公 司简介

Company Brief Introduction

仙桃市兴荣防护用品有限公司成立于 2003 年，位于中国最大的无纺布产品生产基地：仙桃市彭场镇，是中国集无纺布制品研发，生产，销售为一体的专业型企业。我公司在 2013 年，另新建落成荣发卫生用品有限公司，其占地面积达 5 万多平米，成功引进 3.2 米宽幅 SMS 无纺布生产线，并配有 5000 平米标准净化生产车间，总投资约 9 千万，进一步完善了品质控制系统。产品主要包括：一次性口罩，鞋套，帽子，隔离衣，手术衣，防护服等其它一次性卫生防护用品，适用于：医院、电子工厂、食品行业、美容院、装修工程、清洁及日常生活等领域。 公司已通过 ISO13485 质量体系认证，且有 TUV 的 CE 认证及美国的FDA 注册证。我们始终本着“质量第一，用户至上，诚信服务”的宗旨，产品已远销欧美、中东、日韩、东南亚等国家，竭诚欢迎海内外合作伙伴携手并进，共创辉煌！我们将以多元化的产品和更优质的服务丰富您的生活！

Xingrong Protective Products Co., Ltd, founded in 2003, is located in China's largest production base of non-woven products: Pengchang, Xiantao, China. Our factory is a professional enterprise integrating development, production, and sales. In 2013, we established our new factory: Hubei Rongfa Health Products Co., Ltd which covers an area of 50,000 square meters. We successfully introduce the width of 3.2m SMS non-woven production lines ，also ,we have 5,000 square meters of standard purification production workshop .The total investment is 90 million .It further improved the quality control system . The main products are disposable face masks, shoe covers, caps, surgical gowns, patient gowns, and other disposable products for health protection, which are widely used in hospitals, electronics factories, food industry, beauty salons, decoration project, cleaning and daily life and other fields. Fully displaying the local resource advantages, we expand the market outside, intensify the management inside and ISO13485 quality management system runs well.

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*90㎜ , 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*90㎜3 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

4.原材料，生产车间及工厂外景图（Raw Material, Workshops & two FactoriesView）

Xingrong Introdution

5. 口罩车间（Face Mask Workshop）：

*原材料仓（Raw Material）

6.说 明 书 <Instruction for use>

说 明 书 (Instruction for use)

【Product Name】 Disposable Medical Face Mask

【产品名称】 一次性使用医用口罩

【Model】Elastic Earloop

【型号】橡筋口罩

【Specification】145*90mm (L)

【规格】145*90mm(L)

【Material 】

The face mask is composed of 3 ply fabric. Outer layer is waterproof nonwoven fabric,inner layer is common nonwoven fabric, the middle layer is filter paper.

【结构组成】

本产品面罩由三层材料组成，面罩外层为防水无纺布，内层为普通无纺布，中间为聚丙烯熔喷无纺布。

【 Application Range 】

Protection for Medical Organization in the general medical environment

【适用范围】

供医疗单位在普通的医疗环境中作防护使用

【Performance】

BFE, Delta P conform to the standard of 《YY/T 0969-2013》

【产品性能】

细菌过滤效率、通气阻力符合《YY/T 0969-2013 一次性使用医用口罩》的要求

【 Instructions】

1.Wear the inner layer in light-color covering on the mouth and with the nose clip up，then hang the elastic ties behind the ears.

2.Press the nose clip to let it fit the nose and under the eyes tightly, then adjust the mask under the chin.

【使用说明】

1.使用口罩时浅色面料面向口部，有鼻梁夹的那一边向上，然后将两端的口罩带挂于耳后。

2.轻按鼻夹，使其与鼻梁和双眼下部贴合，然后将口罩下端调节至下颌处。

【Notes】

1.Please check the packing before use. And use it within the validity period

2.This product is single used. Do not reuse it.

3.The person who is non woven fabric allergy should use with caution.

【注意事项】

1.使用前请检查包装是否完好。并在有效期内使用

2.产品为一次性用品，禁止重复使用

3.对无纺布过敏者慎用

【Storage】 Storage in a dry, ventilated environment with no corrosive gases.

【储存条件】 建议储存在干燥，通风，无腐蚀性气体的环境中

【Validity Period】 5 years

【有效期】 5 年

7.资质证书

Certificate

7.1 营业执照,医疗器械医疗许可证,医疗器械注册证-医用口罩 Business License, Medical Device ManufacturingLicense, China Medical Device Registration certificate for medical face mask

营业执照

(1—1)

(副 本)

统一社会信用代码 91429004753447771A

名　　称　仙桃市兴荣防护用品有限公司

类　　型　有限责任公司(自然人投资或控股)

住　　所　仙桃市彭场镇彭场大道

法定代表人　刘四祥

注册资本　捌佰万圆整

成立日期　2003年11月26日

营业期限　长期

经营范围　非织造布、服装、无纺布制品、塑料制品、纸制品、针织领口、针织袖口、塑料纽扣、拉链、橡筋、低弹丝、线的生产、加工、销售；经营本企业所需机械设备的生产、加工销售；经营本企业自产产品的货物进出口、技术进出口；医疗器械II类的生产；医疗器械第I类、第II类、第III类的销售。（涉及许可经营项目，应取得相关部门许可后方可经营）

登记机关　仙桃市工商行政管理局

2019 年 01 月 24 日

企业信用信息公示系统网址：/192.0.99.148/Topics/CertTabPrint.do　　中华人民共和国国家工商行政管理总局监制　　2015-1-24

