



**CERTIFICATE**  
ECREP20240531.3



Ver: CERT-202303.V1

CERTIFICATE  
CERTIFICADO  
CERTIFIKAT  
CERTIFICAT  
证书  
자격증

## CMC MEDICAL DEVICES & DRUGS S.L.

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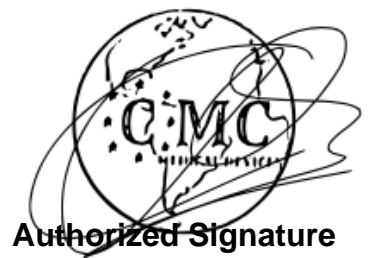
**Shenzhen Reagent Technology Co.,Ltd.**  
**R777, Hangcheng Wisdom Science Park, Hangcheng street, Bao'an District,**  
**Shenzhen 518128 ,China**

The certificate remains valid until the expiration date of the EC REP agreement, or until manufacturing conditions, quality system or relevant legislation are modified.

The validity is subject to positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive/regulation mentioned in Annex I of this certificate and the applicable standards. After fulfilling the relevant EU legislation requirements, the manufacturer shall affix the appropriate CE marking to the relevant models of the medical devices mentioned below.

These products included in the Annex I have been registered in the Spanish MOH (AEMPS) if applicable. In this case, the column categorized as RPS refers to their registration number.



**Issue date: 31/05/2024**

**Expiration date: 08/12/2024**

CMC Medical Devices & Drugs S.L.  
C/ Horacio Lengo Nº18, CP29006, Málaga-Spain  
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## ANNEX I

Product Name	CLASS	REGULATION	RPS	Status RPS	Model
Zilpaterol ELISA Test Kit	CLASS IVD OTHERS	IVD - Directive 98/88	RPS/543/2021	Registered with AEMPS	Reagent
Typhoid IgG/IgM Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/4823/2022	Registered with AEMPS	Test card
Transferrin Rapid Test Kit (Colloidal Gold)	IVD OTHERS	IVD - Directive 98/79	RPS/584/2023	Registered with AEMPS	Test card
Thermal cycler nucleic acid amplification instrument IVD	IVDR Class A		-	Pending: To be registered	Instrument
SP10 Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/658/2024	Registered with AEMPS	Test card
Seven Respiratory Pathogens Real-Time Fluorescence PCR Detection Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/658/2024	Registered with AEMPS	Reagent
Seven Respiratory Pathogens Antigen Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/956/2024	Registered with AEMPS	
SARS-CoV-2/RSV&Flu A/B Antigen Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/4823/2022	Registered with AEMPS	Test card
SARS-CoV-2/RSV/ADV&Flu A/B Antigen Rapid Test Kit	IVD OTHERS	IVD - Directive 98/79	RPS/584/2023	Registered with AEMPS	Test card
SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/2879/2023	Registered with AEMPS	Test card
SARS-CoV-2/RSV/ADV/MP/SP&Flu A/B Antigen Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/658/2024	Registered with AEMPS	Test card
SARS-CoV-2 antigen IVD kit SWAB	CLASS IVD OTHERS	IVD - Directive 98/87	RPS/543/2021	Registered with AEMPS	Test card
SARS-CoV-2 antigen IVD kit SALIVA	CLASS IVD OTHERS	IVD - Directive 98/86	RPS/543/2021	Registered with AEMPS	Test card
SARS-CoV-2 antigen IVD kit NASAL	CLASS IVD OTHERS	IVD - Directive 98/85	RPS/543/2021	Registered with AEMPS	Test card
SARS-CoV-2 Antigen IVD Kit Lollipop	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/46/2022	Registered with AEMPS	Test card
Rheumatoid Factor Detection Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/4823/2022	Registered with AEMPS	Reagent
Procalcitonin Rapid Test Kit (Colloidal Gold)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/46/2022	Registered with AEMPS	Test card
Nucleic Acid Releaser	IVDR Class A	IVDR - Regulation 2017/746	-	Pending: To be registered	Reagent
Nucleic acid extraction/isolation kit IVD	IVDR Class A	IVDR - Regulation 2017/746	-	Pending: To be registered	Reagent
NS1/Pf Antibody Combo Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/2879/2023	Registered with AEMPS	Test card

