EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2021/14092021.20

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

Nantong Diagnos Biotechnology Co.,Ltd.
Room 203, Building 6, Electronic Information Industrial Park,
No. 2 Haiyang South Road, Chengnan Street, Rugao City, Jiangsu Province, China

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 and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 98/79/EEC in vitro diagnostics as amended.

From 26 May 2022, manufacturer must fully comply with the IVDR in order to be placed their products in the European market.

The products in Annex I was registered in Spanish MOH with numbers
RPS/2749/2020, RPS/2318/2020

CE

Issued on: 30/11/2020

Valid until: 30/09/2022

Authorized Signatory
CMC Medical Devices & Drugs SL

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ANNEX I Medical Device Products:

(RPS/2749/2020)

COVID-19 Antigen Test Kit (Fluorescence Immunoassay)

(RPS/2318/2020)

COVID-19 & Influenza A+B Antigen Combo Test Kit (Colloidal Gold)

Influenza A+B Antigen Test Kit (Colloidal Gold)

COVID-19 Antigen Test Kit (Colloidal Gold)

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