Industry Base Phase I, #9 Gaokeyuan 3rd Road, East
Lake High-Tech Zone

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive/regulation and standard mention in Annex I of this certificate, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all below mentioned models of the medical device.

These products included in the Annex I have been registered in the Spanish MOH (AEMPS). The column categorized as RPS refers to their registration number.



Issue date: 28/01/2022

Expiration date: 13/01/2023

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com

Verification code



CERTIFICATE CERTIFICADO CERTIFIKAT CERTIFICAT 证书 자격증



Ver: CERT-202110.V1

CERTIFICATE
CERTIFICADO
CERTIFIKAT
CERTIFICAT
证书
자격증

ANNEX I

Product Name	REGULATION	CLASSIFICATION	RPS (AEMPS)	Model
SARS-CoV-2 Antigen Test Kit (Colloidal Gold)	IVD - Directive 98/79	IVD OTHERS	RPS/200/2022	NA
Novel Coronavirus 2019-nCoV Nucleic Acid Typing Test Kit (Real-Time PCR)	IVD - Directive 98/79	IVD OTHERS	RPS/200/2022	NA



Issue date: 28/01/2022

Expiration date: 13/01/2023

