SMART MEDIC

24 rue Feydeau
75002, Paris
FRANCE
18ret 88304048700018
TVA FR63883040487

MASQUE MÉDICAL
TYPE IIR
NORME EN14683
CERTIFIÉ CE

NORME EN14683 : 2019
CERTIFIÉ CE

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DESCRIPTIF

- Masque médical non tissé(70%) et tissu fondu (30%)
- 3 couches de protection
- Taille 17,5cm x 9,5cm
- Fixation par boucles élastiquées
- Efficacité de filtration bactérienne >98 %
- Couleur bleue

SMART MEDIC

CERTIFICAT DE CONFORMITÉ

Nom du produit: Masque facial médical jetable (non stérile)

Spécification: élastique,Taille de Masque:17.5x9.5cm

Norme exécutive:EN14683:2019

Contenu des ingrédients: 70% de tissu non tissé , 30% de tissu soufflé par fusion

Numéro de lot de production: 25004230

Date de production: 2020-10-14

Date d'expiration: 2022-10-13

Conditions de stockage:Stocker dans un environnement ventilé et sec pour éviter l'humidité et la moisissure.

Quantité : 50 pieces

Numéro d'employé de l'inspection de la qualité: QC01

PASS

QC Dept

Fabricant: GUANGDONG KINGFA SCI.& TECH. CO.,LTD.

Adresse du fabricant: 28 DeLong Avenue, shikok Town, Qingcheng District, Qingyuan City, Guangdong ProvinceProvince du Shandong, Chine.

LE PRODUIT A RÉUSSI LE TEST, POUR ÊTRE AUTORISÉ À QUITTER L'USINE

PRODUCT CERTIFICATE
合 格 证

Product Name: Disposable medical face mask (Non sterile)

Specification : Ear-loop 17.5x9.5cm

Executive standard: EN14683:2019

Content : 70% Non Woven Fabric,30% Melt-Blown cloth

Production Lot No : 25004230

Production Date : 2020-10-14

Expiration Date : 2022-10-13

Storage conditions:store in a dry and ventilated environment to avoid moisture and mildew

Number of products: 50 Pcs

Inspection No.: QC01

PASS

QC Dept

Maufacturers: GUANGDONG KINGFA SCI.& TECH. CO.,LTD.

Manufacturer address : NO.28, Delong Avenue,Shijiao Town, QingchengDistrict,Qingyuan City,Guangdong Province,China.

TheProduct passed the test,to be permitted to leave the factory

COVID–19

CONSIGNES D' UTILISATION

AVERTISSEMENT

Pour prot é ger votre sant é et celle des autres, il est important de respecter ces consignes d'utilisation.

–Portez ce quand vous ê tes en contact avec d'autres personnes que celles avec lesquelles vous vivez.

–Vérifiez toujours que le masque est bien ajust é et couvre votre bouche et votre nez.

–Ce masque ne remplace pas les gestes barri è res (lavage r é gulier des mains, distanciation physique, r é duction des contacts avec d'autres personnes). Il ajoute une barri è re physique, à utiliser notamment lorsque vous ê tes en contact é troit avec d'autres personnes.

Comment mettre mon masque chirurgical?

Comment mettre mon masque

Je me lave les mains | Je tourne mon masque dans la bonne direction (bord rigide en haut, face blanche vers moi) | J'attache le haut de mon masque | Je pince le bord rigide pour l'ajuster à mon nez | J'attache le bas de mon masque | Pour le retirer je ne touche que les attaches | Je jette mon masque et je me lave les mains

Avant de le mettre :

01. Avant de toucher le masque, lavez-vous les mains avec de l' eau et du savon ou une solution hydro-alcoolique.
02. Inspectez le masque et assurez-vous qu' il n' y a pas de trous, d é chirure ou d é gradations.
03. Il est recommand é de porter le masque sur une peau nue, en é vitant le contact avec les cheveux.
04. Ne modifiez jamais le masque de quelque façon que ce soit.

