仙桃市兴荣防护用品有限公司
Xingrong Protective Products Co.,Ltd

1.口罩详情介绍如下

The introduction of Face masks as following:

产品名称：一次性使用医用口罩

规格 145*90mm , 3 层, 橡筋式

认证证书:

营业执照

医疗许可证

医疗器械注册证

TUV CE

ISO13485

FDA

EN14683 Type II

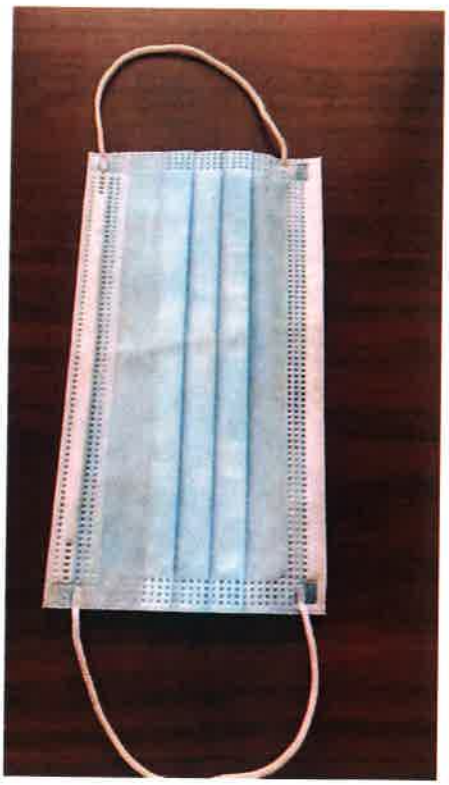
医疗器械产品出口证明\

熔喷布检测报告

尼尔森报告(血液渗透, 阻力报告)(外网可查)

日产量：3000000 片

包装方式: 50 片/盒，2000 片/箱



Product name: Disposable Medical Face Mask

Specification 145*90mm3 ply.elastic ear loop

Certificat

Business license,

Medical license

Medical device registration certificate

TUV CE

ISO13485

FDA

EN 14683 Type II

Certificate For Exportation Medical Products,

BFE test report

(SBP tset report, Microbial Cleanlines report.

Medical Device Manufacturing License of China.

（Can find on Internet）

Daily Capacity: 3000000 pcs

Package:50pcs/box，2000pcs/CTN

7.2.CE 认证 (Website tracking https://www.certipedia.com/)

TÜVRheinland

EC Certificate
Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60133273 0001

Report No.: 15085900 005

Manufacturer:
Xiantao Xingrong Protective
Products Co., Ltd.
No. 46, East of Pengchang Road,
433018 Xiantao, Hubei
China

Products:
Aspects of manufacture concerned with securing and maintaining sterile conditions of Face Masks, Surgical Gowns, Non-woven Caps, Non-woven Shoe Covers, Plastic Shoe Covers, Coveralls

Replaces Approval, Registration No.: DD 60104282 0001

Expiry Date: 2023-12-05

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-12-06

Date: 2018-12-06

Notified Body
TÜV Rheinland LGA Products GmbH
TÜVRheinland
Herbert Zhong
Prüfungsgruppe

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

CE certificate:

7.3.ISO 13485 体系证书 (Website tracking https://www.certipedia.com/)

ISO 13485 certificate

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**Xiantao Xingrong Protective Products Co., Ltd.
No. 46, East of Pengchang Road,
433018 Xiantao, Hubei
China**

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

Manufacture and Distribution of Face Masks, Surgical Gowns, Non-woven Caps, Non-woven Shoe Covers, Plastic Shoe Covers, Coveralls

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:	2018-12-06
Certificate Registration No.:	SX 60133274 0001
An audit was performed. Report No.:	15085900 005
This Certificate is valid until:	2021-12-05

Certification Body

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

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

Date 2018-12-06

Herbert Zi...

