



CERTIFICATE
ECREP20220718.2



Ver: CERT-202110.V1

CMC MEDICAL DEVICES & DRUGS S.L.

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

Testgene LLC
9, 44th Inzhenerny proyezd, office 13, Ulyanovsk,
432072, Russia

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.




Authorized Signature

Issue date: 18/07/2022

Expiration date: 14/04/2023

Verification Code

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



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ANNEX I

Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluir en Certificado	Model
Reagent Kit for Collection, Transportation and Extraction of DNA from Clinical Material	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/134/2022	Si	DNA-Fast
Kit for qualitative detection of mutations in the genes of the HRR system by multiplex real-time PCR with detection of melting curves in a sample of human genome DNA from clinacal material	CIASS IVD OTHERS	IVD - Directive 98/79	RPS/4502/2022	Si	HRR-screening
Kit for qualitative detection of mutations in the BRCA1,2 genes by multiplex real-time PCR with detection of melting curves	CIASS IVD OTHERS	IVD - Directive 98/79	RPS/4502/2022	Si	BRCA1,2-diagnosrics
Kit for qualitative detection of Coronavirus RNA (SARS-COV-2) by real-time PCR	CIASS IVD OTHERS	IVD - Directive 98/79	RPS/4502/2022	Si	COV-2-TEST
Kit for PCA3 mRNA detection and determination of its expression level based on two-step RT real-time PCR	CIASS IVD OTHERS	IVD - Directive 98/79	RPS/4502/2022	Si	Prosta-Test-12

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Product Name	CLASSIFICATION	REGULATION	RPS (AEMPS)	Incluir en Certificado	Model
Kit for human DNA isolation from formalin fixed paraffin embedded tissue	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/4502/2022	Sí	DNA-Tissue-M
Kit for fetal SRY gene detection in maternal blood	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/4502/2022	Sí	Test-SRY
Kit for DNA/RNA Extraction from Clinical Material	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/3/2022	Sí	NA-Extra
Kit for Circulating Free DNA Extraction from Blood Plasma	CLASS IVD OTHERS	IVD - Directive 98/79	RPS/2131/2021	Sí	DNA-Plasma-M-RT

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