Mascarilla Quirúrgica Tipo II

4SAF-e BLACK

DESCRIPCIÓN - REFERENCIA: MK003

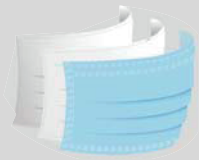
MASCARILLA QUIRÚRGICA TIPO II - Color: Negro

Marcado CE:	UNE 14683:2019
Eficacia de la filtración bacteriana* (BFE) (%):	≥ 98 %
Limpieza microbiana:	< 18 CFU/g
Respirabilidad: Presión diferencial* (Pa/cm2):	< 40 Pa/cm2
Resistencia a las salpicaduras:	≥ 16 kPa

MATERIAL

- Composición:
  100% Polipropileno
  Spun-bonded no tejido
  Melt-blown no tejido

- Cuatro capas de filtración:



CARACTERÍSTICAS

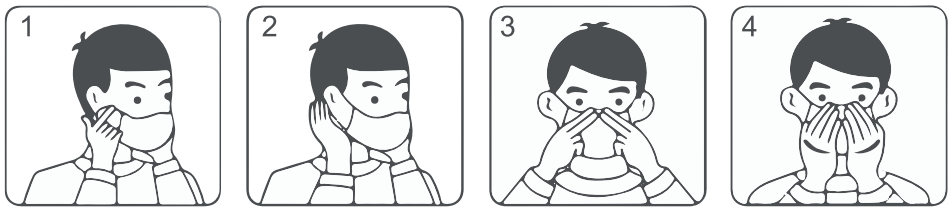
- No estéril y libre de látex. Material hipoalergénico.
- Bandas elásticas resistentes y flexibles.
- Mascarilla pre-formada, con clip nasal, que permitirá un ajuste fácil y rápido.
- Capa interior suave en contacto con la piel.

PRECAUCIONES DE USO

- Cada mascarilla solo puede usarse una vez y debe destruirse después de su uso.
- Prohibido el uso de mascarillas con embalaje dañado o caducado.
- Las personas alérgicas a los materiales de la mascarilla tienen prohibido su uso.
- Uso recomendado: 4 horas.

INSTRUCCIONES DE USO

Asegúrese de que el paquete esté completo,y la mascarilla dentro de la fecha de caducidad.
1.- La cara negra es la exterior. Coja las bandas elásticas con las dos manos. 2.- Posicionar contra la barbilla, colocar las bandas elásticas detrás de las orejas y ajustar. 3.-Presione hacia abajo el clip de la nariz y ajuste a una posición cómoda. 4.- Compruebe el correcto sellado de la mascarilla con las dos manos. 5- Deseche la mascarilla después de su uso.



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CIF A78659398 C/ Vereda de los Barros, 14-B | 28925, Alcorcon, Madrid, Spain | Tlf. +34 91 632 4035 | Fax. +34 91 632 6054

PANTONE P PROCESS BLACK C

PANTONE: 2758 C

Indicaciones de uso

1. Mascarilla quirúrgica destinada a cubrir la boca y la nariz para proteger a los pacientes de agentes infecciosos, y proteger al usuario de la transmisión a través del aire durante la cirugía o el examen del paciente. De un solo uso. No estéril
2. Deben usarse por el personal médico para el aislamiento en la atención general, no para el aislamiento de enfermedades infecciosas del tracto respiratorio.No usar si el embalaje esta dañado o caducado.

Precauciones de uso

1.Cada mascarilla solo puede usarse una vez.
2.Las personas alérgicas a los materiales de la mascarilla tienen prohibido su uso.
3.No usar la mascarilla frente a agentes químicos, ni cerca de llamas.
4.Una vez usada debe de ser desechada de acuerdo con los requisitos de protección ambiental después del uso.

Condiciones de almacenaje

1.Mantener almacenado en un lugar seco y ventilado, sin gas corrosivo,a una temperatura no superior a 50ºC. Con una humedad que no exceda el 80%.
2.Valida por dos años.

NºLote / Batch nº:
Fecha de fabricación / Manufacture date:
Válido hasta / Valid until:

Uso del producto

1.La cara negra es la exterior.Coja las bandas elásticas con las dos manos. 2.Posicionar contra la barbilla, colocarlas bandas elásticas detrás de las orejas y ajustar. 3.Presione hacia abajo el clip de la nariz y ajuste a una posición cómoda. 4.Compruebe el correcto sellado de la mascarilla con las dos manos.