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Product Name	CLASS	REGULATION	RPS	Status RPS	Model
Nine Respiratory Pathogens Antigen Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/1567/2024	Registered with AEMPS	Test card
Neisseria Gonorrhoeae Real-Time Fluorescence PCR Detection Kit	IVD OTHERS	IVD - Directive 98/79	RPS/584/2023	Registered with AEMPS	Reagent
Myoglobin/ CK-MB/ Troponin I Combo Test Kit (Colloidal Gold)	IVD OTHERS	IVD - Directive 98/79	RPS/584/2023	Registered with AEMPS	Test card
Mycobacterium Tuberculosis Real-Time Fluorescence PCR Detection Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/4823/2022	Registered with AEMPS	Reagent
MOP/MET/KET Combo Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/658/2024	Registered with AEMPS	Test card
MOP/MET Combo Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/658/2024	Registered with AEMPS	Test card
Monkeypox Virus Real-Time Fluorescence PCR Detection Kit	IVD OTHERS	IVD - Directive 98/79	RPS/3800/2022	Registered with AEMPS	Reagent
Monkeypox Virus IgM/IgG Antibody Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/4823/2022	Registered with AEMPS	Test card
Monkeypox Virus Antigen Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/4823/2022	Registered with AEMPS	Test card
MET/THC/AMP/MOP Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/658/2024	Registered with AEMPS	Test card
Influenza A/B and Respiratory Syncytial Virus Real-Time Fluorescence PCR Detection Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/658/2024	Registered with AEMPS	Reagent
Influenza A/B and Respiratory Syncytial Virus Real-Time Fluorescence PCR Detection Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/658/2024	Registered with AEMPS	Reagent
Human Papilloma Virus (HPV) Types 16 and 18 Real-Time Fluorescence PCR Detection Kit	IVD OTHERS	IVD - Directive 98/79	RPS/584/2023	Registered with AEMPS	Reagent
Human Chorionic Gonadotropin(HCG) Rapid Test Kit(Colloidal Gold)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/46/2022	Registered with AEMPS	Test card
hs-CRP+CRP Rapid Test Kit (Colloidal Gold)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/46/2022	Registered with AEMPS	Test card
HPV Virus Stain Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/658/2024	Registered with AEMPS	Test card
HCG/LH Combo Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/2879/2023	Registered with AEMPS	Test card
H.pylori Antigen Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/4823/2022	Registered with AEMPS	Test card
Group A Streptococcus Antigen Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/956/2024	Registered with AEMPS	
Glycosylated Hemoglobin (HbA1c) Rapid Test Kit (Colloidal Gold)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/46/2022	Registered with AEMPS	Test card

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Product Name	CLASS	REGULATION	RPS	Status RPS	Model
Glycated Hemoglobin Detection Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/4823/2022	Registered with AEMPS	Reagent
FOB/TRF Combo Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/2879/2023	Registered with AEMPS	Test card
Fecal Occult Blood Rapid Test Kit (Colloidal Gold)	IVD OTHERS	IVD - Directive 98/79	RPS/584/2023	Registered with AEMPS	Test card
Eight Respiratory Pathogens Antigen Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/956/2024	Registered with AEMPS	
Dengue Antibody Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/4823/2022	Registered with AEMPS	Test card
D-Dimer Rapid Test Kit (Colloidal Gold)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/46/2022	Registered with AEMPS	Test card
cTnI/PCT/HS-CRP Rapid Test Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/2879/2023	Registered with AEMPS	Test card
COVID-19&Influenza A/B Real-Time Fluorescence PCR Detection Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/658/2024	Registered with AEMPS	Reagent
COVID-19/Influenza A/RSV Real-Time Fluorescence PCR Detection Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/658/2024	Registered with AEMPS	Reagent
COVID-19 Real-Time Fluorescence PCR Detection Kit Manual (lyophilized)	CLASS IVD OTHERS	IVD - Directive 98/83	RPS/543/2021	Registered with AEMPS	Reagent
COVID-19 Nucleic Acid Detection Kit (Fluorescence PCR )	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/46/2022	Registered with AEMPS	Reagent
COVID-19 Neutralizing Antibody Rapid Test Kit	CLASS IVD OTHERS	IVD - Directive 98/84	RPS/543/2021	Registered with AEMPS	Test card
COVID-19 Neutralizing Antibody ELISA Test Kit	CLASS IVD OTHERS	IVD - Directive 98/82	RPS/543/2021	Registered with AEMPS	Reagent
COVID-19 IgM ELISA Test Kit	CLASS IVD OTHERS	IVD - Directive 98/81	RPS/543/2021	Registered with AEMPS	Reagent
COVID-19 IgG ELISA Test Kit	CLASS IVD OTHERS	IVD - Directive 98/80	RPS/543/2021	Registered with AEMPS	Reagent
COVID-19 & Influenza A/B Antigen Combo Test Kit	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/543/2021	Registered with AEMPS	Test card
Cardiac Troponin I (cTnI) Rapid Test Kit (Colloidal Gold)	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/46/2022	Registered with AEMPS	Test card
Anti-Streptolysin "O" (ASO) Detection Kit	IVD OTHERS	IVDD - Directive 98/79	RPS/4823/2022	Registered with AEMPS	Reagent

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