KINGFA
金发科技

PARTICLE FILTERING HALF MASK EN149:2001+A1:2009 FFP2 KF-A F10(SC)

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:

4	Company Founders	Over6500	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-A F10(SC)
FFP2

KINGFA
金发科技

Color Box
(30 pcs/box)

Size: 140*120*121mm
Gross Weight: 290±10g

Master Box
(36 color boxes/
Master box)

Size: 585*375*385mm
Gross Weight: 14446±500g

Mask

Size: 230*120mm
Weight: 6.8±0.3g

The actual product you receive may be (slightly) different from this photo,
the packing may update,please make the object as the standard

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-884

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Guangdong Kingfa Sci.&Tech. Co., Ltd.

28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: KINGFA **Model:** KF-A F10(SC)
Filtering half mask
Classification: FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **29/06/2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

Certificate CN20/42082

The management system of

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

No.28, Delong Avenue, Shijiao Town, Qingcheng District,
Qingyuan City, Guangdong Province, 511545, P.R. China

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

Module D

For the following activities

Manufacture of FFP1/FFP2 Protective Respirator (Note: all products marked CE0598 must have a valid EU Type Examination Certificates issued under Module B or a valid EC type examination certificate issued under Article 10 of the PPE Directive 89/686/EEC.)

This certificate is valid from 10 June 2020 until 9 June 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 26 May 2023
Issue 1. Certified since 10 June 2020

FINAS
Finnish Accreditation Service
S003 (EN ISO/IEC 17065)

Authorised by

SGS FIMKO OY, Notified Body 0598
Takomotie 8, FI-00380 Helsinki, Finland
t +358 9 696 361 f +358 9 692 5474 www.sgs.com

TÜVRheinland®

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

FDA EUA

https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#imported

Appendix A: Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China (Updated: July 23, 2020)

The table below includes a list of non-NIOSH respirators authorized by this Umbrella EUA for emergency use during the COVID-19 public health emergency.

As stated in the EUA, authorized respirators should be used in accordance with CDC's recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for Optimizing the Supply of N95 Respirators.

Search:

Guangdong KINGFA SCI. & TECH. Co. Ltd.	KF-A F01, KF-A F10(SC)	

June 16, 2020

GUANGDONG KINGFA SCI. & TECH. CO. LTD.
28 DELONG AVENUE, SHIJIAO TOWN
QINGCHENG DISTRICT
QINGYUAN CITY CN - CHINA

EUA201196

Re: FFRs Made in China

Dear David Wu:

This letter is in response to your request that the Food and Drug Administration (FDA) add your respirator model KF-A-F01 as an authorized respirator to the May 7, 2020 Emergency Use Authorization (EUA)[1], which was issued under Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). We have reviewed your email and determined that the models included meet the eligibility criteria in the May 7, 2020 EUA for non-NIOSH approved respirators made in China. As such, your respirator(s) is hereby added to Appendix A[2] as an authorized respirator.

Having concluded that the eligibility criteria are met, I am adding your respirators to Appendix A, as described in the Scope of Authorization (Section II). As such, the respirator is authorized for use by healthcare personnel in healthcare settings in accordance with CDC recommendations and subject to the Conditions of Authorization (Section IV) of the attached letter. We remind you that, among other things, you are required to meet the following labeling requirements:

Manufacturers

A. Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized models that are imported and authorized under this EUA on their website in English. Additionally, manufacturers must notify FDA by emailing FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov of the website address (URL) that meets this condition. The subject line of this email should read "URL for FFR Made in China." FDA will make this information available to the public on its EUA website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe. Manufacturers must notify FDA of any changes to this page.

B. In addition to the above electronic labeling condition, manufacturers of authorized respirators are additionally required to include a letter, in English, that can be distributed to each end user facility (e.g., each hospital, etc.) that receives the authorized respirator model. This letter must include the

[1] The EUA Letter of Authorization is available at, https://www.fda.gov/media/136664/download.
[2] Appendix A is available at, https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations.

authorized respirator's manufacturer, model, intended use, manufacturer's webpage (if applicable), etc.

Additionally, please be advised that if your firm does not have the appropriate fluid resistance testing, the respirator should not be labeled as "surgical."

Import information can be found on the Information for Filing Personal Protective Equipment and Medical Devices During COVID-19 page. If you need to resolve entry issues for shipments, please contact 301-796-0356 or COVID19FDAIMPORTINQUIRIES@fda.hhs.gov.

