CERTIFICATE

ECREP20220523.13



Ver: CERT-202110.V1

CMC MEDICAL DEVICES & DRUGS S.L.

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

Hunan Runmei Gene Technology Co., Ltd. Room 401-1, Building 3, Shanhe Medical and Health Industrial Park, No. 1048, Zhongqing Road, Shaping Street, Kaifu District

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.



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Issue date: 23/05/2022

Expiration date: 26/04/2027





ANNEX I

Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido	Model
Anti-Cardiolipin Antibody IgA Chemiluminescent Immunoassay Kit	Others	IVDD	RPS/3303/2022	Yes	RM-E-G1538



Issue date: 23/05/2022 Expiration date: 26/04/2027