EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/15102020.1

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

HANGZHOU BIOTEST BIOTECH CO., LTD
No. 17, Futai Road, Zhongtai Street, Yuhang District, Hangzhou -311121 P.R.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.

The products in Annex I was registered in Spanish MOH with number **RPS/2368/2020**

CE

Issued on: 15/10/2020

Valid until: 14/10/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

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ANNEX I Medical Device Products

COVID-19 Antigen Rapid Test Cassette

SARS-CoV-2 + Flu A&B Antigen Combo Rapid Test Cassette
(Nasopharyngeal Swab)

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