

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

SIRIN DIAGNOSTICS

20/21 3rd Industrial Sector - 2nd cell - Plot E, Matahra Industrial City, Minia, Egypt

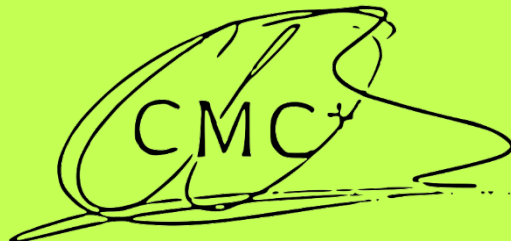
The certificate remains valid until the expiration date of the EC REP agreement or until manufacturing conditions, the quality system or relevant legislation are modified.

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: 18th of June 2025

Manuel Mateos

Chief Executive Officer



Expiration date: 15th of March 2026
Certificate #: ECREP20250618.1
Ver: CERT-EC-2407
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ANNEX I

PRODUCT NAME	REGULATION	CLASS	MODEL OR REF	RPS	STATUS
Gabapentin (GAB) Rapid Test Cassette (Urine)	IVDD - Directive 98/79	IVD OTHERS	M:SD-GAB-1 // R:SD-GAB-1	RPS/1313/2025	Registered with AEMPS
One Step Fecal Occult Blood Test Device (Feces)	IVDD - Directive 98/79	IVD OTHERS	M:SD-FOB-1 // R:SD-FOB-1	RPS/1313/2025	Registered with AEMPS
One step Calprotectin Semi- Quantitative Rapid Test Device (Feces)	IVDD - Directive 98/79	IVD OTHERS	M:SD-FCP-1 // R:SD-FCP-1	RPS/1313/2025	Registered with AEMPS
Pregabalin (PGB) Rapid Test Cassette (Urine)	IVDD - Directive 98/79	IVD OTHERS	M:SD-PGB-1	RPS/1313/2025	Registered with AEMPS
Siri Disc Antimicrobial Susceptability test Discs	IVDD - Directive 98/79	IVD OTHERS	M:SD-AK-01 SD- TPZ-01 SD-NA-01 SD-N-01 SD-F-01 SD-NOR-01 SD- OFX-01 SD-PEF- 01 SD-PRL-01 SD-P-01 SD-LEV- 01 SD-RA-01 SD- RA-02 SD-S-01 SD-TOB-01 SD- SXT-01 SD-VA-01 SD-MEM-01 SD- IPM-01 SD-AX-01 SD-AMC-01 SD- CXM-01 SD-ATM- 01 SD-ATM-02 SD-CFR-01 SD- CEP-01 SD-FOX- 01 SD-CL-01L 01 SD-GAT-01 SD- CN-01 SD-CE-01 SD-DA-01 SD- DA-02 SD-DO-01 SD-FL-01 SD- SAM-01 SD-CES- 01 SD-AZM-01 SD-E-01 SD-TE- 01 SD-CRO-01 SD-CIP-01 SD- CFM-01 SD-AM- 01 SD-CTX-01 SD-CEC-01 // R:SD-AK-01 SD-	RPS/1313/2025	Registered with AEMPS



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			TPZ-01 SD-NA-01 SD-N-01 SD-F-01 SD-NOR-01 SD- OFX-01 SD-PEF- 01 SD-PRL-01 SD-P-01 SD-LEV- 01 SD-RA-01 SD- RA-02 SD-S-01 SD-TOB-01 SD- SXT-01 SD-VA-01 SD-MEM-01 SD- IPM-01 SD-AX-01 SD-AMC-01 SD- CXM-01 SD-ATM- 01 SD-ATM-02 SD-CFR-01 SD- CEP-01 SD-FOX- 01 SD- CL-01L 01 SD-GAT-01 SD- CN-01 SD-CE-01 SD-DA-01 SD- DA-02 SD-DO-01 SD-FL-01 SD- SAM-01 SD-CES- 01 SD-AZM-01 SD-E-01 SD-TE- 01 SD-CRO-01 SD-CIP-01 SD- CFM-01 SD-AM- 01 SD-CTX-01 SD-CEC-01		
Sirin Diagnostic Troponin I rapid test cassette (WB/SERUM / PLASMA)	IVDD - Directive 98/79	IVD OTHERS	M:SD-CTnI-1 // R:SD-CtnI-1	RPS/1283/2023	Registered with AEMPS
Sirin Diagnostics (THC) Rapid Test Cassette (Urine)	IVDD - Directive 98/79	IVD OTHERS	M:SD-THC-1	RPS/1313/2025	Registered with AEMPS
Sirin Diagnostics (TRA) Rapid Test Cassette	IVDD - Directive 98/79	IVD OTHERS	M:SD-TRA-1	RPS/1313/2025	Registered with AEMPS
Sirin Diagnostics H. Pylori Ag Test Cassette	IVDD - Directive 98/79	IVD OTHERS	M:SD-H.PYLORI - AG-1 // R:SD-H.PYLORI -AG-1	RPS/1138/2022	Registered with AEMPS
Sirin Diagnostics H.Pylori Ab Test Cassette	IVDD - Directive 98/79	IVD OTHERS	M:SD-H.PYLORI- AB-1 // R:SD-H.PYLORI -AB-1	RPS/1138/2022	Registered with AEMPS
Sirin Diagnostics HAV IgG/IgM Rapid Test Device (Whole	IVDD - Directive 98/79	IVD OTHERS	M:SD-HAV-1 // R:SD-HAV-1	RPS/1313/2025	Registered with AEMPS



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blood/Plasma/Serum)					
Sirin Diagnostics HCG Pregnancy Test (Cassette)	IVDD - Directive 98/79	IVD OTHERS	M:SD-HCG-2 // R:SD-HCG-2	RPS/1138/2022	Registered with AEMPS
Sirin Diagnostics Malaria p.f rapid Test Device (whole Blood)	IVDD - Directive 98/79	IVD OTHERS	M:SD-MALARIA P.F-1 // R:SD- MALARIA PF-1	RPS/1283/2023	Registered with AEMPS
Sirin Diagnostics Multi-Drug Test Panel (THC,MOP,TRA,B ZO)	IVDD - Directive 98/79	IVD OTHERS	M:SD-DOA-4 // R:SD-DOA-4	RPS/1313/2025	Registered with AEMPS
Sirin Diagnostics Multi-drug screen test (COC, AMP, THC,MOP , TRA, BAR, BZO)	IVDD - Directive 98/79	IVD OTHERS	M:SD-DOA-7 // R:SD-DOA-7	RPS/1283/2023	Registered with AEMPS
Synthetic Cannabis Rapid (K2) Rapid Test Cassette (Urine)	IVDD - Directive 98/79	IVD OTHERS	M:SD-K2-1 // R:SD-K2-1	RPS/1313/2025	Registered with AEMPS
U-TEST PREGNANCY TEST	IVDD - Directive 98/79	IVD OTHERS	M:SD-HCG-1 // R:SD-HCG-1	RPS/4236/2022	Registered with AEMPS

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