Sincerely,

Suzanne Schwartz, MD, MBA
Deputy Director (& Acting Office Director)
Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health

EU DECLARATION OF CONFORMITY

This declaration of conformity is issued under the sole responsibility of the manufacturer:

Manufacturer and address	GUANGDONG KINGFA SCI.&TECH. CO., LTD. NO.28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China
Product name	Particle Filtering half mask
Model/ Serial No.	KF-A F10(SC) FFP2 NR
Applicable Regulation:	PPE Regulation 2016/425
Notified body for EU type-examination (Module B)	UNIVERSAL- NB 2163 Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye / İSTANBUL / TÜRKİYE
Certificate number (Module B)	2163-PPE-884
Notified body for EU type-examination (Module D)	SGS FIMKO OY - NB 0598 Takomotie 8, FI-00380 Helsinki, Finland
Certificate number(Module D)	Certificate CN20/42082

We declared that given information on the above statement and attached documents/records are true and correct to the best of our knowledge.

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

(date of signature):2020-6-30

(title of signatory):General Manager

(signature):

161019130764

中国认可
国际互认
检测
TESTING
CNAS L10118

国检检测
CHINA COMPONENTS TEST

Test Report

（2020） WSZ FHL NO.W0708

Product Name Particle Filtering half mask

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

Manufacturer

Test Type Entrusted inspection

Jiangsu Guojian Testing Technology Co., Ltd.

江苏国健检测技术有限公司
检验专用章

Test Report

[2020] WSZ FHL NO.W0708

Product name	Particle Filtering half mask	Specification	KF-A F10(SC)
		Brand	—
Client/Add/Tel	Guangdong KINGFA SCI.&TECH.Co.,Ltd./28 Delong Avenue, Shijiao Town, Qingcheng District, Qingyuan City, Guangdong Province, China/—		
Manufacturer/ Add/Tel	—/—/—		
Sample grade	FFP2	Sample number	GWW0708-2020
Sample quantity	110 pcs	Receiving date of sample	21/05/2020
Test type	Entrusted inspection	Article number/Batch number/Style number	—
Test date	23/05/2020~29/05/2020	Testing sites	Testing room
Sample state	Meeting the requirements of testing	Sample description	—
Test standard(s)	EN 149:2001+A1:2009 Respiratory protective devices-Filtering half masks to protect against particles- Requirements,testing, marking		
Test items	Visual inspection, practical performance, finish of parts, compatibility with skin, flammability, carbon dioxide content of the inhalation air, material, head harness, field of vision, penetration of filter material, breathing resistance, total inward leakage		
Test conclusion	The sample upon testing, the test items meet the requirements of the EN 149:2001+A1:2009 standard. The detail of test results see on Pages 2-6. Issue date: 31/05/2020		
Note	For the entrusted sample test, the technical responsibilities are undertaken for the test results of the supplied samples only. 		

Approver: Reviewer: Chief Tester:

Test Report

S.No.	Test item		Unit	Technical requirements	Test result		Single item decision
1	Visual inspection	Packaging	—	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	Packaging withstands mechanical damage and contamination.		Qualified
		Material	—	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.	Materials withstand handling and wear.		
2	Practical performance	Head harness comfort	—	Head harness should be comfort.	Sample 1 has the feeling of comfortable wearing		Qualified
					Sample 2 has the feeling of comfortable wearing		
		Security of fastenings	—	Fastenings are safe and reliable	Sample 1: All fastenings are firm.		
					Sample 2: All fastenings are firm		
		Field of vision	—	Field of vision is acceptable	Sample 1: Having a wider visual field		
					Sample 2: Having a wider visual field		
3	Finish of parts		—	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Parts of the device have no sharp edges and burrs		Qualified
4	Compatibility with skin		—	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	A.R.	5 pcs all don't cause irritation	Qualified
					T.C.	5 pcs all don't cause irritation	
5	Flammability		—	When tested,the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame.	A.R.	The Sample is burning. Burning time:0.1s	Qualified
						The Sample is burning. Burning time:0.1s	
					T.C.	The Sample is burning. Burning time:0.1s	
						The Sample is burning. Burning time:0.1s	

Test Report

S.No.	Test item		Unit	Technical requirements	Test result				Single item decision
6	Carbon dioxide content of the inhalation air		—	≤1.0% (by volume)	Sample 1	0.5960%			Qualified
					Sample 2	0.6040%			
					Sample 3	0.6025%			
					Average	0.60%			
7	Material		—	After undergoing S.W., none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Sample 1: neither facepiece nor straps have mechanical failure				Qualified
					Sample 2: neither facepiece nor straps have mechanical failure				
					Sample 3: neither facepiece nor straps have mechanical failure				
				After undergoing S.W. and T.C. , none of the particle filtering half masks shall not collapse.	Sample 1: no collapse				
					Sample 2 : no collapse				
					Sample 3: no collapse				
8	Head harness		—	The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position	A.R.	All of 5 pieces particle filtering half mask meet the requirements			Qualified
					T.C.	All of 5 pieces particle filtering half mask meet the requirements			
9	Field of vision		—	The field of vision is acceptable if determined so in practical performance tests.	The two samples both have a wider visual field				Qualified
10	Penetration of filter material	Sodium chloride	—	≤6%	A.R.	0.1%	0.1%	0.1%	Qualified
					S.W.	0.1%	0.1%	0.1%	
					M.S+T.C.	0.1%	0.2%	0.1%	
		Paraffin oil	—	≤6%	A.R.	0.2%	0.2%	0.3%	Qualified
					S.W.	0.2%	0.3%	0.2%	
					M.S+T.C.	0.4%	0.5%	0.4%	