Versión etiqueta: noviembre 2020

HECHO EN CHINA

4SAF-e

4SAF-e

Fabricado por / Produced by:
Fujian Suka Food Co., Ltd.
Nº29, Lima Road, Wuli Economic Development Zone (Wuli YUAN), Jinjiang City, Fujian, China

EC REP
European Authorized Representative:
CMC Medical Devices & Drugs S.L.
Horacio Lengo nº 18, CP 29006, Málaga, España

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C/ Vereda de los Barros, 14-B 28925,
Alcorcón, Madrid, España, CIF A78659398.

Standard: EN 14683:2019+AC:2019 TIPO IIR
Material: 100% Polipropileno
71% Spun-bonded no tejido
29% Melt-blown no tejido
Talla: Única
Modelo: MK003
Uso recomendado: Máx 4h.

Eficacia de la filtración bacteriana (BFE) (%) ≥ 98%

4SAF-e BLACK

MASCARILLA QUIRÚRGICA TIPO II

DISPOSABLE SURGICAL MASK. TYPE II

CE EN 14683:2019+AC:2019

MD

NON STERILE

Medidas del producto: 17,5 cm x 9,5 cm

25 PCS

5 cm

10 cm

20 cm

EC REP CERTIFICATE

CMC MEDICAL DEVICES & DRUGS SL
NO. CMC/CE/2020/30072020.4

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

Fujian Suka Food Co., Ltd

No.29 lima Road , Economic Development Zone(Wuliyuan) , Jinjiang City , Quanzhou City , Fujian Province , P.R.China

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 and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

The products in Annex I was registered in Spanish MOH with number **RPS/1843/2020**

CE

Issued on: 30/07/2020

Valid until: 29/07/2021

Authorized Signatory
CMC Medical Devices & Drugs SL

EC REP CERTIFICATE

ANNEX I Medical Device Products

Disposable Medical Mask

CE

EU Declaration of Conformity

Manufacturer:	Fujian Suka Food Co., Ltd. No.29 lima Road , Economic Development Zone （Wuliyuan） ,Jinjiang City Quanzhou City , Fujian Province , P.R.China Tel:+86-13506951998
SRN:	/
European Representative:	CMC Medical Devices & Drugs S.L. Horacio Lengo Nº 18, CP 29006, Málaga, Spain
SRN:	
Product Name:	Disposable Medical Mask
Model:	MK001,MK002,MK003
Produce Type	II
Specification:	17.5cm×9.5cm（±5%),14.5cm×9.5cm（±5%）
UMDN Code:	12-458

Classification (MDR, Annex VIII): Class I, Rule 1.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.
Fujian Suka Food Co., Ltd.is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:
EN 14683:2019+AC:2019, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, ASTM D4169-2016, MDCG 2019-15.

Signature:

Name:

Position: General Manager

Place/date JinJiang, Quanzhou City, Fujian Province/2020-8-12

Test Report

(Electronic version)

Verification Code: KDQH-7272-04
Verification Website: www.gttc.net.cn

No:20R005154 Issue Date: 2020-08-15

Applicant: FUJIAN SUKA FOOD CO.,LTD
Address: NO.29 LIMA ROAD,ECONOMICDEVELOPMENT ZONE (WULIYUAN),JINJIANG CITY, FUJIAN PROVINCE,P.R.CHINA

Information confirmed by applicant:

Disposable medical mask

Quantity: 60 pieces

Brand: Molex Knight

Lot number: MK003

Model: 17.5cm×9.5cm

Classification: Type Ⅱ

Manufacture's name: FUJIAN SUKA FOOD CO.,LTD

Standard Adopted:

EN 14683:2019+AC:2019 <Medical face masks-Requirements and test methods>

Date Received/Date Test Started: 2020-08-06

Conclusion:

Bacterial filtration efficiency (BFE)	M
Microbial cleanliness	M
Differential pressure	M

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "---"-No comment

Remark:
This report is the english translation version of the report 20R005153.
All the tested items are tested under the standard condition (except for indication).
Copies of the report are valid only re-stamped.
The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.

