

Kit IVD per antigene SARS-CoV-2 Tampone



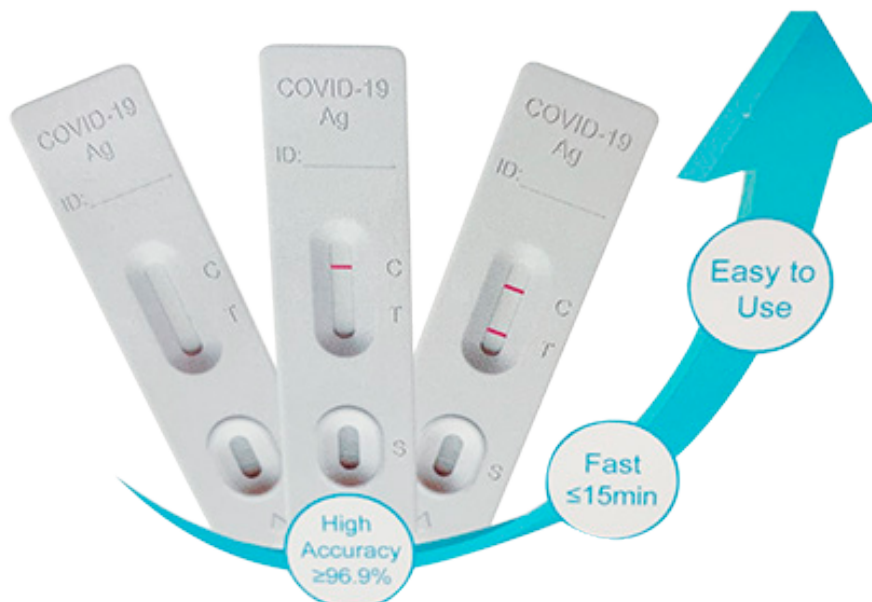
Foglio illustrativo
con
istruzioni in italiano



Tampone sterile



Tubo di estrazione
del campione





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Medical & Drug ☒ IVD& POCT ☒ Food & Safety

CE certificate

EC REP CERTIFICATE



CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/19032021.7

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

Shenzhen Reagent Technology Co.,Ltd.

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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/543/2021**



Issued on: 19/03/2021



Valid until: 18/03/2022

Authorized Signatory
CMC Medical Devices & Drugs SL

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ANNEX I Medical Device Products



COVID-19 & Influenza A/B Antigen Combo Test Kit

COVID-19 IgG ELISA Test Kit

COVID-19 IgM ELISA Test Kit

COVID-19 Neutralizing Antibody ELISA Test Kit

COVID-19 Real-Time Fluorescence PCR Detection Kit Manual (lyophilized)

COVID-19 Neutralizing Antibody Rapid Test Kit

SARS-CoV-2 antigen IVD kit NASAL

SARS-CoV-2 antigen IVD kit SALIVA

SARS-CoV-2 antigen IVD kit SWAB

Zilpaterol ELISA Test Kit

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