Test Report

S.No.	Test item		Unit	Technical requirements	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
11	Breathing resistance	Inhalation 30 L/min	mbar	≤0.7	A.R.	0.2	0.2	0.3	0.2	0.3	Qualified
						0.2	0.3	0.2	0.3	0.2	
						0.3	0.2	0.3	0.2	0.3	
					S.W.	0.3	0.2	0.3	0.2	0.3	
						0.3	0.3	0.2	0.3	0.2	
						0.2	0.3	0.3	0.3	0.3	
					T.C.	0.3	0.3	0.2	0.3	0.3	
						0.2	0.3	0.3	0.2	0.3	
						0.3	0.2	0.3	0.3	0.2	
		Inhalation 95 L/min		≤2.4	A.R.	1.2	1.3	1.3	1.3	1.2	Qualified
						1.3	1.2	1.3	1.2	1.3	
						1.3	1.3	1.2	1.3	1.3	
					S.W.	1.3	1.2	1.2	1.3	1.3	
						1.2	1.3	1.3	1.2	1.3	
						1.3	1.3	1.3	1.3	1.2	
					T.C.	1.3	1.2	1.3	1.2	1.3	
						1.3	1.3	1.2	1.3	1.3	
						1.2	1.3	1.3	1.3	1.2	
		Exhalation 160 L/min		≤3.0	A.R.	1.8	1.9	1.9	2.0	1.9	Qualified
						1.8	1.8	2.0	1.9	1.8	
						1.9	1.9	1.9	1.9	1.9	
					S.W.	1.9	1.9	1.9	1.9	1.9	
						1.9	1.8	2.0	1.8	1.8	
						1.8	1.9	1.9	1.9	1.9	
					T.C.	1.9	1.8	2.0	1.9	1.9	
						1.8	1.9	1.9	2.0	1.9	
						1.9	1.9	1.9	2.0	2.0	

Test Report

S.No.	Test item	Unit	Technical requirements	Test result								Single item decision
				Exercises		E1 (%)	E2 (%)	E3 (%)	E4 (%)	E5 (%)	TIL (%)	
12	Total inward leakage	—	At least 46 out of the 50 individual exercise results shall be not greater than 11%; And in addition,at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 8%.	A.R.	1#	1.1	1.7	1.5	1.5	1.1	1.4	Qualified
					2#	1.4	2.2	2.0	2.3	1.6	1.9	
					3#	0.8	1.2	1.2	1.2	0.8	1.0	
					4#	0.7	1.2	1.6	1.6	0.9	1.2	
					5#	1.0	1.7	1.7	2.0	1.3	1.5	
				T.C.	6#	1.0	1.9	1.7	1.7	1.3	1.5	
					7#	1.4	1.9	2.4	2.0	1.6	1.9	
					8#	0.6	1.3	1.4	1.3	0.7	1.1	
					9#	0.6	1.4	1.5	1.2	0.7	1.1	
					10#	1.1	1.7	1.6	1.7	1.1	1.4	
Note												

The end

SUPPLEMENTARY TEST REPORT

Facial dimensions of ten test subjects:

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
1	120	130	109	59
2	122	140	115	65
3	119	160	139	55
4	112	122	119	63
5	110	130	118	60
6	115	119	110	59
7	112	123	113	55
8	103	130	100	50
9	118	139	130	63
10	115	129	120	50

The end

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:

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.

