

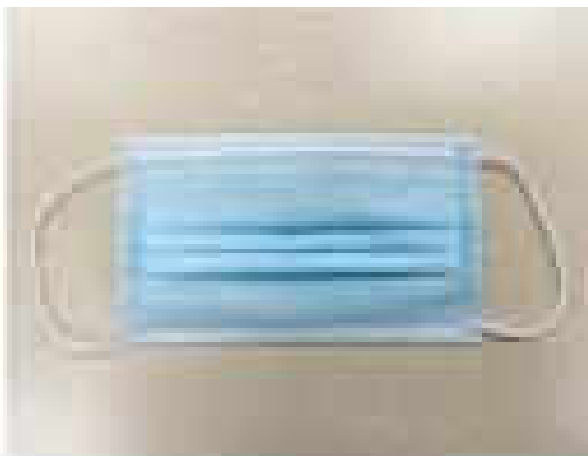


ESPECIFICACIONES

KAELIS WORLD S.L.

Mascarilla Quirúrgica Desechable - Tipo I

Nombre de producto: Mascarilla Quirúrgica Desechable - Tipo I	Tipo de logo:
Referencia Kaelis: KL-020707	Referencia Fabricante: KF-B P01
Unidad de medida: Unit	Colores de logo:
Nombre de diseño:	Etiqueta de lavado:
Tamaño (cm): 17.5 x 9.5	Etiquetado:
Peso (kg): 0,004	Logo de etiqueta:
Colores:	Código de producto de proveedor:
Material: PP Non-woven	Requisitos especiales de empaquetado:
Certificaciones requeridas:	Usage:

FOTO:	Descripción técnica:
	Directiva Europea: 93/42/CEE - Producto Sanitario Clase I Norma armonizada: EN14683:2019+AC:2019 Clasificación: Tipo I Eficacia de Filtración Bacteriana (BFE): 95% Presión diferencial: < 40Pa/cm2 Limpieza microbiana: 30ufc/g Dimensiones: 180*95mm (±5%) Color: Azul Material: Tejido no tejido y tejido hilado Puente nasal ajustable Estilo: Bucles elásticos Presentación: 25 unidades/bolsa Caja: 50 unidades (2 bolsas x 25 unidades)

Información de embalaje

Descripción de embalaje: CARTON	Volumen caja (m3): 0.074588
Unidades / Caja: 2.000	CTN Net Weight (NW) (kg) : 8.0000
Unidades / Caja interior: 50	Peso bruto (kg): 9
Ancho caja (cm): 51	Tara de caja (kg): 1
Largo caja (cm): 39	Código HS: 630790
Alto caja (cm): 37,5	

CONFIDENCIAL

KINGFA
金发科技

MORE
PROTECTIVE

MORE
COMFORTABLE

**DISPOSABLE
MEDICAL MASK(CE)
EN14683:2019+AC:2019
TYPE I
KF-B P01(EN-M)**



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:

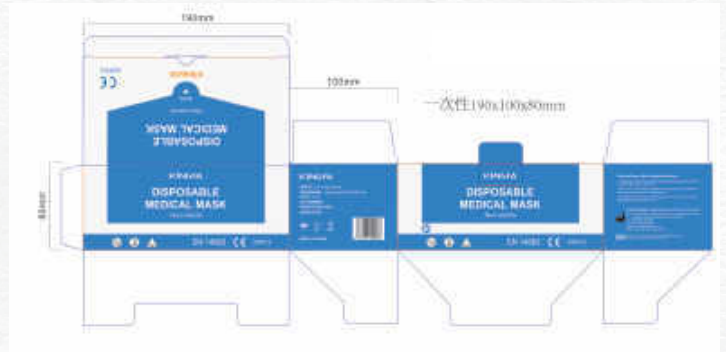
4	Company Founders	Over 6500	Employees
20	Thousand CNY Capital	29.1	Billion Total Assets(CNY)
1	Small Workshop	47	Subsidiary Companies
0	CNY Sales Volume	29.2	Billion Sales Volume(CNY)