Pour le mettre :

01. Tournez le masque dans la bonne direction (bord rigide en haut, face blanche vers vous).
02. Posez-le sur votre visage
03. Faites passer les boucles autour de vos oreilles (masques à boucles aux oreilles), ou attachez la partie sup é rieure (masque à lani è res é lastiques ou à attaches à nouer en haut et en bas)
04. Ajustez la bande pour le nez.
05. Attachez la partie inf é rieure si n é cessaire (masques à lani è res é lastiques ou à attaches à nouer en haut et en bas).
06. Ajustez le masque de façon à recouvrir le nez, la bouche et que le bord inf é rieur recouvre votre menton.

Lorsque vous le portez :

01. Evitez de le toucher et de le d é placer.
02. Ne le mettez jamais en position d' attente sur le front ou sur le menton.

Il faut changer le masque :

01. Quand vous avez port é le masque 4 h.
02. Quand vous souhaitez boire ou manger.
03. Quand il devient difficile de respirer.
04. Si le masque s' humidifie.
05. Si le masque est endommag é.
06. Si le masque est d é form é et ne tient plus correctement contre votre visage.

Pour l' enlever :

01. Lavez-vous les mains avec de l' eau et du savon ou de la solution hydro-alcoolique.
02. D é crochez les lani è res pour d é coller le masque de votre visage ou d é nouez les nœuds, puis enlevez le masque en le maintenant par les attaches du haut.
03. Vous ne devez l' enlever qu' en touchant les bords, les attaches ou les boucles. Ne touchez pas la partie qui couvre votre bouche et votre nez.
04. Jetez-le tout de suite dans une poubelle qui se ferme.
05. Pour terminer : lavez-vous à nouveau les mains avec de l' eau et du savon ou de la solution hydro-alcoolique.

Ne pas r é utiliser — Jeter le masque dans une poubelle ferm é e apr è s usage (4h)

Put the masks in a closed bag after use (4h).

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EU Declaration of Conformity

according to the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

***Class I** Medical Device*

(non-sterile)

Manufacturer:	GUANGDONG KINGFA SCI.&TECH. CO., LTD.
Address:	No.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Single Registration Number (SRN) of the Manufacturer:	--
European Representative (ER):	Share Info GmbH
Address:	Heerdter Lohweg 83, 40549 Düsseldorf
Single Registration Number (SRN) of ER:	DE-AR-000005132

We, the manufacturer, declare under our sole responsibility that

the medical device(s)	**Product Name:**	Medical surgical mask
	Type/model, identification of product allowing traceability (Where applicable):	KF-C P01(R), KF-B P01(R), KF-K P01(R), KF-IP01(R), KF-B P01(R-BD), KF-L P01(R), KF-J P01(R), KF-B P08(R), KF-B P09(WK), KF-B P06(R), KF-B P06B(R)
	Intended Purpose:	Medical surgical masks providing barrier to minimize the direct transmission of infective agent between staff and patients are principally intended for use by healthcare professionals in an operating room and other medical settings with similar requirements, additionally, protect the wearer against splashes of potentially contaminated liquids. This is a single-use, non-sterile device.
	Classification: (Annex VIII of the MDR)	Class I Medical Device
	Basic UDI-DI:	KF-C P01(R): 697316340KF-CP01(R)83 KF-B P01(R): 697316340KF-BP01(R)7J KF-K P01(R): 697316340KF-KP01(R)CB KF-I P01(R): 697316340KF-IP01(R)B9 KF-B P01(R-BD): 697316340KF-BP01(R-BD)W4 KF-L P01(R): 697316340KF-LP01(R)CU KF-J P01(R): 697316340KF-JP01(R)BS KF-B P08(R): 697316340KF-BP08(R)93 KF-B P09(WK): 697316340KF-BP09(WK)TB KF-B P06(R): 697316340KF-BP06(R)8M KF-B P06B(R): 697316340KF-BP06B(R)R8
Conformity assessment route:		EU Declaration of Conformity + Technical Documentation (Annex II) + Technical Documentation on Post-Market Surveillance (Annex III)

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is/are in conformity with the relevant provisions and requirements of the Council and the parliament regulation (EU) 2017/745 for medical device and all applicable harmonized standards and Common Specification. All supporting documents are retained under the premises of the manufacturer.