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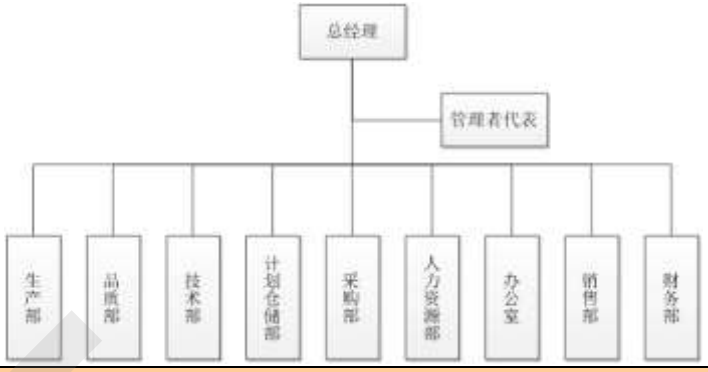
SGS-CSTC Standards Technical Services Co., Ltd.
Consumer Testing Services
B-15/F, No.900, Yishan Road, Xuhui District, Shanghai, China 200233 t (86-21) 61156703 f (86-21) 61152274 www.cn.sgs.com
中国·上海·徐汇区宜山路900号B-15层 邮编: 200233 t (86-21) 61156703 f (86-21) 61152274 e sa.cn@sgs.com
Member of the SGS Group (SGS SA)

Section 2: Personnel

2.1 Company Org Chart



2.2 Headcount and Key Staff

According to	[ ] Attendance record [X] 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	[X] All staff [ ] Key station [ ] No Training records [ ] Others
Are there uniforms for all staff in company?	There are uniforms for all workers

6-15/F, No.900, Yishan Road, Xuhui District, Shanghai, China 200233 t (86-21) 61156703 f (86-21) 61152274 www.cn.sgs.com
中国·上海·徐汇区宜山路900号B-15层 邮编: 200233 t (86-21) 61156703 f (86-21) 61152274 e sa.cn@sgs.com

Section 3: Main Market

3.1 Foreign Trading Staff

There were 24 foreign trading members in the company.

Education Level	Headcount
Doctor	0
Master	19
University	5
Junior college	0
Technical secondary school	0

Working Experience	Headcount
Over 20 Years	0
Over 10 Years	12
Over 5 Years	12
2-5 Years	0
1Year	0

English Level	Headcount
TEM-8	0
CET-6	24
CET-4	0
CET-3	0
PETS-3	0

Export means: [X] 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

6-15/F, No.900, Yishan Road, Xuhui District, Shanghai, China 200233 t (86-21) 61156703 f (86-21) 61152274 www.cn.sgs.com
中国·上海·徐汇区宜山路900号B-15层 邮编: 200233 t (86-21) 61156703 f (86-21) 61152274 e sa.cn@sgs.com

Section 4: Manufacturing Ability

4.1 Main Facilities

	Facility name	Brand/Model	Quantity	Year made	Condition
Please list the major machinery / utilities on site.	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

	Facility name	Brand/Model	Quantity	Year made	Condition
Please list the major test instruments on site.	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

	Product	Monthly output	Yearly output
Output in last year	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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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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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/packaged 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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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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Testing Report	Testing Report
	
Testing Report	**Testing Report**
	

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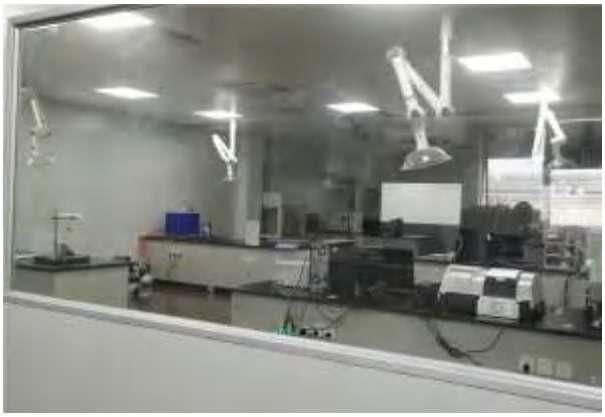
9.2 Photos of Company and Product Sample	
Company Gate	**Office Building**
	
Office	**Lab.**
	
Testing Machine	**Testing Machine**
	

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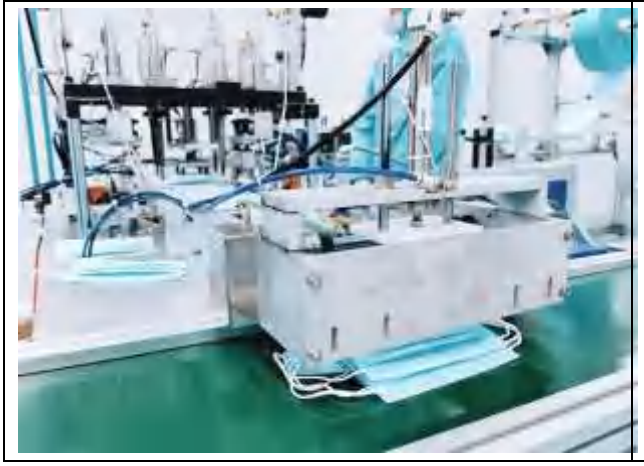
Workshop Building	Workshop Building
	
Workshop	**Workshop**
	
Automatic Production line	**Automatic Production line**
	

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