

KİNGFA 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:

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-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)

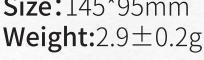
Size:525*335*420mm

Gross Weight:10116±500g

	526mm	335mm		
423mm	KINGFA DISPOSABLE MEDICAL MASK	Minister Committee States (1972) Minist	KINGFA DISPOSABLE MEDICAL MASK	AMBRICAN - TREAT VIEW TO A 1 III. AND THE TREAT VIEW TO A 1 II
l	68/09/68/09/09 W.T. (19/34/X), (19)	one make the control of the control	desiration forces were received.	Man Na Protestingly across

Mask

Size: 145*95mm







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 Shena

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 No.28 Delong Avenue, Shijiao Town, Qingcheng District,

manufacturer: 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)

CE

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

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	

Anz	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				
	S Erstanzeige / Initial notification				
	£ Änderungsanzeige / Notification of change				
	£ Widerrufsanzeige / Notification of withdrawal				
	Frühere Registriernummer bei Änderungs- und Widerru Previous registration number if notification has been ch				
	Anzeigender nach § 25 MPG / Reporter pursuant to § 2	5 Medical Devices Act, MPG			
	£ Hersteller / Manufacturer				
	S Bevollmächtigter / Authorised Representative				
	£ Einführer / Importer				
	£ Verantwortlicher für das Zusammensetzen von Syste	emen 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				
	\pm Betrieb oder Einrichtung (aufbereiten) nach \S 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	s. 2 i. V. m. § 10 Abs. 3 MPG			
	Institution (sterilizing) pursuant to § 25 (2) in connec	tion with § 10 (3) Medical Devices Act, MPG			

Anzeigender / Reporting organisation (person)				
Code DE/0000047946				
Bezeichnung / Name Share Info Consultant Service LLC Repräsentanzb	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 D	istrict, Qingyuan City, Guangdong Province, China		
	Telefon / Phone +86-135-7095-2157	Telefax / Fax +86-763-3203108		
	E-Mail / E-mail yuxiaoge@kingfa.com.cn			

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			



Medizinprodukt (Erstmaliges Inverkehrbringen) / Medical device (First placing on the market) Klasse / Class SI £ 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)

Produktbezeichnung / Name of device

Disposable medical mask

Nomenklaturcode / Nomenclature code

Nomenklaturbezeichnung / Nomenclature term

Handelsname des Produktes / Trade name of the device

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

Me	dizinprodukte (Aufbereiten) / Medical devices (Reprocess	sing)		
	£ Semikritische Medizinprodukte / Semicritical m	nedical devi	ces		
	£ Gruppe A / Group A				
	£ Gruppe B / Group B				
	£ Kritische Medizinprodukte / Critical medical de	vices			
	£ Gruppe A / Group A				
	£ Gruppe B / Group B				
	£ Gruppe C / Group C				
	Nummer der Bescheinigung / Certificate numb	oer			
	Sterilisationsverfahren / Sterilisation procedures				
	£ Dampfsterilisation / Steam sterilisation				
	£ Gassterilisation / Gas sterilisation				
	£ Strahlensterilisation / Radiation sterilisation				
	£ andere / others				
	Angewandtes Verfahren / Applied procedure				
Ich v	ersichere, dass die Angaben nach bestem Wissen met that the information given above is correct to the	und Gewis e best of m	ssen gemacht wurd y knowledge.	en.	
Ort City	Duesseldorf	Datur Date	n	2020-06-09	
		Name		Jiehan Li	
					Unterschrift Signature
Be a	arbeitungsvermerke / Processing notes r von der zuständigen Behörde auszufüllen / To be	e filled in on	ly by the competer	at authority	
	Bearbeiter / Person responsible		Telefon / Phone		
	Frau Nadine Schlingmeier		0211-475-3853		







(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









(Electronic version)

No: 20R001744











(Electronic version)

Verification Website: www.gttc.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., SHIJIAO 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)

Microbial cleanliness

M

Differential pressure

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.

Nan Ma

Approved By: Nan Ma Engineer









(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:

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Section 2: Personnel

2.1 Company Org Chart						
		总经理				
	管理者代	管理者代表				
1						
生产部	品質部 技术部 部		销售 新 售 新			
2.2 Headcount and Key S						
According to	[] Attendance rec [] On-site observa		rs list			
	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		
Headcount	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			
	Full Name	Position	Working experience in this filed			
Key Staff	Mr. Hongtao Ning	General Manager	About 20 years working experience			
Ney Stall	Mr. Xiaojun Deng	Factory Director	About 15 years working experience			
	Mr. Min Ding	Export Manager	8 years foreign	trading experience		
raining Procedure and Plan or Staff	[X] All staff [] No Training reco	[] Key station	on			
are there uniforms for all taff in company?	There are uniforms for					

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1 (86-21) 61156703 1 (86-21) 61152274 1 (86-21) 61156703 1 (86-21) 61152274



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

3.2 Export Information					
Item		Content			
	Area	% of Total Business Volume (last year)			
	North America	23.5			
	South America	0.12			
	West Europe	6.5			
	East Europe	0			
Maio Mantos	East Asia (Japanese/ Korea)	58			
Main Market	Africa	0			
	Australia	6.9			
	Southeast Asia	3			
	Mideast	0			
	Others	1.98			
	Domestic	0			
	Annual volume in last year	Confidential			
Sales Volume	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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Section 4: Manufacturing Ability

4.1 Main Facilities						
	Facility name	Brand/Model	Quantity	Year made	Condition	
Please list the major machinery / utilities	Medical Mask Production Line 医用口罩生产线	Guoji	132	2020	Good	
on site.	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	
	Mask BFE Tester 口罩细菌过滤效率检 测仪	ZR-1000	1	2020	Good	
Please list the major	Mask Tensile Strength Tester 口罩拉力机	KT22	1	2020	Good	
test instruments on site.	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 war	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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Any holder of this dosponant 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 lindings 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 exceed the parties to a transaction from exercising all their rights and obligations under the transaction documents. Any unauthorized alteration, forgery or fall fication of the content of appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law.

Attention: To be authorized appearance of testing inspection report & certificate, please contact us at telephone: (66-755) 63071443, or small: CN. Doccheck@sgs.com

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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

	Section 6: Quality Control Management						
Item	Content	Grading			Observations /Comments		
Item		Poor	Mid	Good	ODGET VALIOUS / GOTTIMENTS		
6.1	Are the environmental conditions such as tidiness and cleanliness being controlled and suitable for the operation performed?			V	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			V	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)?	X		$\sqrt{}$	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?			V	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?			V	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?			1	All inspection procedures were implemented before packaging.		
6.7	Are non-conforming units clearly marked/ segregated to prevent accidental dispatch?			V	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?			V	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?			V	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



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



4.Packing 包装



5. Store 成品储存

N/A

N/A

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Section 9: Attachment



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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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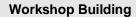
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Workshop Building







Workshop

Workshop





Automatic Production line

Automatic Production line





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