




KINGFA
金发科技



**DISPOSABLE
MEDICAL MASK
EN14683:2019+AC:2019
TYPE I
KF-C P02/KF-C P03
(Small Size:145*95mm)**



**MORE
PROTECTIVE**

**MORE
COMFORTABLE**

KINGFA INTRODUCTION



Established in **1993**

Research, production and sales of **advanced polymer materials**

Listed on Shanghai Stock Exchange in 2004

Over 6500 employees

Annual production capacity exceeds **2 million tons**



WITHIN 27 YEARS OF DEVELOPMENT KINGFA REALIZED:



KF-C P02

Color box(50pcs/box)

Size:160*100*80mm

Gross Weight:182±10g



Master Box (50 color boxes/ Master box)

Size:525*335*420mm

Gross Weight:10116±500g



Mask

Size:145*95mm

Weight:2.9±0.2g



KF-C P03

Color box(50pcs/box)

Size:160*100*80mm

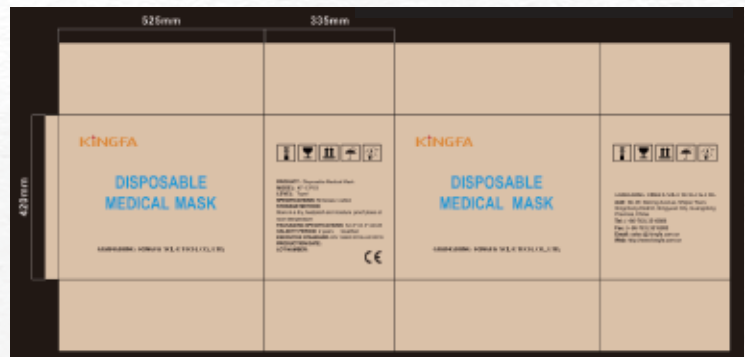
Gross Weight:182±10g



Master Box (50 color boxes/ Master box)

Size:525*335*420mm

Gross Weight:10116±500g



Mask

Size:145*95mm

Weight:2.9±0.2g



Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**GuangDong Kingfa Science and
Technology Co., Ltd.**
No.28, Delong Road, Qingcheng Dist.
Qingyuan City
511545 Guangdong
P.R. China

has established and applies a quality management system for medical devices
for the following scope:

**Design and Development, Manufacture and Distribution of
Disposable Medical Face Masks (non-sterile)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.


Effective Date: 2020-07-13
Certificate Registration No.: SX 60150441 0001
An audit was performed. Report No.: 17054679 002
This Certificate is valid until: 2023-07-12

Certification Body



Date 2020-07-13




Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com <http://www.tuv.com/safety>

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1430282**

Certificate Holder: **GuangDong Kingfa Science and Technology Co., Ltd.**
Unified Social Credit Code: 91441802077867032A
Registration Address: No. 28, DeLong Road, Qingcheng Dist.
Shijiao Town, Qingyuan City, 511545 Guangdong, P. R. China
Operation Address: same as above

Scope: Design and Manufacturing of Modified Plastics;
Design and Manufacturing of Masks and Non-Powered Air-
Purifying Particle Respirator

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-07-19 until 2023-07-18.
It remains valid subject to satisfactory surveillance audits.
First certification 2014

This certificate information can be searched on CNCA official website <http://www.cnca.gov.cn>

2020-06-08



TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

DECLARATION OF CONFORMITY

Manufacturer: GUAGNDONG KINGFA SCI.&TECH. CO., LTD.
Address of manufacturer: No.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Product: Disposable medical mask
Model Ref.: KF-C P02, KF-C P03
Class characteristics: Class I (not sterile or measuring according to Annex IX, Rule 1)
UMDNS-Code: 12447

The product is certified to meet the Essential requirements and relevant provisions of
EC Directive: **Medical Devices Directive 93/42/EEC**

Standard(s)/Directive(s): EN 14683: 2019+AC: 2019(Type I)
EN ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2010
EN ISO 13485: 2016
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 62366: 2008
EN 1041: 2008


Conformity assessment procedure: EC Declaration of Conformity (Annex VII) + Technical Files)

EC representative: Share Info Consultant Service LLC Repräsentanzbüro

Address: Heerdter Lohweg 83, 40549 Düsseldorf

This DoC is valid from 02 Jun., 2020.

