Ficha técnica- Mascarilla FFP2 JIAYUAN

NUMERO DEL TEST REPORT: 4Q200407M.SJTUT57; OHC8621

1. Datos del Producto

Nombre del producto	Respirador antipartículas con filtro autocebante
Modelo	No-estéril, Elástico para oreja
Especificación	Tamaño plegado15.5*10.6CM(+-0.5CM) 50 unidades/caja
Normativa	GB2626-2006; EN149:2001+A1:2009
Ingredientes principales	Tela no tejida Tela Melt-blown
Fecha de caducidad	24 meses

2. Elementos de prueba

Elemento de prueba	Requisito	Resultado
Eficiencia de filtración	≥95.00%	99.50
Resistencia Inspiratorio ［PA］	≤350	104.63
Resistencia a la exhalación	≤250	106.60
Resistencia respiratoria-Exhalación(160L/min)	≤3.0	Aprobado

嘉远科技

MascarillasprotectorasFFP2

Certificate – Сертификат – 證明書 – Certificat – 인증서 – شهادة

form QAT_10-M04, version 00, effective since March 4th, 2020

Certificate of Compliance

No. 4Q2200407M.SJTUT57

Technical Construction file no. TCF20C0027FEA3F

Certificate's Holder:	Shenzhen Jiayuan Technology Industry Co., Ltd. 305, Building 5, No. 1 Sanhe Road, Gaofeng Community, Dalang Street, Longhua District, Shenzhen, Guangdong, China
Certification ECM Mark:	Type Approved
Product:	Disposable Face Mask
Model(s):	KN95, N95 (Protection Level: FFP2)
Verification to:	Standard: EN149:2001+A1:2009
	related to CE Directive[s]: R 2016/425 (Personal Protective Equipment)

Remark: The document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

CE

The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a Notified Body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.emtecermo.it

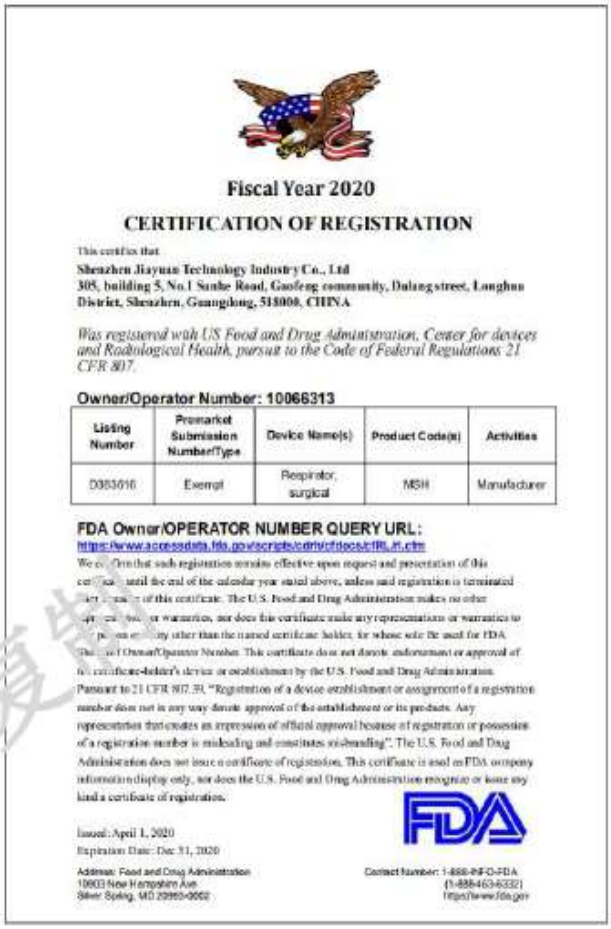
Issuance date: 07 April 2020

Expiry date: 06 April 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bo

Ente Certificazione Macchine Srl
Via Col' Bello, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) - ITALY
+39 051 6703141 | +39 051 6703156 | info@emtecermo.it | www.emtecermo.it



Fiscal Year 2020

CERTIFICATION OF REGISTRATION

This certifies that

Shenzhen Jiayuan Technology Industry Co., Ltd
305, building 5, No.1 Sanhe Road, Gaofeng community, Dalang street, Longhua District, Shenzhen, Guangdong, 518000, CHINA

Was registered with US Food and Drug Administration, Center for devices and Radiological Health, pursuit to the Code of Federal Regulations 21 CFR 807.

Owner/Operator Number: 10066313

Listing Number	Premarket Submission Number/Type	Device Name(s)	Product Code(s)	Activities
D383016	Exempt	Respirator, surgical	MSH	Manufacturer

FDA Owner/OPERATOR NUMBER QUERY URL:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm

We certify that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated [illegible] of this certificate. The U.S. Food and Drug Administration makes no other [illegible] warranties, nor does this certificate make any representations or warranties to [illegible] any other than the named certificate holder, for whose sole [illegible] for FDA [illegible] Owner/Operator Number. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding". The U.S. Food and Drug Administration does not issue a certificate of registration. This certificate is used on FDA company information display only, nor does the U.S. Food and Drug Administration recognize or issue any kind a certificate of registration.

FDA

Issued: April 1, 2020
Expiration Date: Dec 31, 2020

Address: Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

Contact Number: 1-888-INFO-FDA
(1-888-463-6332)
https://www.fda.gov

嘉远科技

MascarillasprotectorasFFP2