



Ver: CERT-202110.V1

CERTIFICATE
ECREP20220120.2



CMC MEDICAL DEVICES & DRUGS S.L.

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

Hangzhou Funworld Biotech Co., Ltd.
Room 301, Buliding 1#, 136 Zhiyi Rd, Yuhang Sub-
district, Yuhang District

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.




Authorized Signature

Issue date: 20/01/2022

Expiration date: 14/10/2026

Verification Code

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



CERTIFICATE
CERTIFICADO
CERTIFIKAT
CERTIFICAT
证书
자격증



ANNEX I

Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Typhoid/Para Typhoid Ag Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Typhoid Ag Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Typhoid Ab Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
TML One Step Tramado Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
THC One Step Marijuana Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
TCA One Step Tricyclic Antidepressants Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
TB Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Strep A Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
SARS-CoV-2 Neutralizing Antibody Rapid Test Device	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/161/2021	Yes
SARS-CoV-2 IgG/IgM Rapid Test Device (WB/P/S)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/2471/2020	Yes
SARS-CoV-2 Ag Rapid Test Device (Nasopharyngeal swabs/ Nasal swab)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/2471/2020	Yes
Rotavirus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Rota/Adeno combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Procalcitonin Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
PPX One Step Propoxyphene Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
PCP One Step Phencyclidine Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
OXY One Step Oxycodone Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
OPI One Step Opiates Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Norovirus GI+GII Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes

Issue date: 20/01/2022

Expiration date: 14/10/2026

Verification Code





CERTIFICATE

ECREP20220120.2



Ver: CERT-202110.V1

Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
MTD One Step Methadone Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
MQL One Step Methaqualone Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
MOP One Step Morphine Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Microalbumin Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
MET One Step Methamphetamine Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
MDMA One Step Ecstasy Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Malaria pf/pv Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Malaria pf/pan Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Malaria pf Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
KET One Step Ketamine Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
K2 One Step Synthetic Cannabis Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Influenza A+B/ SARS-CoV-2 Ag Rapid Test Device (Nasopharyngeal swabs/ Nasal swab)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/2471/2020	Yes
Influenza A+B Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Influenza A+B Ag Rapid Test Device (Nasopharyngeal swabs/ Nasal swab)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/2471/2020	Yes
iGFBP-1 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Hs C-Reactive Protein Semi-Quantitative Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
HCG One Step Pregnancy Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
HCG One Step Pregnancy Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
H. Pylori Ag Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
H. Pylori Ab Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
FYL One Step Fentanyl Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
FOB Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes

Issue date: 20/01/2022

Expiration date: 14/10/2026

Verification Code

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



CERTIFICATE CERTIFICADO CERTIFIKAT CERTIFICAT 证书 자필증



CERTIFICATE

ECREP20220120.2



Ver: CERT-202110.V1

Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
fFN Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Ferritin Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
EDDP One Step Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Dengue Ns1 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Dengue IgG/IgM+Ns1 Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Dengue IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
D-dimer Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
cTnI Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
COT One Step Cotinine Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
COC One Step Cocaine Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
C-Reactive Protein Semi-Quantitative Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
BZO One Step Benzodiazepines Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
BUP One Step Buprenorphine Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
BAR One Step Barbiturates Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
AMP One Step Amphetamine Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes
Adenovirus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/128/2022	Yes

Issue date: 20/01/2022

Expiration date: 14/10/2026

Verification Code

CMC Medical Devices & Drugs S.L.
C/ Horacio Lengo N°18, CP29006, Málaga-Spain
www.cmcmedicaldevices.com



CERTIFICATE CERTIFICADO CERTIFIKAT CERTIFICAT 证书 자격증