

CMC MEDICAL DEVICES & DRUGS S.L.

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

Hangzhou Jucheng Medical Products Co., Ltd 3rd floor, building 1, No.8 Mingyuan Road, Gaohong Town, Lin'an District, Hangzhou City, Zhejiang Province

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 reffers to their registration number.



Authorized Signature

Issue date: 14/12/2023 Expiration date: 30/12/2024

Verification code



Ver: CERT-202110.V1



ANNEX I

| Product Name | REGULATION | CLASS | Model | RPS | Status RPS |
|---|--------------------------|------------------------|-------|---------------|-----------------------|
| SARS-CoV-2 Ag Rapid Test Kit | IVD - Directive 98/79 | CLASS IVD OTHERS | | RPS/28/2021 | Registered with AEMPS |
| SARS-CoV-2 / Influenza Virus A/B Antigens Multiple Detection Kit | IVD - Directive 98/79 | CLASS IVD OTHERS | | RPS/28/2021 | Registered with AEMPS |
| MOP/MET/ KET/MDMA/ COC/THC Multiple Drugs Rapid Test Kit | IVD - Directive 98/79 | CLASS IVD OTHERS | | RPS/5282/2022 | Registered with AEMPS |
| MOP/MET/ KET Rapid Test Kit (Hair) | IVD - Directive 98/79 | CLASS IVD OTHERS | | RPS/5282/2022 | Registered with AEMPS |
| Monkeypox Virus (MPV) Antigen Rapid Test Kit | IVD - Directive 98/79 | CLASS IVD OTHERS | | RPS/4447/2022 | Registered with AEMPS |
| Monkeypox Virus (MPV) Antibody Rapid Test Kit | IVD - Directive 98/79 | CLASS IVD OTHERS | | RPS/4447/2022 | Registered with AEMPS |
| Methcathinone Rapid Test Kit | IVD - Directive 98/79 | CLASS IVD OTHERS | | RPS/5282/2022 | Registered with AEMPS |
| Fentanyl and Its Derivatives Rapid Test Kit | IVD - Directive 98/79 | CLASS IVD OTHERS | | RPS/5282/2022 | Registered with AEMPS |
| COVID-19 Neutralizing Antibody Detection Kit | IVD - Directive 98/79 | CLASS IVD OTHERS | | RPS/28/2021 | Registered with AEMPS |
| Malaria pf/pan Rapid Test Kit | IVD - Directive 98/79 | CLASS IVD OTHERS | | RPS/5282/2022 | Registered with AEMPS |

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