



Hereby confirms that CMC Medical Devices & Drugs S.L. located in C/Horacio Lengo, 18, 29006, Málaga, Spain and with SRN ES-AR-000000293 is the Authorised Representative (EC REP) of

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

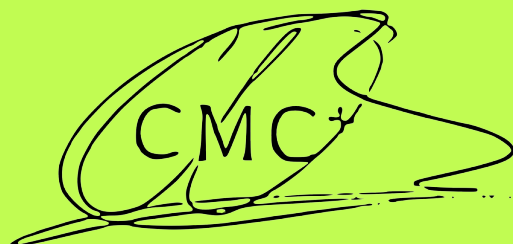
The certificate remains valid until the expiration date of the EC REP agreement or until manufacturing conditions, the quality system or relevant legislation are modified.

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

The product liability rests with the manufacturer in accordance with the applicable directive/regulation mentioned in Annex I of this certificate and the applicable standards.

After fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to the relevant models of the medical devices mentioned below.

The table in the Annex I lists, where applicable, the registration status with the Spanish MOH (AEMPS) and their registration number (RPS).



Issue date: 16 oct. 2024

Manuel Mateos
Chief Executive Officer



Expiration date: 8 dic. 2025
Certificate #: ECREP20241016.2
Ver: CERT-EC-2406
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ANNEX I

PRODUCT NAME	REGULATION	CLASS	MODEL OR REF	RPS	STATUS
Zilpaterol ELISA Test Kit	IVD - Directive 98/88	CLASS IVD OTHERS	M:Reagent	RPS/543/2021	Registered with AEMPS
Vitamin D3 Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2752/2024	Registered with AEMPS
Typhoid IgG/IgM Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/4823/2022	Registered with AEMPS
Transferrin Rapid Test Kit (Colloidal Gold)	IVD - Directive 98/79	IVD OTHERS	M:Test card	RPS/584/2023	Registered with AEMPS
Ten Respiratory Pathogens Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2752/2024	Registered with AEMPS
SP10 Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/658/2024	Registered with AEMPS
Seven Respiratory Pathogens Real-Time Fluorescence PCR Detection Kit	IVDD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/658/2024	Registered with AEMPS
Seven Respiratory Pathogens Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	R:	RPS/956/2024	Registered with AEMPS
SARS-CoV-2/RSV&Flu A/B Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/4823/2022	Registered with AEMPS
SARS-CoV-2/RSV/ADV&Flu A/B Antigen Rapid Test Kit	IVD - Directive 98/79	IVD OTHERS	M:Test card	RPS/584/2023	Registered with AEMPS
SARS-CoV-2/RSV/ADV/MP&Flu A/B Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2879/2023	Registered with AEMPS
SARS-CoV-2/RSV/ADV/MP/SP&Flu A/B Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/658/2024	Registered with AEMPS
SARS-CoV-2 antigen IVD kit SWAB	IVD - Directive 98/87	CLASS IVD OTHERS	M:Test card	RPS/543/2021	Registered with AEMPS
SARS-CoV-2 antigen IVD kit SALIVA	IVD - Directive 98/86	CLASS IVD OTHERS	M:Test card	RPS/543/2021	Registered with AEMPS
SARS-CoV-2 antigen IVD kit NASAL	IVD - Directive 98/85	CLASS IVD OTHERS	M:Test card	RPS/543/2021	Registered with AEMPS
SARS-CoV-2 Antigen IVD Kit Lollipop	IVD - Directive 98/79	CLASS IVD OTHERS	M:Test card	RPS/46/2022	Registered with AEMPS
Rheumatoid Factor Detection Kit	IVDD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/4823/2022	Registered with AEMPS





Procalcitonin Rapid Test Kit (Colloidal Gold)	IVD - Directive 98/79	CLASS IVD OTHERS	M:Test card	RPS/46/2022	Registered with AEMPS
NSI/Pf Antibody Combo Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2879/2023	Registered with AEMPS
Nine Respiratory Pathogens Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/1567/2024	Registered with AEMPS
Neisseria Gonorrhoeae Real-Time Fluorescence PCR Detection Kit	IVD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/584/2023	Registered with AEMPS
Myoglobin/ CK-MB/ Troponin I Combo Test Kit (Colloidal Gold)	IVD - Directive 98/79	IVD OTHERS	M:Test card	RPS/584/2023	Registered with AEMPS
Mycobacterium Tuberculosis Real-Time Fluorescence PCR Detection Kit	IVDD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/4823/2022	Registered with AEMPS
MOP/MET/KET Combo Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/658/2024	Registered with AEMPS
MOP/MET Combo Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/658/2024	Registered with AEMPS
Monkeypox Virus Real-Time Fluorescence PCR Detection Kit	IVD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/3800/2022	Registered with AEMPS
Monkeypox Virus IgM/IgG Antibody Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/4823/2022	Registered with AEMPS
Monkeypox Virus Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/4823/2022	Registered with AEMPS
MET/THC/AMP/MOP Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/658/2024	Registered with AEMPS
Influenza A/B and Respiratory Syncytial Virus Real-Time Fluorescence PCR Detection Kit	IVDD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/658/2024	Registered with AEMPS
Influenza A/B and Respiratory Syncytial Virus Real-Time Fluorescence PCR Detection Kit	IVDD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/658/2024	Registered with AEMPS
Human Papilloma Virus (HPV) Types 16 and 18 Real-Time Fluorescence PCR Detection Kit	IVD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/584/2023	Registered with AEMPS
Human Chorionic Gonadotropin(HCG) Rapid Test Kit(Colloidal Gold)	IVD - Directive 98/79	CLASS IVD OTHERS	M:Test card	RPS/46/2022	Registered with AEMPS



