EC REP CERTIFICATE



CMC MEDICAL DEVICES & DRUGS SL NO. CMC/CE/2020/05112020.1

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

Beijing Tigsun Diagnostics Co.,Ltd. No. 16, Region 1, Guba Road, Chengguan Street, Fangshan District, 102400 Beijing, 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/2534/2020

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Issued on: 05/11/2020

Valid until: 04/11/2021

CMC Medical Devices & Drugs SL

uthorized Signatory

EC REP CERTIFICATE



ANNEX I Medical Device Produ

Tigsun COVID-19 Antigen Rapid Test (FIA)

Tigsun COVID-19 Antigen Rapid Test

Tigsun COVID-19 Saliva Antigen Rapid Test

Tigsun Flu A/B, COVID-19 Ag Combo test

Tigsun Flu A/B, RSV, COVID-19 Ag Combo test

(Model: 1/20/25/40/50/80/100 tests)