KF-B P01(EN-M) TYPE I

Color Box (50 pcs/Box)

Size : 190*100*80mm

Gross Weight : 216±10g



Master Box (50 color boxes/ Master box)

Size : 525*395*420mm

Gross Weight : 11970±500g



Mask

Size : 175*95mm

Mask Weight : 3.5±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: Guangdong 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.: Ear hanging type
Class characteristics: Class I (not sterile or measuring via Annex IX Rule X)
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: 2009/AC:2010
EN ISO 10993-5: 2009
EN ISO 10993-10: 2010
EN ISO 14971: 2012
EN ISO 15223-1: 2016
EN 1041: 2008
Conformity assessment procedure: EC Declaration of Conformity (Annex II) + Technical Files)
EC representative: Share Info Consultant Service LLC Repräsentanzbüro
Address: Heerdter Lohweg 83, 40549 Düsseldorf

This DoC is valid from 27 Apr., 2020.
Authorized by:



Signature
General manager
Place: Qingyuan, China
Date: Apr. 27, 2020

广东金发科技有限公司

GUANGDONG KINGFA SCI. & TECH. CO., LTD

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 09.04.2020	Registriernummer / Registration number DE/CA20/01-share-Info-consultant-20/20
Typ der Anzeige / Notification type ☒ Erstanzeige / Initial notification ☐ Änderungsanzeige / Notification of change ☐ 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 ☐ Hersteller / Manufacturer ☒ Bevollmächtigter / Authorised Representative ☐ Einführer / Importer ☐ 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 ☐ 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 ☐ 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 511600	
Straße, Haus-Nr. / Street, house no. 28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China			
Telefon / Phone 0086 7633516800		Telefax / Fax	
E-Mail / E-mail			

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 ☒ Änderungsanzeige / Notification of change		

Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market)	
Klasse / Class	☒ 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 ☒ 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 Einwegmaske schützen den Patienten als auch anderes Personal vor dem Patienten zu Übertragung von Mikroorganismen, Körperflüssigkeiten und Partikelmateriale, insbesondere bei Epidemien oder Pandemien Situationen. Dies ist ein Einweggerät, das nicht steril geliefert wird
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: Ear hanging type

Medizinprodukte (Aufbereiten) / Medical devices (Reprocessing)	
☐	Semikritische Medizinprodukte / Semicritical medical devices ☐ Gruppe A / Group A ☐ Gruppe B / Group B
☐	Kritische Medizinprodukte / Critical medical devices ☐ Gruppe A / Group A ☐ Gruppe B / Group B ☐ Gruppe C / Group C Nummer der Bescheinigung / Certificate number
☐	Sterilisationsverfahren / Sterilisation procedures ☐ Dampfsterilisation / Steam sterilisation ☐ Gassterilisation / Gas sterilisation ☐ Strahlensterilisation / Radiation sterilisation ☐ andere / others 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	2020-04-01
		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



Declaration

Manufacturer Information:

Company Name	GUANGDONG KINGFA SCI.&TECH. CO., LTD.
Company Address	NO.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China

Product Information

Product Name	Disposable medical mask
Model	KF-B P01 (EN-M)

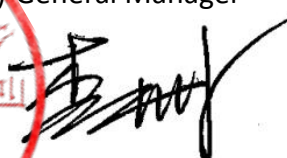
We declare the products described above do not contain or released:

- a) latex,
 - b) carcinogenic substances with H350 or H351,
 - c) mutagenic substances with H340 or H341,
 - d) toxic substances for reproduction with H360, H361 or H362,
 - e) formaldehyde with the concentration exceeding 75ppm,
 - f) substances that are considered to be potentially endocrine disrupting according to official lists within the EU and the Nordic countries,
 - g) substances that cause allergies or skin irritants,
 - h) substances that are on the EU Candidate List published in accordance with Article 59(10) of the REACH Regulation,
 - i) metal noseband with nickel,
- during recommended conditions of use.