Authorized by:



Signature
General Manager
Place: Qingyuan, China
Date: Jun. 02, 2020



Allgemeine Anzeigepflicht nach §§ 25 und 30 Abs. 2 MPG General Obligation to Notify pursuant to §§ 25 and 30 (2) Medical Devices Act, MPG

Formblatt für Medizinprodukte, außer In-vitro-Diagnostika Form for Medical Devices except In Vitro Diagnostic Medical Devices

Zuständige Behörde / Competent authority			
	Code DE/CA20		
	Bezeichnung / Name Bezirksregierung Düsseldorf, Dezernat 24		
	Staat / State Deutschland		Land / Federal state Nordrhein-Westfalen
	Ort / City Düsseldorf		Postleitzahl / Postal code 40474
	Straße, Haus-Nr. / Street, house no. Cecilienallee 2		
	Telefon / Phone +49-211-4750		Telefax / Fax +49-211-4752671
	E-Mail / E-mail dez24.mpg@brd.nrw.de		

Anzeige / Notification			
	Registrierdatum bei der zuständigen Behörde Registration date at competent authority 16.06.2020		Registriernummer / Registration number DE/CA20/01-share-Info-consultant-187/20
	Typ der Anzeige / Notification type <input type="checkbox"/> Erstanzeige / Initial notification <input type="checkbox"/> Änderungsanzeige / Notification of change <input type="checkbox"/> Widerrufsanzeige / Notification of withdrawal		
	Frühere Registriernummer bei Änderungs- und Widerrufsanzeige Previous registration number if notification has been changed or withdrawn		
	Anzeigender nach § 25 MPG / Reporter pursuant to § 25 Medical Devices Act, MPG <input type="checkbox"/> Hersteller / Manufacturer <input type="checkbox"/> Bevollmächtigter / Authorised Representative <input type="checkbox"/> Einführer / Importer <input type="checkbox"/> Verantwortlicher für das Zusammensetzen von Systemen oder Behandlungseinheiten nach § 10 Abs. 1 und 2 MPG \ Assembler of systems or procedure packs pursuant to § 10 (1) and (2) Medical Devices Act, MPG <input type="checkbox"/> Betrieb oder Einrichtung (aufbereiten) nach § 25 Abs. 1 MPG i. V. m. § 4 Abs. 2 MPBetreibV Institution (processing) pursuant to § 25 (1) Medical Devices Act, MPG in connection with § 4 (2) MPBetreibV <input type="checkbox"/> Betrieb oder Einrichtung (sterilisieren) nach § 25 Abs. 2 i. V. m. § 10 Abs. 3 MPG Institution (sterilizing) pursuant to § 25 (2) in connection with § 10 (3) Medical Devices Act, MPG		

Anzeigender / Reporting organisation (person)	
Code	DE/0000047946
Bezeichnung / Name	Share Info Consultant Service LLC Repräsentanzbüro
Staat / State	Deutschland
Land / Federal state	Nordrhein-Westfalen
Ort / City	Düsseldorf
Postleitzahl / Postal code	40549
Straße, Haus-Nr. / Street, house no. Heerdter Lohweg 83	
Telefon / Phone	017670057022
Telefax / Fax	
E-Mail / E-mail	eu-rep@share-info.cn

Hersteller / Manufacturer	
Bezeichnung / Name	GUANGDONG KINGFA SCI.&TECH.CO.,LTD
Staat / State	CN
Ort / City	Qingyuan
Postleitzahl / Postal code	511545
Straße, Haus-Nr. / Street, house no. NO.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China	
Telefon / Phone	+86-135-7095-2157
Telefax / Fax	+86-763-3203108
E-Mail / E-mail	yuxiaoge@kingfa.com.cn

Sicherheitsbeauftragter für Medizinprodukte nach § 30 Abs. 2 MPG 9) Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG	
Bezeichnung / Name	Jiehan Li
Staat / State	Deutschland
Land / Federal state	Nordrhein-Westfalen
Ort / City	Düsseldorf
Postleitzahl / Postal code	40549
Straße, Haus-Nr. / Street, house no. Heerdter Lohweg 83	
Telefon / Phone	017670057022
Telefax / Fax	
E-Mail / E-mail	eu-rep@share-info.cn

Vertreter / Deputy (optional)	
	Bezeichnung / Name
	Telefon / Phone
	Telefax / Fax
	E-Mail / E-mail
	£ Erstanzeige / Initial notification S Änderungsanzeige / Notification of change

