



Ver: CERT-202303.V1

CERTIFICATE
ECREP20230614.1



CMC MEDICAL DEVICES & DRUGS S.L.

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

**Zhejiang QL Biotech Co., Ltd.
Room 501, Building 1#, 178# Chuangye Rd, Qingshanhu Sub-district, Lin'an
District, 311121, Hangzhou, 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.




Authorized Signature

Issue date: 14/06/2023

Expiration date: 06/05/2027

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

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ANNEX I

Product Name	REGULATION	CLASS	RPS	Status RPS	Model	REF
Typhoid/Para Typhoid Ag Rapid Test	IVDD - Directive 98/79	IVD OTHERS	RPS/2885/2022	Registered with AEMPS		
Typhoid Ag Rapid Test	IVDD - Directive 98/79	IVD OTHERS	RPS/2885/2022	Registered with AEMPS		
Typhoid Ab Rapid Test	IVDD - Directive 98/79	IVD OTHERS	RPS/2885/2022	Registered with AEMPS		
Tuberculosis Rapid Test (Whole Blood/ Serum/Plasma)	IVD - Directive 98/79	CLASS IVD OTHERS	RPS/859/2023	Registered with AEMPS	ITB-422	
Tuberculosis Rapid Test (Whole Blood/ Serum/Plasma)	IVD - Directive 98/79	CLASS IVD OTHERS	RPS/859/2023	Registered with AEMPS	ITB-421	
Troponin I Rapid Test (Whole Blood/ Serum/Plasma)	IVDR - Regulation 2017/746	IVD CLASS B		CE in progress	CTI-402	
TML One Step Tramado Rapid Test	IVDD - Directive 98/79	IVD OTHERS	RPS/2885/2022	Registered with AEMPS		
THC One Step Marijuana Rapid Test	IVDD - Directive 98/79	IVD OTHERS	RPS/2885/2022	Registered with AEMPS		
TCA One Step Tricyclic Antide pressants Rapid Test	IVDD - Directive 98/79	IVD OTHERS	RPS/2885/2022	Registered with AEMPS		
TB Rapid Test	IVDD - Directive 98/79	IVD OTHERS	RPS/2885/2022	Registered with AEMPS		
Syphilis Rapid Test (Whole Blood/Serum/ Plasma)	IVDR - Regulation 2017/746	IVD CLASS B		CE in progress	ISY-401	
Syphilis Rapid Test (Whole Blood/Serum/ Plasma)	IVDR - Regulation 2017/746	IVD CLASS B		CE in progress	ISY-402	

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