Approved By: Zishan Guo

ZiShan Guo Senior Engineer

Guangzhou Inspection Testing and Certification Group Co.,Ltd. Inspection & Testing services

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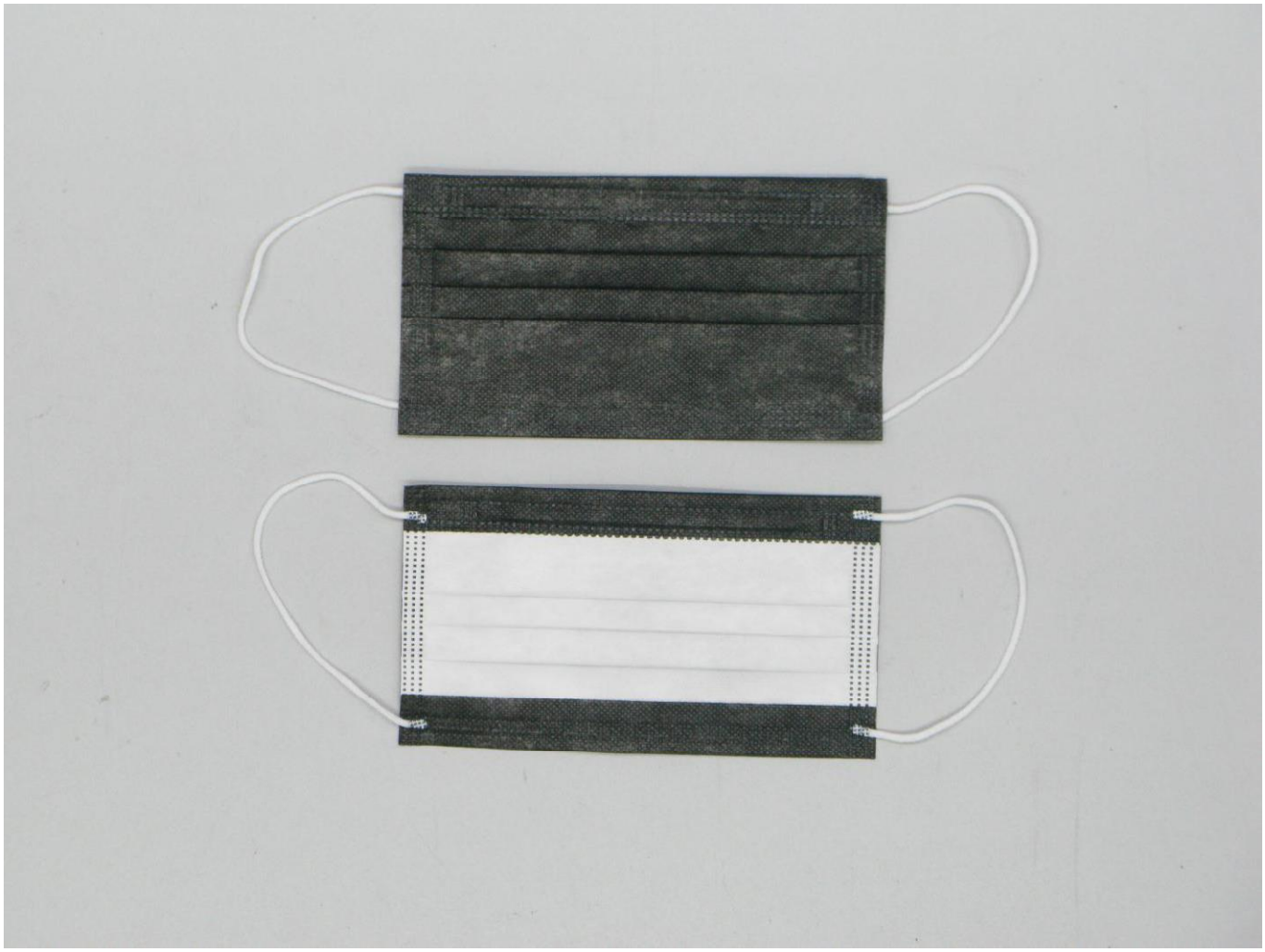
Test Report

(Electronic version)