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

7.4 美国 FDA 证书

USA FDA Certificate

（website tracking: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm）

The Owner/Operator Number for this Registration is: 3007084580

Sungo

FDA Registration Confirmation

This is to confirm that, as the US Agent, we have completed the registration activation confirmation for the **FDA Establishment Registration and Device Listing** with the US Food & Drug Administration for the **Fiscal Year 2020** of

Xiantao Xingrong Protective Products Co., Ltd
No.46 Pengchang Ave, Xiantao, Hubei, China

The facility registration and device listing information:

Registration Number: 3007084580		
Device Listing No.	Product Code	Product Name(s)
D317957	FME	GOWN EXAMINATION
D317958	KME	BEDDING,DISPOSABLE MEDICAL
D317959	FXP	COVER SHOE ,OPERATING -ROOM
D317961	OEA	NON-SURGICAL ,ISOLATION GOWN
D317962	FYF	CAP,SURGICAL
D317963	MSH	MASK,SCAVENGING
D389720	LYU	Disposable Mask, Disposable Medical Mask
D389721	QKR	Disposable Mask, Disposable Medical Mask

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this attestation until the end of the calendar year stated above, unless said registration is terminated after issuance of this attestation. SUNGO Technical Service Inc. makes no other representations or warranties, nor does this attestation make any representations or warranties to any person or entity other than the named attestation holder, for whose sole benefit it is issued. This attestation does not denote endorsement or approval of the attestation-holder's device or establishment by the U.S. Food and Drug Administration. SUNGO Technical Service Inc. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a attestation of registration, nor does the U.S. Food and Drug Administration recognize a attestation of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.

Reference Number: 2006US809548
Issue date: Apr.11, 2020

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CHICAGO, ILLINOIS 60630, USA
sungo.group@yahoo.com

7.8 BFE 口罩的过滤效应＞98

BFE and Delta P Final Report＞98

NELSON LABORATORIES

Sponsor
Lan Chen
Xiantao Xingrong Protective Products Co. Ltd
Ave. 46 Pengcheng Ave
Xiantao, Hubei CN 433018
CHINA

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article: SXFC10
Laboratory Number: 791558
Study Received Date: 01 Dec 2014
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 11

Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 2,200 ± 500 colony forming units (CFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM F2101-07 and EN 14683:2014, Annex B.

The Delta P test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer at a constant flow rate. The Delta P test was designed to comply with Mil.-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Inside
BFE Area Tested: ~45.6 cm^2
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 Liters per minute (L/min)
Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	99.8	3.2	31.6
2	99.8	3.0	29.6
3	99.7	3.0	29.2
4	99.9	2.9	28.9
5	99.8	3.0	29.1

Positive Control Average: 1,971 CFU
Negative Monitor Count: <1 CFU
MPS: 3.0 µm
Test Article Dimensions: ~153 mm x ~150 mm

Study Director: Sarah Smit, B.S.
Study Completion Date: [illegible] 2014

NELSON LABORATORIES

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} \times 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request.

7.9 SBP 合成血液渗透阻力

Synthetic Blood Penetration Resistance Final Repor

NELSON LABORATORIES

Sponsor
Justin Zhao
Xiantao Xingrong Protective Products Co Ltd
Ave 46 PengChang Ave
Xiantao Hubei 433018
CHINA

Synthetic Blood Penetration Resistance Final Report

Test Article SXFC10
Laboratory Number 801781
Study Received Date 02 Feb 2015
Test Procedure(s) Standard Test Protocol (STP) Number STP0012 Rev 08

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2014) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5° C and a relative humidity of 85 ± 10 %. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested: 32
Number of Test Articles Passed: 29
Test Side: Outside
Pre-Conditioning: Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions: 23.2°C and 24% RH

Study Director: Brandon L. Williams
Study Completion Date:

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥29 of 32 test articles show passing results.