KINGFA

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
Klasse / Class	
S I	
£ I - steril / sterile	
£ I - mit Messfunktion / with measuring function	
£ I - steril und mit Messfunktion / sterile and with measuring function	
£ IIa	
£ IIb	
£ III	
£ III - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012	
manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012	
£ Aktives implantierbares Medizinprodukt / Active implantable medical device	
£ Aktives implantierbares Medizinprodukt - hergestellt unter Verwendung von Gewebe tierischen Ursprungs im Sinne der Verordnung (EU) Nr. 722/2012	
Active implantable medical device - manufactured utilising tissues of animal origin in terms of Commission Regulation (EU) No 722/2012	
App (Software auf mobilen Endgeräten)	£ ja / yes S nein / no
Nummer(n) der Bescheinigung(en) / Certificate number(s)	
Handelsname des Produktes / Trade name of the device	Disposable medical mask
Produktbezeichnung / Name of device	
Nomenklaturcode / Nomenclature code	
Nomenklaturbezeichnung / Nomenclature term	
Kategoriecode / Category code	10
Kategorie / Category	Produkte zum Einmalgebrauch
Kurzbeschreibung deutsch / German short description	Die medizinische Einwegmaske soll getragen werden, um sowohl den Patienten als auch anderes Personal vor der Übertragung von Mikroorganismen, Körperflüssigkeiten und Partikelmaterial zu schützen, insbesondere in epidemischen oder pandemischen Situationen. Dies ist ein Einweggerät, das nicht steril geliefert wird. Modell: KF-C P02, KF-C P03. Tippe I
Kurzbeschreibung englisch / English short description	The Disposable medical mask is intended to be worn to protect both the patient and other personnel from the transfer of microorganisms, body fluids and particulate material, particularly in epidemic or pandemic situations. This is a single use, disposable device, provided non-sterile. Model: KF-C P02, KF-C P03. Type I

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
	<input type="checkbox"/> Semikritische Medizinprodukte / Semicritical medical devices <input type="checkbox"/> Gruppe A / Group A <input type="checkbox"/> Gruppe B / Group B
	<input type="checkbox"/> Kritische Medizinprodukte / Critical medical devices <input type="checkbox"/> Gruppe A / Group A <input type="checkbox"/> Gruppe B / Group B <input type="checkbox"/> Gruppe C / Group C <input type="checkbox"/> Nummer der Bescheinigung / Certificate number
	Sterilisationsverfahren / Sterilisation procedures <input type="checkbox"/> Dampfsterilisation / Steam sterilisation <input type="checkbox"/> Gassterilisation / Gas sterilisation <input type="checkbox"/> Strahlensterilisation / Radiation sterilisation <input type="checkbox"/> andere / others <input type="checkbox"/> Angewandtes Verfahren / Applied procedure

Ich versichere, dass die Angaben nach bestem Wissen und Gewissen gemacht wurden.
I affirm that the information given above is correct to the best of my knowledge.

Ort City	Duesseldorf	Datum Date	2020-06-09
		Name	Jiehan Li
			Unterschrift Signature

Bearbeitungsvermerke / Processing notes Nur von der zuständigen Behörde auszufüllen / To be filled in only by the competent authority	
Bearbeiter / Person responsible Frau Nadine Schlingmeier	Telefon / Phone 0211-475-3853

Test Report

(Electronic version)

Verification Website: www.gttc.net.cn

Verification Code: MQDK-0592-44

No: 20R001744

Issue Date: 2020-05-25

Applicant: GUANG DONG KINGFA SCI.& TECH.CO.,LTD

Address: NO.28 DELONG AVE.,SHIJIAO TOWN,QINGCHENG DISTRICT,QING
YUAN, GUANGDONG, CHINA

Information confirmed by applicant:

Disposable medical mask

Quantity: eighty pieces

Type: KF-C P02

Classification: Type I

Standard Adopted:

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

Date Received/Date Test Started: 2020-05-14

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:

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:

WanLi.Hu Engineer

WanLi.Hu



Test Report

(Electronic version)

No: 20R001744



Test Report

(Electronic version)

Verification Website: www.gtcc.net.cn

Verification Code: GAQD-4428-04

No:20R001743

Issue Date: 2020-05-25

Applicant: GUANG DONG KINGFA SCI.& TECH.CO.,LTD

Address: NO.28 DELONG AVE.,SHUIJIAO TOWN,QINGCHENG DISTRICT,QING
YUAN,GUANGDONG,CHINA

Information confirmed by applicant:

Disposable medical mask

Quantity: eighty pieces

Type: KF-C P03

Classification: Type I

Standard Adopted:

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

Date Received/Date Test Started: 2020-05-14

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:

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:

Nan Ma

Nan Ma Engineer



Test Report

(Electronic version)

No: 20R001743



Supplier Creditability & Capacity Audit Report

Report:			
Supplier Name	Guangdong KINGFA SCI.&TECH. Co., Ltd. 广东金发科技有限公司		
Supplier Address	No. 28, Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China		
Client Information	/		
Name of Assessor	James Lee	Reviewed by	Roger Wang
Audited Date	04 May, 2020	Expiry Date	03 May, 2021

Assessment Scope:
Section 1: Company Profile Section 2: Personnel Section 3: Main Market Section 4: Manufacturing Ability Section 5: Certificate Section 6: Quality Control Management Section 7: Development Plan Section 8: Production Flow Chart Section 9: Attachment

Comments
Guangdong KINGFA SCI.&TECH. Co., Ltd. is a trader and manufacturer combined company with 2097 employees; it was established in 2013, located in No. 28, Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China. They have passed ISO9001, ISO14001, OHSAS18001 certifications in 2017. Guangdong KINGFA SCI.&TECH. Co., Ltd. has successful foreign trading experience in Europe, North America and East Asia.

Important Notes:
<p>This report is issued by the SGS –CSTC under its General Terms and Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.</p> <p>Any holder of this document is advised that information contained hereon reflects the Company's actual findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.</p>

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm.

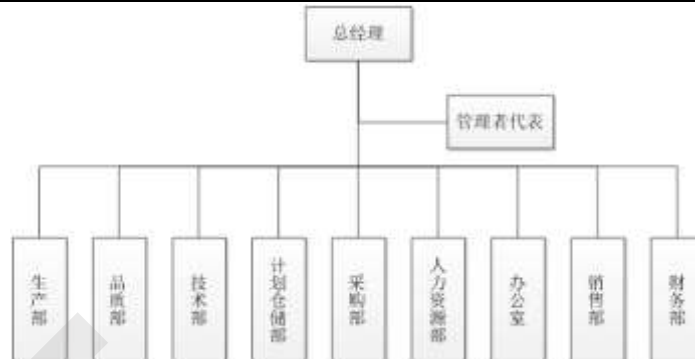
Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon is solely limited to visual examination of the safely and readily accessible portions of the consignment and reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Attention: To ensure the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doccheck@sgs.com

Section 2: Personnel

2.1 Company Org Chart



2.2 Headcount and Key Staff

According to	<input type="checkbox"/> Attendance record <input checked="" type="checkbox"/> Members list <input type="checkbox"/> On-site observation <input type="checkbox"/> Others			
Headcount	Department	Full time	Part time	Total
	GM	1	0	1
	Management Represents	1	0	1
	Production Dept.	1666	0	1666
	QC Dept.	80	0	80
	Technology Dept.	20	0	20
	Warehouse Dept.	220	0	220
	Purchase Dept.	15	0	15
	HR Dept.	15	0	15
	Office	48	0	48
	Marketing Dept.	24	0	24
	Fin. Dept.	7	0	7
	Total	2097		
Key Staff	Full Name	Position	Working experience in this filed	
	Mr. Hongtao Ning	General Manager	About 20 years working experience	
	Mr. Xiaojun Deng	Factory Director	About 15 years working experience	
	Mr. Min Ding	Export Manager	8 years foreign trading experience	
Training Procedure and Plan for Staff	<input checked="" type="checkbox"/> All staff <input type="checkbox"/> Key station <input type="checkbox"/> No Training records <input type="checkbox"/> Others			
Are there uniforms for all staff in company?	There are uniforms for all workers			

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm.

Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon is solely limited to visual examination of the safely and readily accessible portions of the consignment and reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Attention: To ensure the authenticity of testing / inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doccheck@sgs.com

Section 3: Main Market

3.1 Foreign Trading Staff

There were 24 foreign trading members in the company.

