



Ver: CERT-202110.V1

CERTIFICATE
ECREP20220406.5



CMC MEDICAL DEVICES & DRUGS S.L.

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

Hangzhou Tongzhou Biotechnology Co., Ltd
Room 102, Building 4, No. 191, Xintian Road, Yunhe
Street, Linping District, Hangzhou, 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/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: 06/04/2022

Expiration date: 25/01/2027

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CMC Medical Devices & Drugs S.L.
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ANNEX I

Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Zopiclone (ZOP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Zolpidem (ZOL) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Zika NS1 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Zika IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Zika IgG/IgM and NS1 Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Vitamin D Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Vibrio cholerae O139 (VC O139) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Vibrio cholerae O1 (VC O1) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Vibrio cholerae O1/O139 Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Typhoid IgG/IgM Rapid Test(Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Typhoid IgG/IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Tuberculosis (TB) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
TSH Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Tricyclic Antidepressants (TCA) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Transferrin and FOB Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Tetanus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Syphilis Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Synthetic Marijuana (K2) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Streptococcus pneumoniae Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Strep B Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Strep A Rapid Test(Control Line in Red)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

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Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Strep A Rapid Test(Control Line in Blue)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
SP-10 Male Fertility Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Salmonella typhi Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
SAA Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
SAA and CRP Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
RSV&Influenza A+B Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
RSV Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Rotavirus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Rotavirus and Adenovirus Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Rheumatoid Factor Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Procalcitonin (PCT) Rapid Test (Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Procalcitonin (PCT) Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test Midstream	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test (Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test (Urine)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test (Serum/Plasma/Urine)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Pregnancy (hCG) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Phencyclidine (PCP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Oxycodone (OXY) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ovulation (LH) Rapid Test Midstream	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ovulation (LH) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Opiates (OPI) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
NT-proBNP Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

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Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Norovirus, Rotavirus, Adenovirus and Astrovirus Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Norovirus, Rotavirus and Adenovirus Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Norovirus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Myoglobin/CK-MB/Troponin I Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Myoglobin Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Mycoplasma Pneumoniae IgG/ IgM Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Mycoplasma pneumoniae Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Multi-Drugs Rapid Test Key Cup	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Multi-Drugs Rapid Test 1-Step Cup	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Multi-Drugs Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Morphine (MOP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
MONO Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Micro-Albumin Semi-Quantitative Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Micro-Albumin Qualitative Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Methylphenidate(MPD) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Methamphetamine (MET) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Methadone (MTD) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Marijuana (THC) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Malaria P.f./P.v. Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Malaria P.f./P.v. /Pan Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Malaria P.f./ Pan Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Malaria P.f. Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Lyme IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Leptospira IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

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Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Leishmania IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Lactoferrin Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ketamine (KET)Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Insulin-like Growth Factor-binding Protein 1 (iGFBP-1) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Influenza A+B Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Influenza A Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
IgE Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Human Semen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgM Rapid Test (Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgG/IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HSV 1/2 IgG/IgM Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HEV IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
HbA1c Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Hb+Hb-Hp Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H. pylori Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H. pylori Antibody Rapid Test(Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H. pylori Antibody Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H-FABP Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H-FABP and cTnI Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Gonorrhea Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Gonorrhea and Chlamydia Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Giardia Lamblia Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
FSH Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
FOB Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

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Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Filariasis IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Filariasis IgG/IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Fetal Fibronectin (fFN) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ferritin Semi-Quantitative Rapid test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ferritin Rapid test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Fentanyl (FYL) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ethylendiamine-dimethylphosphinic acid (EDDP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ethyl Glucuronide (ETG) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Entamoeba/Giardia/Crypto Rapid Test (1 Window)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Entamoeba/Giardia/Crypto Combo Rapid Test (3 Windows)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Entamoeba histolytica Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Ecstasy (MDMA) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Dengue NS1 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Dengue IgG/IgM Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Dengue IgG/IgM and NS1 Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
D-dimer Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cryptosporidium Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cryptosporidium and Giardia Lamblia Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cotinine (COT) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cocaine (COC) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Clostridium difficile Toxin A +Toxin B Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Clostridium difficile GDH+ Toxin A +Toxin B Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Clostridium difficile GDH Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

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Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
CK-MB Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Chikungunya IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Chikungunya IgG/IgM Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Chagas Rapid Test(Whole Blood/Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Chagas Rapid Test (Serum/Plasma)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
CEA Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cardiac Troponin T (cTnT) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Cardiac Troponin I (cTnI) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Candida albicans Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Campylobacter Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Calprotectin Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Calprotectin and Lactoferrin Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Calprotectin and FOB Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
CA19-9 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
CA15-3 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
CA125 Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
C-reactive protein Semi-Quantitative Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
C-reactive protein Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Buprenorphine (BUP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Brucella Abortus Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Blood Stain Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Benzodiazepines (BZO) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Barbiturate (BAR) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Astrovirus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Amphetamine (AMP) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

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AMH Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
AFP Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Adenovirus&RSV Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Adenovirus, RSV and Influenza A+B Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Adenovirus Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
Adenovirus pneumoniae Antigen Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
7-Aminoclonazepam (7-ACL) Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes
H-FABP and Myoglobin/CK-MB/Cardiac Troponin I Combo Rapid Test	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/215/2022	Yes

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