Test Pressure 120 mm Hg

Test Article Number	Synthetic Blood Penetration	Test Article Number	Synthetic Blood Penetration
1	None Seen	17	None Seen
2	None Seen	18	None Seen
3	None Seen	19	None Seen
4	None Seen	20	None Seen
5	None Seen	21	Yes
6	None Seen	22	None Seen
7	None Seen	23	None Seen
8	None Seen	24	None Seen
9	None Seen	25	Yes
10	None Seen	26	Yes
11	None Seen	27	None Seen
12	None Seen	28	None Seen
13	None Seen	29	None Seen
14	None Seen	30	None Seen
15	None Seen	31	None Seen
16	None Seen	32	None Seen

Test Report SL520352985481O1TX **Date:September 30,2020**

XIANTAO XINGRONG PROTECTIVE PRODUCTS CO.,LTD
NO.46 PENGCHANG AVENUE, PENGCHANG TOWN, XIANTAO CITY, HUBEI PROVINCE

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

Sample Description	:	(A)Disposable medical mask
SGS Internal Ref.No.	:	SHHL2009542949MD
Sample Color	:	(A)blue
Style No.	:	17.5cmx9.5cm
Lot No.	:	XR2020008
Manufacturer	:	XIANTAO XINGRONG PROTECTIVE PRODUCTS CO.,LTD
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Sep 18, 2020
Testing Period	:	Sep 18, 2020 - Sep 30, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. for further details, please refer to the following page(s).

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

Sara Guo (Account Executive)

Dongjing Liu / Haifan Xuan (Authorized Signatory)

Test Result

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

Clause 5.2 Performance Requirement

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

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~180mm x 157mm
Positive Control Average	:	2742 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

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

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

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

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

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm^2)	The average value for each test specimen (Pa/cm^2)
1	1-1	39.9	38
	1-2	39.7	
	1-3	37.5	
	1-4	39.6	
	1-5	35.4	
2	2-1	35.4	38
	2-2	36.7	
	2-3	38.9	
	2-4	39.6	
	2-5	38.7	
3	3-1	39.5	39
	3-2	38.6	
	3-3	39.4	
	3-4	38.3	
	3-5	36.9	
4	4-1	38.4	37
	4-2	37.6	
	4-3	38.4	
	4-4	36.5	
	4-5	35.6	
5	5-1	36.9	37
	5-2	34.5	
	5-3	36.7	
	5-4	38.5	
	5-5	36.4	

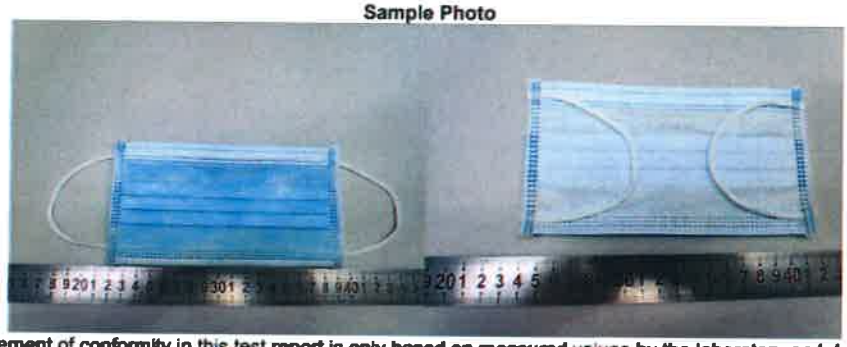
Remark:
1) Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample Number	Mask Weight(g)	Total Bioburden, (cfu/mask)	Total Bioburden, (cfu/g)
1#	2.98	12	4.03
2#	3.04	<3	<0.99
3#	3.08	6	1.95
4#	3.03	15	4.95
5#	3.05	<3	<0.98

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo



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

End of Report

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中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64956763 e sgs.china@sgs.com