We declare the products described above contain dyes:

Product name	Chemical formula	CAS no.
Pigment Blue K6911D	C32H16CUN8	12239-87-1

Signed for and on behalf of: GUANGDONG KINGFA SCI.&TECH. CO., LTD.

(date of signature): 2020-11-03
(title of signatory): General Manager
(signature): 





Test Report

(Electronic version)

Verification Website: www.gtgc.net.cn

Verification Code: MVMW-9409-54

No: 20R001541

Issue Date: 2020-05-28

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

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

Information confirmed by applicant:

Disposable medical mask

Quantity: 80 pieces

Type: Ear hanging type

Classification: Type I

Standard Adopted:

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

Date Received/Date Test Started: 2020-05-18

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:

ZiShan Guo

ZiShan Guo Senior Engineer

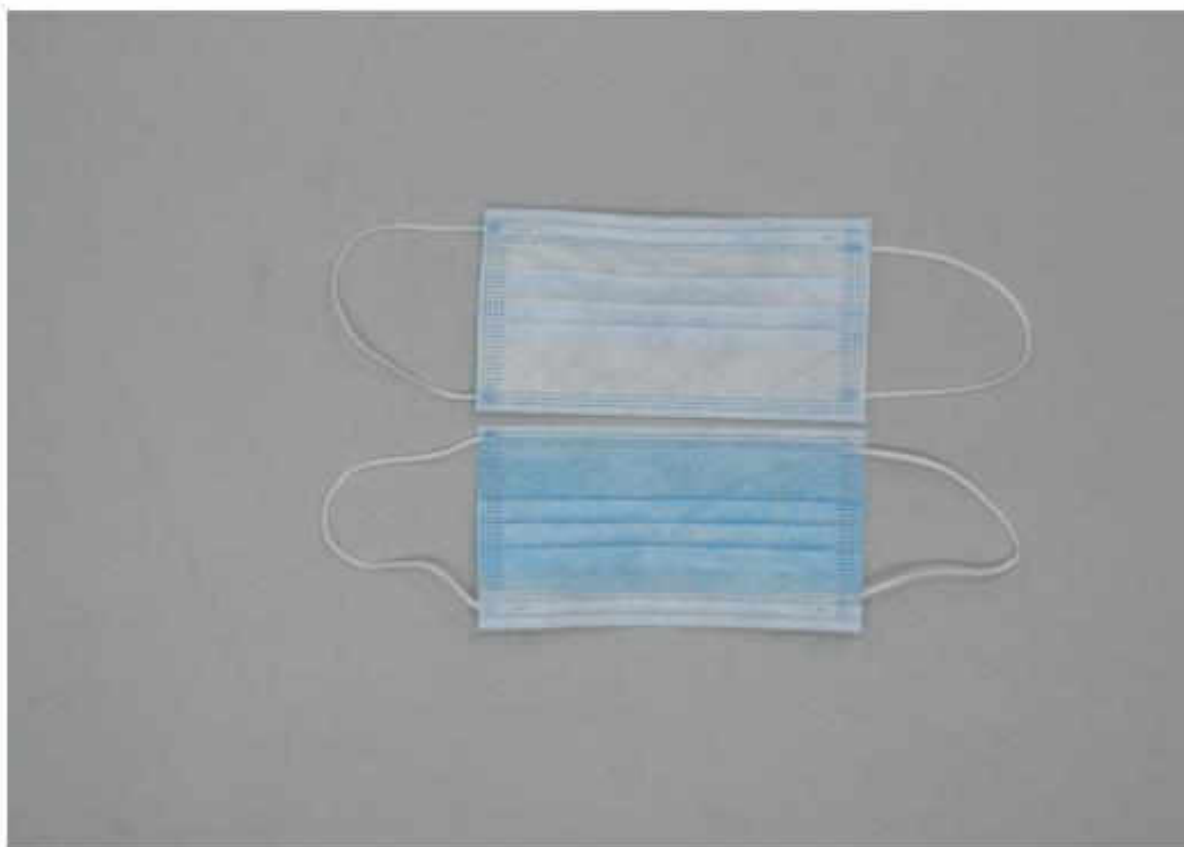


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Test Report

(Electronic version)

