CERTIFICATE CERTIFICADO CERTIFIKAT CERTIFICAT 证书 자격증

EC REP

CERTIFICATE

ECREP20220525.23

Ver: CERT-202110.V1

CMC MEDICAL DEVICES & DRUGS S.L.

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

Healgen Scientific Limited Liability Company
3818 Fuqua Street, Houston, TX 77047, USA.

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.

CE

Authorized Signature

Issue date: 25/05/2022

Expiration date: 17/01/2027

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

Verification Code

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ANNEX I

Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluido
Rapid Monkeypox Virus DNA Test	IVD OTHERS	IVDD - Directive 98/79	RPS/3699/2022	Yes
One Step Multi-Drug Screen Test Cup (Urine)	IVD OTHERS	IVDD - Directive 98/79	RPS/3699/2022	Yes
Monkeypox Virus Detection Kit (Fluorescence PCR)	IVD OTHERS	IVDD - Directive 98/79	RPS/3699/2022	Yes
Monkeypox IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)	IVD OTHERS	IVDD - Directive 98/79	RPS/3699/2022	Yes
Monkeypox Antigen Rapid Test Cassette	IVD OTHERS	IVDD - Directive 98/79	RPS/3699/2022	Yes

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