No: 20R005154



总部:广州市番禺区珠江路1号
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电话:020-61994598/61994599
电话:020-37721161/66348638

Test Report

(Electronic version)

No: 20R005154

Bacterial filtration efficiency (BFE)
Test method: EN 14683: 2019+AC: 2019 Annex B

Test principle:
A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency (BFE) of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test equipment:
Incubator
Electronic balance
Autoclave
Experimental system for bacterial filtration efficiency (BFE) of mask

The environmental conditions of the laboratory and test condition:
Total bacteria: 0 CFU/plate
Total fungi: 0 CFU/plate
Blank experiment: Aseptic growth
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Culture medium: TSA agar medium
Culture temperature: 37℃， Culture time: 48h
Test bacteria : staphylococcus aureus ATCC 6538
Concentration of bacterium: 5.0×10^{5} CFU /ml
Positive control average (C): 1.9×10^{3} CFU
Negative monitor count: ＜1 CFU
Test area: 49 cm^{2}
Dimensions of the test specimens: 15cm×15cm
Flow rate: 28.3 l/min
Pretreatment: Condition each specimen for 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%
Mean particle size: 3.0 μm
The medical face mask in contact with the bacterial challenge: inside

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Test Report

(Electronic version)

No: 20R005154

Results:

Sample	T	BFE (%)	Requirement (%)	Classification	Conclusion
1	8	99.58	≥98 EN 14683:2019+AC:2019	Type Ⅱ	Pass
2	6	99.68			
3	12	99.37			
4	5	99.74			
5	7	99.63			

Remarks:

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

$B = (C - T) / C \times 100$

where

B is bacterial filtration efficiency (BFE), %;

C is positive control average;

T is the total plate count for the test specimen.

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Inspection & Testing services

Test Report

(Electronic version)

No: 20R005154

Microbial cleanliness
Test method: EN ISO 11737-1:2018, Membrane filtration

Test principle:
Take the required samples from the original packaging. Weigh a certain amount of sample and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l Tween 20). The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45 µm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) for fungi enumeration. The plates are incubated for 3 days at 30℃ and 7 days at (20 to 25)℃ for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts.

Test equipment:
Constant temperature incubator
Electronic balance
Pressure steam sterilizer
Biosafety cabinet

The environmental conditions of the laboratory and test condition:
Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth

Guangzhou Inspection Testing and Certification Group Co.,Ltd.
Inspection & Testing services

Test Report

(Electronic version)

No: 20R005154

Results:

Sample	Weight (g)	Bacteria (CFU per mask)	Fungi (CFU per mask)	Microbial cleanliness (CFU per mask)	Microbial cleanliness (CFU/g)	Requirement (CFU/g)	Classification	Conclusion
1	3.4	13	6	19	6	≤30 EN 14683:2019+AC:2019	Type Ⅱ	Pass
2	3.4	15	7	22	6			
3	3.3	14	8	22	7			
4	3.3	13	7	20	6			
5	3.4	13	6	19	6			

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Test Report

(Electronic version)

No: 20R005154

Differential pressure

Test method: EN 14683:2019+AC:2019 Annex C

Test principle:

This procedure was performed to evaluate the differential pressure of the medical face mask material by measuring the air exchange pressure through a measured surface area at a constant air flow rate.

Test equipment:

GTTC-YLC-1 Apparatus for measuring differential pressure

The environmental conditions of the laboratory and test condition:

Air flow: 8 l/min

Test area: 4.9cm^2

Pretreatment: Condition each specimen for a minimum of 4 h by exposure to a temperature of (21±5)℃ and a relative humidity of (85±5)%

Test location: Top left, Bottom left, Middle, Top right and Bottom right

Test Report

(Electronic version)

No: 20R005154

Results:

Sample		1	2	3	4	5	Requirement (Pa/cm²)	Classification	Conclusion
Measured value (Pa)	Top left	191	176	156	181	178	＜40 EN 14683:2019+AC:2019	Type Ⅱ	Pass
	Bottom left	183	198	189	176	178			
	Middle	203	192	157	177	208			
	Top right	189	140	156	154	190			
	Bottom right	185	153	140	142	184			
	Average	190	172	160	166	188			
Differential pressure (Pa/cm²)		38.8	35.1	32.7	33.9	38.4			

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———End of Report———

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