



**CERTIFICATE**  
ECREP20211220.15



Ver: CERT-202110.V1

## CMC MEDICAL DEVICES & DRUGS S.L.

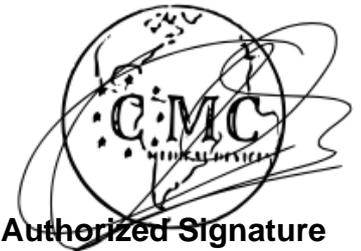
CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of

**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). The column categorized as RPS refers to their registration number.



Issue date: 20/12/2021

Expiration date: 15/04/2026





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### ANNEX I

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

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