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hs-CRP+CRP Rapid Test Kit (Colloidal Gold)	IVD - Directive 98/79	CLASS IVD OTHERS	M:Test card	RPS/46/2022	Registered with AEMPS
HPV Virus Stain Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/658/2024	Registered with AEMPS
HCG/LH Combo Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2879/2023	Registered with AEMPS
H.pylori Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/4823/2022	Registered with AEMPS
Group A Streptococcus Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	R:	RPS/956/2024	Registered with AEMPS
Glycosylated Hemoglobin (HbA1c) Rapid Test Kit (Colloidal Gold)	IVD - Directive 98/79	CLASS IVD OTHERS	M:Test card	RPS/46/2022	Registered with AEMPS
Glycated Hemoglobin Detection Kit	IVDD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/4823/2022	Registered with AEMPS
FOB/TRF Combo Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2879/2023	Registered with AEMPS
Filariasis Antigen Rapid Test Kit			M:Test card		Pending: To be registered
Fecal Occult Blood Rapid Test Kit (Colloidal Gold)	IVD - Directive 98/79	IVD OTHERS	M:Test card	RPS/584/2023	Registered with AEMPS
Eleven Respiratory Pathogens Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2752/2024	Registered with AEMPS
Eight Respiratory Pathogens Antigen Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	R:	RPS/956/2024	Registered with AEMPS
Dengue Antibody Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/4823/2022	Registered with AEMPS
D-Dimer Rapid Test Kit (Colloidal Gold)	IVD - Directive 98/79	CLASS IVD OTHERS	M:Test card	RPS/46/2022	Registered with AEMPS
cTnl/PCT/HS-CRP Rapid Test Kit	IVDD - Directive 98/79	IVD OTHERS	M:Test card	RPS/2879/2023	Registered with AEMPS
COVID-19&Influenza A/B Real-Time Fluorescence PCR Detection Kit	IVDD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/658/2024	Registered with AEMPS
COVID-19/Influenza A/RSV Real-Time Fluorescence PCR Detection Kit	IVDD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/658/2024	Registered with AEMPS
COVID-19 Real-Time Fluorescence PCR Detection Kit Manual (lyophilized)	IVD - Directive 98/83	CLASS IVD OTHERS	M:Reagent	RPS/543/2021	Registered with AEMPS



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COVID-19 Nucleic Acid Detection Kit (Fluorescence PCR)	IVD - Directive 98/79	CLASS IVD OTHERS	M:Reagent	RPS/46/2022	Registered with AEMPS
COVID-19 Neutralizing Antibody Rapid Test Kit	IVD - Directive 98/84	CLASS IVD OTHERS	M:Test card	RPS/543/2021	Registered with AEMPS
COVID-19 Neutralizing Antibody ELISA Test Kit	IVD - Directive 98/82	CLASS IVD OTHERS	M:Reagent	RPS/543/2021	Registered with AEMPS
COVID-19 IgM ELISA Test Kit	IVD - Directive 98/81	CLASS IVD OTHERS	M:Reagent	RPS/543/2021	Registered with AEMPS
COVID-19 IgG ELISA Test Kit	IVD - Directive 98/80	CLASS IVD OTHERS	M:Reagent	RPS/543/2021	Registered with AEMPS
COVID-19 & Influenza A/B Antigen Combo Test Kit	IVD - Directive 98/79	CLASS IVD OTHERS	M:Test card	RPS/543/2021	Registered with AEMPS
Cardiac Troponin I (cTnI) Rapid Test Kit (Colloidal Gold)	IVD - Directive 98/79	CLASS IVD OTHERS	M:Test card	RPS/46/2022	Registered with AEMPS
Anti-Streptolysin "O" (ASO) Detection Kit	IVDD - Directive 98/79	IVD OTHERS	M:Reagent	RPS/4823/2022	Registered with AEMPS

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