

CMC MEDICAL DEVICES & DRUGS S.L.

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

Biomiga,Inc. 10637 Roselle St Ste C, 92121, San Diego, United States

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 reffers to their registration number.



Authorized Signature

Issue date: 12/06/2024 Expiration date: 14/11/2024

Ver: CERT-202303.V1



ANNEX I

Product Name	CLASS	REGULATION	RPS	Status RPS
Universal Pathogen DNA/RNA Extraction Kit, mini column based	Others	IVDD-Directive 98/79	RPS/1689/2024	Registered with AEMPS
STI trilex, CT/NG/TV, real time PCR detection kit	Others	IVDD-Directive 98/79	RPS/1689/2024	Registered with AEMPS
STI Panel Real Time PCR Detection Kit	Others	IVDD-Directive 98/79	RPS/1689/2024	Registered with AEMPS
RPP SC2 FluA&B, RSV A/RSV B 5-Plex real time PCR detection kit	Others	IVDD-Directive 98/79	RPS/1689/2024	Registered with AEMPS
Nail Funal Real Time PCR detection kit	Others	IVDD-Directive 98/79	RPS/1689/2024	Registered with AEMPS
Mycoplasma hominis/ Mycoplasma genitalium/ Ureaplasma urealyticum/ Ureaplasma parvum serovar 4- plex real time PCR detection kit	Others	IVDD-Directive 98/79	RPS/1689/2024	Registered with AEMPS
MgPure Universal Pathogen DNA/ RNA Purification Kit, magnetic beads based	Others	IVDD-Directive 98/79	RPS/1689/2024	Registered with AEMPS
Invasive Fungal Pathogen (IFP) Real Time PCR Assay	Others	IVDD-Directive 98/79	RPS/1689/2024	Registered with AEMPS
HPV Real Time PCR Detection Kit	Others	IVDD-Directive 98/79	RPS/1689/2024	Registered with AEMPS
Gastrointestinal panel real time PCR detection kit	Others	IVDD-Directive 98/79	RPS/1689/2024	Registered with AEMPS
Dengue Virus/ Zika Virus/ Plasmodium falciparum real time PCR detection kit	Others	IVDD-Directive 98/79	RPS/1689/2024	Registered with AEMPS

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