



CERTIFICATE
ECREP20221205.2



Ver: CERT-202110.V1

CMC MEDICAL DEVICES & DRUGS S.L.

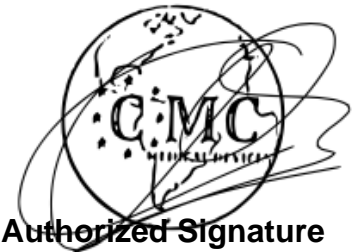
CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

Wellmien Healthcare Tech. (Suzhou) Co., Ltd.
1-3603, Global 188, No.88 Suhui Road, Suzhou Industrial Park,
Jiangsu, China, 215021

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.

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.



Issue date: 05/12/2022

Expiration date: 15/04/2026

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

Verification code



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ANNEX I

Product Name	REGULATION	CLASS	RPS	Status RPS
Type IIR Surgical Mask (MDR)	MDR - Regulation 2017/745	CLASS I	RPS/2666/2021	Registered with AEMPS
Sleeve cover (MDR)	MDR - Regulation 2017/745	CLASS I	RPS/2666/2021	Registered with AEMPS
Shoe cover (MDR)	MDR - Regulation 2017/745	CLASS I	RPS/2666/2021	Registered with AEMPS
Pillowcase (MDR)	MDR - Regulation 2017/745	CLASS I	RPS/2666/2021	Registered with AEMPS
PE Apron (MDR)	MDR - Regulation 2017/745	CLASS I	RPS/2666/2021	Registered with AEMPS
Emergency blanket (MDR)	MDR - Regulation 2017/745	CLASS I	RPS/2666/2021	Registered with AEMPS
Clothing (MDR)	MDR - Regulation 2017/745	CLASS I	RPS/2666/2021	Registered with AEMPS
Cap (MDR)	MDR - Regulation 2017/745	CLASS I	RPS/2666/2021	Registered with AEMPS
Bed Cover (MDR)	MDR - Regulation 2017/745	CLASS I	RPS/2666/2021	Registered with AEMPS
Beard Cover (MDR)	MDR - Regulation 2017/745	CLASS I	RPS/2666/2021	Registered with AEMPS
Bandage (MDR)	MDR - Regulation 2017/745	CLASS I	RPS/5386/2022	Registered with AEMPS

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