Test Report **SL52035261176401TX** **Date:July 13,2020**

XIANTAO XINGRONG PROTECTIVE PRODUCTS CO., LTD.
NO. 46 PENGCHANG AVENUE, PENGCHANG TOWN, XIANTAO CITY, HUBEI PROVINCE

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

Sample Description	:	(A)Disposable medical mask
SGS Internal Ref No.	:	SHHL2006523700MD
Style No.	:	17.5cm X9.5cm
Sample Color	:	(A)Blue
Manufacturer	:	XIANTAO XINGRONG PROTECTIVE PRODUCTS CO., LTD.
Roll/ Lot No.	:	XR200612001
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Jun 22, 2020
Testing Period	:	Jun 22, 2020 - Jul 13, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

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

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)

Test Result

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

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial filtration efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Conditioning Parameters	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~177 mm x 153 mm
Test Area	:	~60 cm^2
Test Side	:	Inside
Flow Rate	:	28.3 l/min
Positive Control Average	:	2247 CFU
Negative Monitor Count	:	< 1 CFU

	1#	2#	3#	4#	5#
(BFE), %	99.9	99.9	99.9	99.9	99.9

Remark: Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%

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

Sample: A

Test number and location	:	5 random areas for each specimen (face mask)
Conditioning Parameters	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Area	:	4.9 cm^2
Flow Rate	:	8 l/min

	1#	2#	3#	4#	5#
Differential pressure ΔP (Pa/cm^2)	39	38	37	38	38

Remark: Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2

Clause 5.2.4 Splash Resistance
(ISO 22609 :2004, Pressure 16.0 kPa)

Penetration on inside surface							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Number of Pass:			32				
Overall result:			Acceptable				

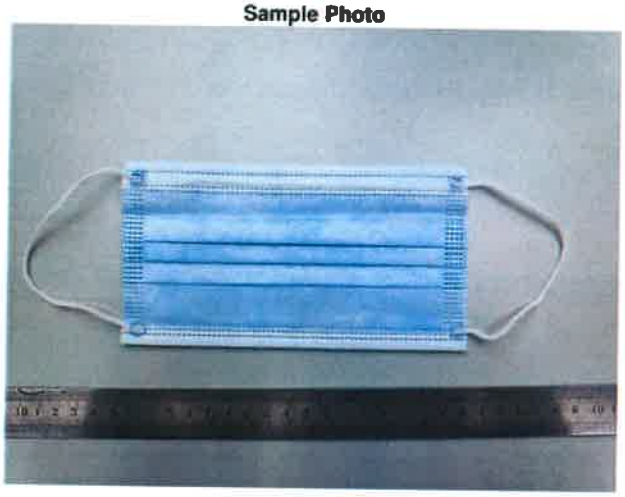
Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
3) Condition and Test temperature (21±5)° C, relative humidity (85±10)%
4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results

Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample Number	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	2.86	18	6.29
2#	2.83	3	1.06
3#	2.77	15	5.42
4#	2.81	9	3.20
5#	2.80	12	4.29

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo



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

End of Report

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QUALIFICATION CERTIFICATE 合格证

Disposable Medical Mask For Kid
一 次 性 使 用 医 用 口 罩

SPECIFICATIONS	规格	EAR LOOP TYPE	挂耳式

MEDICAL DEVICE PRODUCTION LICENS
医疗器械生产许可证编号：鄂食药监械生产许20180815号

MEDICAL DEVICE REGISTRATION CERTIFICATE NO
中华人民共和国医疗器械注册证：鄂械注准20162642286

MATERIALS 材料	70%NON WOVEN FABRIC 30%MELTBLOWN CLOTH
SIZE尺寸	145mmX90mm
STANDARD执行标准	(EN14683-2019 Type II)
QUANTITY/数量	50PCS
LOT NUMBER/批次号	20201028
PRODUCTION DATE/生产日期	20201028
EXPIRATION DATE/过期日期	20251027
EXPIRY/有效期	5Years 五年

检验合格 PASS

MANUFACTURER/制造商

Xiantao Xingrong Protective Products Co. Ltd
仙 桃 市 兴 荣 防 护 用 品 有 限 公 司

Eastern Section of Pengchang Avenue, pengchang, Xiantao City
仙 桃 市 彭 场 镇 彭 场 大 道 东 段

MADE IN CHINA