

CERTIFICATE OF CONFORMITY



Certificate Number: UNICO20260126SE01

Test Report no. TZSHZH260126G01

Holder of Certificate:

Name	Sichuan Shuer Medical Devices Co, Ltd
Address	No. 2, Building 37, Haowang Electromechanical & New Materials Industrial Park, No. 24 Jinle Road, Chengdu-Aba Industrial Concentration Development Zone, Jintang County, Chengdu City, Sichuan Province, P.R.China

European Representative:

Name: HUMISS TRADING S. L. Add: Calle Luis Buñuel 12, Madrid, 28018, Spain

SRN: ES-AR-000040177

The submitted sample of the above product has been tested for CE marking according to the following European Directives:

Regulation (EU) 2017/745 on Medical Devices (MDR)

Standard(s) used for showing compliance with the essential requirements in the specifies directive(s):

Product:	medical mask
Model:	N95 mask/KN95 mask/flat mask/3D mask/FFP2 cup shape mask/surgical mask/protective mask
Conformity Assessment procedure:	Annex II +III of Regulation (EU) 2017/745 on Medical Devices
Classification acc. to MDR Ax. VIII:	Class I, Non-sterile, No measuring function(Annex VIII, Rule 1)
Reference standards:	EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, ISO 15223-1:2021/Amd.1:2025, EN 62366-1:2015, EN ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021

Based on our assessment we confirm that the product is in accordance with the technical requirements of the above standards and hence fulfils the technical requirements of the **Regulation (EU) 2017/745 on Medical Devices (MDR)** The manufacturer shall affix the CE marking to each product that is in conformity with those described in this Certificate, after completion of the EC Declaration of Conformity and in accordance with the above directive.

Issue Date: January 26, 2026

Expiry Date: January 26, 2031



RENOWS CERTIFICATION TESTING CO., LTD

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Signature of Authorized Person: Jacqueline Marti

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Jacqueline Marti