No: 20R001541





Report No.: NKG2020050401

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:
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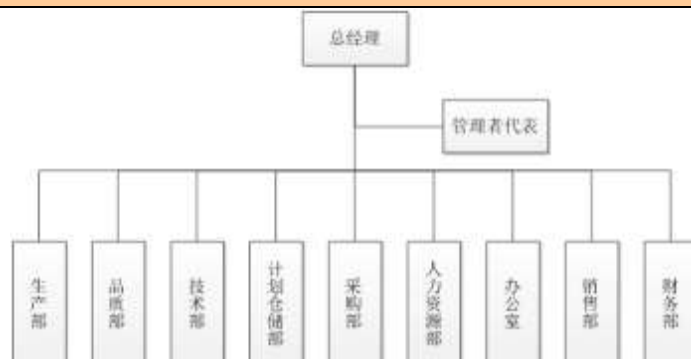
Page No.: 1 of 19



Report No.: NKG2020050401

Section 2: Personnel

2.1 Company Org Chart



2.2 Headcount and Key Staff

According to	☐ Attendance record ☒ Members list ☐ On-site observation ☐ 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	☒ All staff ☐ Key station ☐ No Training records ☐ Others			
Are there uniforms for all staff in company?	There are uniforms for all workers			

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Report No.: NKG2020050401

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

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Report No.: NKG2020050401

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

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Report No.: NKG2020050401

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)

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Report No.: NKG2020050401

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.

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Report No.: NKG2020050401

Section 7: Development Plan

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

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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

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Section 9: Attachment

9.1 Photos of Document and Certificate

Business License	Medical Device Production License
	
Medical Device Registration Certificate	Medical Device Registration Certificate
	
Export License	Land Certificate
	

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ISO9001 Certificate	ISO14001 Certificate
	
OHSAS18001 Certificate	Verification of Conformity
	
FDA Registration	Registration in German Safety Office for Medical Devices
	

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Report No.: NKG2020050401

Testing Report

GTTC **MA** **ISO 9001** **ISO 14001** **ISO 45001**

Test Report (Electronic version)

Verification Website: www.gtts.net.cn
Verification Code: VGM5-1189-09

No. 20000009553 Issue Date: 2020-05-21

Applicant: GUANGDONG KINGFA SCI & TECH CO., LTD.
Address: NO.24 DELONG AVE., SHILIAO TOWN, QINGCHENG DISTRICT, QINGYUAN, GUANGDONG, CHINA

Information confirmed by applicant:
Disposable medical waste-bin cover?
Quantity: 1000 pieces
Lot number: 20011001
Spec: 17-Nov-19 Spec
Model and Sampling type:
Classification Type: IIR

Standard: Adapted
EN 13658-2:2019+AC:2019 Medical protective equipment and use methods
Data Received Date: Test Report: 2020-05-21

Conclusion:

Respirator filtration efficiency (BFE)	M
Microbial resistance	M
Differential pressure	M
Spillage resistance pressure	M
Material and construction	M
Design	M
General	M

Note: 1. All items for medical equipment "T" and for medical equipment "C" are confirmed.
Remark:
Medical equipment (MMA, CE mark, and CE mark) are confirmed.
This report is based on the report 20000009553 which has been issued previously.
All the test results are based on the tested condition (except for laboratory).
Copies of this report are valid only for reference.
This report is not valid for use as a T or C mark for medical equipment (except for laboratory).