Education Level	Headcount	Working Experience	Headcount	English Level	Headcount
Doctor	0	Over 20 Years	0	TEM-8	0
Master	19	Over 10 Years	12	CET-6	24
University	5	Over 5 Years	12	CET-4	0
Junior college	0	2-5 Years	0	CET-3	0
Technical secondary school	0	1Year	0	PETS-3	0

Export means: Directly export through own export right
 Export business operated by other foreign trading company
 Others

3.2 Export Information

Item	Content	
Main Market	Area	% of Total Business Volume (last year)
	North America	23.5
	South America	0.12
	West Europe	6.5
	East Europe	0
	East Asia (Japanese/ Korea)	58
	Africa	0
	Australia	6.9
	Southeast Asia	3
	Mideast	0
	Others	1.98
	Domestic	0
Sales Volume	Annual volume in last year	Confidential
	Export volume in last year	Confidential
	Estimated export in this year	Confidential
Key Client	Confidential	Confidential
Lead time	From PO Confirmation to Ex works	7-15 days

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm.

Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon is solely limited to visual examination of the safely and readily accessible portions of the consignment and reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Attention: To ensure the authenticity of testing / inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doccheck@sgs.com

Section 4: Manufacturing Ability

4.1 Main Facilities					
Please list the major machinery / utilities on site.	Facility name	Brand/Model	Quantity	Year made	Condition
	Medical Mask Production Line 医用口罩生产线	Guoji	132	2020	Good
	Protective Mask Production Line 防护口罩生产线	Kuaiyuda	80	2020	Good

4.2 Main Test Instruments					
Please list the major test instruments on site.	Facility name	Brand/Model	Quantity	Year made	Condition
	Mask BFE Tester 口罩细菌过滤效率检测仪	ZR-1000	1	2020	Good
	Mask Tensile Strength Tester 口罩拉力机	KT22	1	2020	Good
	Clean Bench 超净工作台	YJ-840	1	2020	Good
	Mildew Incubator 霉菌培养箱	MJ-80	1	2020	Good
	Constant Temperature Incubator 恒温培养箱	DHP-9082	1	2020	Good

4.3 Output			
Output in last year	Product	Monthly output	Yearly output
	N/A	N/A	N/A
Output in this year	Protective Mask/ Medical Mask (Non-sterile) 防护口罩/医用口罩 (非灭菌)	300,000,000 Pcs	N/A

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm.

Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon is solely limited to visual examination of the safely and readily accessible portions of the consignment and reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Attention: To ensure the authenticity of testing / inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doccheck@sgs.com

Section 5: Certificate

5.1 Management System Certificate				
Certificate	Number	Expiry date	Certifying Body	Scope
ISO 9001:2015	01 100 1430282	31 Oct., 2017	TUV Rheinland	Design and production of modified plastics
ISO14001:2004	01 104 1430282	18 Jul., 2020	TUV Rheinland	Design and production of modified plastics
OHSAS 18001:2007	01 113 1430282	18 Jul., 2020	TUV Rheinland	Design and production of modified plastics

5.2 Product Certificate				
Certificate	Number	Issued date	Certifying Body	Product and model / type
Test Report	20R000099 MT	23 Apr. 2020	GTT	Disposable medical mask(non-sterile) Standard EN14693:2019+ac:2019
Test Report	(2020) WSZ FHL No. 2852	27 Mar., 2020	Jiangsu Guojian Testing Technology Co., Ltd.	Labor Protective Mask Standard: GB2626-2006
FDA Registration	10065634	2020	FDA	Disposable Protective Mask Model: Adult; Protective Mask Model: KF-A(Adult)

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm.

Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon is solely limited to visual examination of the safely and readily accessible portions of the consignment and reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Attention: To ensure the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doccheck@sgs.com