Applied harmonized standards and Common Specification	Regulation (EU) 2017/745	EN 14683: 2019+AC: 2019
	EN ISO 10993-1: 2018	EN 1041: 2008
	EN ISO 10993-5: 2009	EN ISO 14971: 2019
	EN ISO 10993-10: 2010	EN ISO 15223-1: 2016
	EN ISO 13485: 2016	EN 62366-1:2015
	MEDDEV 2.7.1: 2016	
Notified Body:	Not Applicable	
Address:	Not Applicable	
Identification Number:	Not Applicable	
EC Certificate(s):	Not Applicable	

Signed on: Place: Qingyuan, China

2021-6-2

Signature (on behalf of the manufacturer) : GUANGDONG KINGFA SCI.&TECH CO., LTD.

Name of authorized signatory: Linanjing

Position held in the company: General Manager

CE

GUANGDONG KINGFA SCI.&TECH.CO.,LTD.
NO.28 DELONG AVENUE, SHIJIAO TOWN, QINGCHENG DISTRICT, QINGYUAN CITY, GUANGDONG PROVINCE, CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Disposable medical mask/Medical surgical mask
Composition	:	(A)Polypropylene
Sample Color	:	(A)Blue
Style No.	:	KF-B P01(R)
Lot No.		25004230
Manufacturer	:	GUANGDONG KINGFA SCI.&TECH.CO.,LTD.
Country of Destination	:	European Union
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Oct 13, 2020
Testing Period	:	Oct 13, 2020 - Oct 26, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Helen Xuan (Authorized Signatory)

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Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial Filtration Efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~171mm x 155mm
Positive Control Average	:	2582 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.7%
	2	99.8%
	3	99.8%
	4	99.9%
	5	99.8%

Remark:
1) Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.3 Breathability
(EN 14683 :2019+AC:2019 Annex C)

Sample: A
Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Area : 4.9 cm^2
Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm^2)	The average value for each test specimen (Pa/cm^2)
1	1-1	38.9	34
	1-2	38.3	
	1-3	29.4	
	1-4	32.4	
	1-5	32.2	
2	2-1	32.8	31
	2-2	31.4	
	2-3	30.6	
	2-4	29.6	
	2-5	32.6	
3	3-1	28.2	30
	3-2	29.2	
	3-3	32.0	
	3-4	30.7	
	3-5	27.6	
4	4-1	35.4	32
	4-2	34.1	
	4-3	33.2	
	4-4	30.0	
	4-5	29.2	
5	5-1	35.5	32
	5-2	35.0	
	5-3	31.2	
	5-4	28.6	
	5-5	29.9	

Remark:
1) Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.4 Splash Resistance
(ISO 22609 :2004)

Sample: A
Test Blood Pressure : 16.0kPa
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Distance of the mask to the tip of cannula : 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:		32			
Overall result:		Acceptable			

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Test was conducted within 60s after removal from conditioning chamber.
3) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.

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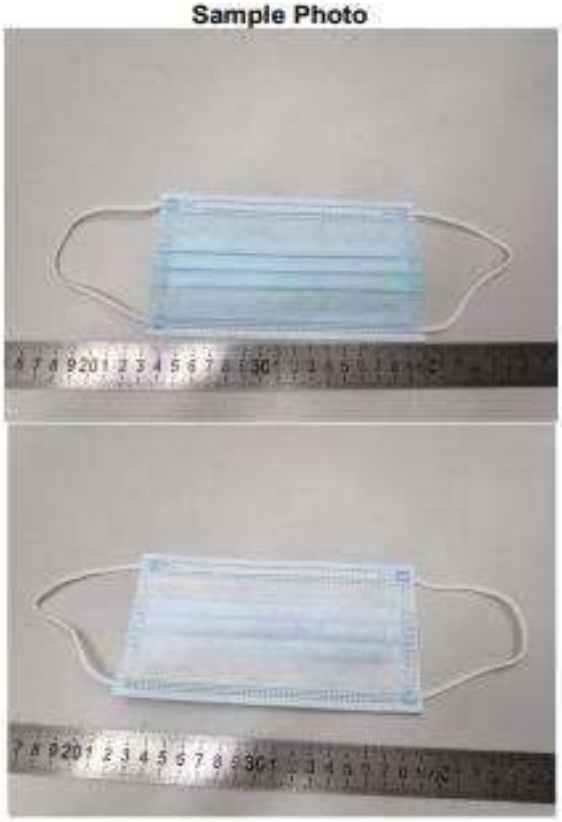
Sample Photo



The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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