Approved By: *Han Ma*
Test Date: 2020-05-21

Page 1 of 2

Testing Report

Test Report

(2020) WSP FHL NO.2852 Page 1 of 4

Product Name	Protective Mask	Specification	Serial
Guangdong KINGFA SCI & TECH Co., Ltd. (Shiliao Town, Qingcheng District, Qingyuan City, Guangdong Province, China)	Guangdong KINGFA SCI & TECH Co., Ltd. (Shiliao Town, Qingcheng District, Qingyuan City, Guangdong Province, China)	Guangdong KINGFA SCI & TECH Co., Ltd. (Shiliao Town, Qingcheng District, Qingyuan City, Guangdong Province, China)	Guangdong KINGFA SCI & TECH Co., Ltd. (Shiliao Town, Qingcheng District, Qingyuan City, Guangdong Province, China)

Sample grade: FFP1 Sample number: 17W-00002-2020

Sample quantity: 110 PCS Receiving date of sample: 2020-05-21

Test type: Entrusted inspection Article number/Block number/Style number: 1701-2020

Test date: 2020-05-21-2020-05-21 Testing place: Testing room

Notes: Meeting the requirements of testing
GB 2626-2006 Respiratory protective equipment (Filtering half mask or personal agent particle respirator, Respiratory protection, Visual inspection, Physical performance, Filter efficiency, Compatibility with skin, Flammability, Carbon dioxide indicator of the indicator, etc. Material, Head form, Field of vision, Resistance to static electricity, Breathing resistance, Total inward leakage)

Test conclusion: The sample upon inspection, the project meets the requirements of the GB 2626-2006 standard, the specific test results see page 2-4.

Remarks: For the submitted sample test, the technical responsibilities are undertaken for the submitted sample only.

Approved: *张永* Reviewed: *万程* Test Date: *杨立*

Testing Report

MA **ISO 9001** **ISO 14001** **ISO 45001** **国检检测**

Test Report

(2020) WSP 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

(2020) WSP FHL NO.2852 Page 1 of 4

Product Name	Labar Protective Mask	Specification	Serial
Guangdong KINGFA SCI & TECH Co., Ltd. (Shiliao Town, Qingcheng District, Qingyuan City, Guangdong Province, China)	Guangdong KINGFA SCI & TECH Co., Ltd. (Shiliao Town, Qingcheng District, Qingyuan City, Guangdong Province, China)	Guangdong KINGFA SCI & TECH Co., Ltd. (Shiliao Town, Qingcheng District, Qingyuan City, Guangdong Province, China)	Guangdong KINGFA SCI & TECH Co., Ltd. (Shiliao Town, Qingcheng District, Qingyuan City, Guangdong Province, China)

Sample grade: — Sample number: 20W-2020-2020

Sample quantity: 80 pcs Receiving date of sample: 2020/05/21

Test type: Entrusted inspection Article number/Block number/Style number: —

Test date: 2020/05/21-2020/05/21 Testing place: Testing room

Notes: Meeting the requirements of testing
GB 2626-2006 Respiratory protective equipment (Non-powered purifying particle respirator)
General requirements, appearance requirements, Filter efficiency, respiratory resistance, Head shape, vision, Head form, Flammability, total inward leakage of disposable mask

Test conclusion: The sample upon testing, the test items meet the requirements of the GB 2626-2006 standard. The detail of test results see page 2-4.

Remarks: The client requires the test items to be judged in accordance with GB 2626-2006. For the submitted sample test, the technical responsibilities are undertaken for the test results of the submitted sample only.

Approved: *张永* Reviewed: *万程* Test Date: *杨立*

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Member of the SGS Group (SGS SA)

9.2 Photos of Company and Product Sample

Company Gate	Office Building
	
Office	Lab.
	
Testing Machine	Testing Machine
	

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Workshop Building	Workshop Building
	
Workshop	Workshop
	
Automatic Production line	Automatic Production line
	

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