Section 6: Quality Control Management

Item	Content	Grading			Observations /Comments
		Poor	Mid	Good	
6.1	Are the environmental conditions such as tidiness and cleanliness being controlled and suitable for the operation performed?			√	Refer to site observation; the environmental condition was suitable for the operation performed.
6.2	Are the following items /documents provided at appropriate location and under control when necessary? - Work Instructions /procedures - Workmanship standard /acceptance - Golden sample			√	Refer to site observation; there were documented work instructions, workmanship standard provided in the workshops.
6.3	Does the company establish and implement an effective suppliers/ sub-contractors assessment procedure (which covers the acceptable criteria of supplier/ sub-contractor)?			√	The company had established this procedure for supplier assessment, latest record has been reviewed.
6.4	Are written instructions available for incoming material inspections /testing? Is the relevant records maintained?			√	Refer to on-site observation; there were documented instructions for incoming material inspection. And inspection records were maintained well.
6.5	Are written inspections /testing instructions available for finished products? Is the relevant records maintained?			√	The company had established the procedure for this inspection. And records were maintained well.
6.6	Is there a procedure to conduct random product inspection after final packaging in place?			√	All inspection procedures were implemented before packaging.
6.7	Are non-conforming units clearly marked/ segregated to prevent accidental dispatch?			√	Refer to site observation; non-conforming units would be marked with label and placed in the non-conforming parts area
6.8	Is there a clear procedure for handling customer complaint?			√	Refer to relevant documentation; the company had a clear procedure for handling customer complaint.
6.9	Can the finished/package product be traced by lot identification to the appropriate raw materials test reports?			√	Auditor noted that the company had established this procedure for lot identification.
6.10	Are corrective & preventive actions mechanism established and implemented effectively (including the suppliers/ sub-contractors' control, incoming inspection, process control, final inspection and customer complaint)?			√	The company had documented procedure for corrective & preventive actions mechanism and records were kept well.

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm.

Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon is solely limited to visual examination of the safely and readily accessible portions of the consignment and reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Attention: To ensure the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doccheck@sgs.com

Section 7: Development Plan

7.1		
Item	Actions	Time Frame
1	Enlarge the mask production capacity	2020

KINGFEA




This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm.

Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon is solely limited to visual examination of the safely and readily accessible portions of the consignment and reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Attention: To ensure the authenticity of testing / inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doccheck@sgs.com

Section 8: Production Flow Chart

8.2 Product: Solar Module		
		
1. Medical Mask (Non-sterile) Production 医用口罩（非灭菌）生产	2. Protective Mask Production 防护口罩生产	3. Lab. Testing 实验室检验
		N/A
4. Packing 包装	5. Store 成品储存	N/A

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm.

Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon is solely limited to visual examination of the safely and readily accessible portions of the consignment and reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Attention: To ensure the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doccheck@sgs.com

Section 9: Attachment

9.1 Photos of Document and Certificate	
<p>Business License</p>	<p>Medical Device Production License</p>
<p>Medical Device Registration Certificate</p>	<p>Medical Device Registration Certificate</p>
<p>Export License</p>	<p>Land Certificate</p>

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm.

Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon is solely limited to visual examination of the safely and readily accessible portions of the consignment and reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Attention: To ensure the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doccheck@sgs.com

<p align="center">ISO9001 Certificate</p>	<p align="center">ISO14001 Certificate</p>
	
<p align="center">OHSAS18001 Certificate</p>	<p align="center">Verification of Conformity</p>
	
<p align="center">FDA Registration</p>	<p align="center">Registration in German Safety Office for Medical Devices</p>
	

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm.

Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon is solely limited to visual examination of the safely and readily accessible portions of the consignment and reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Attention: To ensure the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doccheck@sgs.com

Testing Report





Test Report

Verification Website: www.gtts.com.cn
Verification Code: Y0015-100-00

No. 20200009341 Issue Date: 2020/05/21

Applicant: GUANG DONG KINGFA SCI & TECH CO., LTD.
Address: NO.28 DELIANG AVE., SHILIAO TOWN, HONGDING DISTRICT, DINGYUAN GUANGDONG, CHINA

Information confirmed by applicant:
Dependable material specification number:
Quantity: every piece
Lot number: 20201640
Date: 17 Nov-19 Asia
Method: air leakage type
Classification: Type IFF

Standard adopted:
GB 19083-2019/AC:2019 Medical face masks-Requirements-and-test-methods
Date Received/Issue Test Report: 2020-03-21

Conclusion:

Bacterial filtration efficiency (BFE)	M
Microbial resistance	M
Differential pressure	M
Spillage resistance pressure	M
Materials and construction	M
Design	M
General	M

Note: "M" means the results are positive. "F" and "not" indicate the results are negative. "C" indicates compliance.

Remarks:
Medical purpose: measured CMA efficiency and CMV resistance data.
This report is valid only for the specified conditions and materials.
All the test results are based on the provided conditions unless otherwise specified.
Copies of this report are valid only if unchanged.
The certificate was issued at No.11, Zhongyuan Road, Pudong District, Shanghai, China, 201306.

Approved By: *Han Ma*
Title: Engineer

Page 1 of 12

Testing Report

Test Report

Page 1 of 4

Product name	Protective Mask	Specification	GB 19083
		Brand	

Applicant name	Guangdong KINGFA SCI & TECH Co., Ltd. 28 Deli Road, Shiliao Town, Hongding District, Dingyuan, Guangdong City, Guangdong Province, China		
Manufacturer	Guangdong KINGFA SCI & TECH Co., Ltd. 28 Deli Road, Shiliao Town, Hongding District, Dingyuan, Guangdong City, Guangdong Province, China		
Sample grade	FFP2	Sample number	GW-2020-2020
Sample quantity	110 PCS	Receiving date of sample	2020/03/26
Test type	Entrusted inspection	Article number/Brand number/Type number	1701/2020
Test date	2020/05/20-2020/05/20	Testing site	Testing room

Note: Meeting the requirements of testing.

Test standards: GB 19083-2019/AC:2019 Respiratory protective devices-Filtration half masks to protect against particles-Requirements-testing method

Test items: Visual inspection, Physical performance: Pressure of parts, Compatibility with skin, Flammability, Carbon dioxide content of the filtration etc. Material: Head harness, Total inward leakage, Penetration of filter material, Breathing resistance, Total inward leakage

Test conclusion: The sample upon inspection, the projects meet the requirements of the GB 19083-2019/AC:2019 standard, the specific test results see page 3/4.

Note: For the entrusted inspection, the technical responsibilities are undertaken for the submitted samples only.

Approved: *[Signature]* Reviewer: *[Signature]* Chief Tester: *[Signature]*

Testing Report







Test Report

(2020) WSZ FHL NO.2852

Product Name: Labor Protective Mask

Client: Guangdong KINGFA SCI & TECH Co., Ltd.

Manufacturer: Guangdong KINGFA SCI & TECH Co., Ltd.

Test Type: Entrusted inspection

Jiangsu Guojian Testing Technology Co., Ltd

Testing Report

Test Report

Page 1 of 4

Product name	Labor Protective Mask	Specification	
		Brand	

Client/Manufacturer	Guangdong KINGFA SCI & TECH Co., Ltd. 28 Deli Road, Shiliao Town, Hongding District, Dingyuan, Guangdong City, Guangdong Province, China		
Manufacturer	Guangdong KINGFA SCI & TECH Co., Ltd. 28 Deli Road, Shiliao Town, Hongding District, Dingyuan, Guangdong City, Guangdong Province, China		
Sample grade		Sample number	GW-2020-2020
Sample quantity	10 pcs	Receiving date of sample	2020/03/26
Test type	Entrusted inspection	Article number/Brand number/Type number	
Test date	2020/05/20-2020/05/20	Testing site	Testing room

Note: Meeting the requirements of testing.

Test standards: GB 19083-2019 Respiratory protective equipment-Non-powered working particle respirator?

Test items: General requirements, appearance requirements, Filter efficiency, respiratory resistance, Head strap, chin, head harness, Flammability, total inward leakage of disposable mask.

Test conclusion: The sample upon testing, the test items meet the requirements of the GB 19083-2019 standard. The detail of test results see in Page 2-4.

Note: The client requires the test items to be judged in accordance with GB 19083. For the entrusted sample test, the technical responsibilities are undertaken for the test results of the supplied samples only.

Approved: *[Signature]* Reviewer: *[Signature]* Chief Tester: *[Signature]*

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon is solely limited to visual examination of the safely and readily accessible portions of the consignment and reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Attention: To ensure the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doccheck@sgs.com

9.2 Photos of Company and Product Sample

Company Gate	Office Building
	
Office	Lab.
	
Testing Machine	Testing Machine
	

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm.

Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon is solely limited to visual examination of the safely and readily accessible portions of the consignment and reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Attention: To ensure the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doccheck@sgs.com



<p align="center">Workshop Building</p>	<p align="center">Workshop Building</p>
	
<p align="center">Workshop</p>	<p align="center">Workshop</p>
	
<p align="center">Automatic Production line</p>	<p align="center">Automatic Production line</p>
	

This document is issued by the Company under its General Conditions of Service accessible at http://www.sgs.com/terms_and_conditions.htm. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.

Any holder of this document is advised that information contained hereon is solely limited to visual examination of the safely and readily accessible portions of the consignment and reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Attention: To ensure the authenticity of testing/inspection report & certificate, please contact us at telephone: (86-755)83071443, or email: CN.Doccheck@sgs.com