医疗器械生产许可证

许可证编号：鄂食药监械生产许20180815号

企业名称：仙桃市兴荣防护用品有限公司　　生产地址：仙桃市彭场镇彭场大道东段86号（整个厂区）

法定代表人：刘四祥　　生产范围：二类：6864医用卫生材料及敷料。***

企业负责人：刘四祥

住　　所：仙桃市彭场镇彭场大道　　发证部门：湖北省食品药品监督管理局

有效期限：至　2023　年 7　月 25　日　　发证日期：　2018　年 7　月 26　日

国家食品药品监督管理总局制

中华人民共和国医疗器械注册证

注册证编号：鄂械注准 20162642286

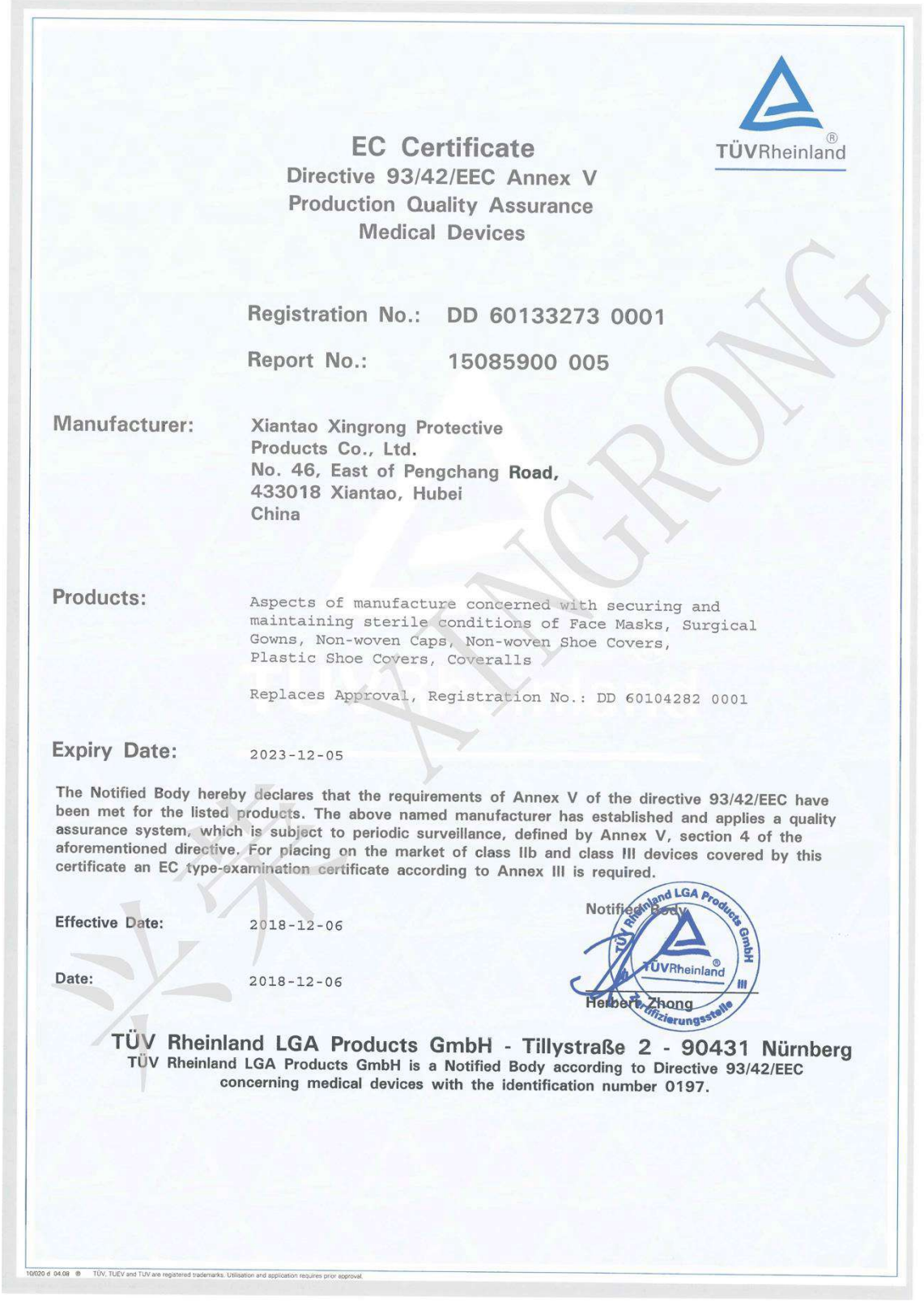
注册人名称	仙桃市兴荣防护用品有限公司
注册人住所	仙桃市彭场镇彭场大道北侧
生产地址	仙桃市彭场镇彭场大道北侧
代理人名称	不适用
代理人住所	不适用
产品名称	一次性医用口罩
型号、规格	橡筋口罩：12cm×7cm（S） 14.5cm×9cm（M）17.5m×9.5cm（L）；绑带口罩：12cm×11cm（S） 13cm×12cm（M） 14cm×13cm（L）。卫生级别为灭菌级
结构及组成	本品由非织造布、熔喷过滤布、鼻梁条、口罩带（或橡皮筋）组成。由两层非织造布夹一层熔喷过滤布经折叠超声波复合而成。口罩上配有鼻夹，鼻夹由可弯折的可塑性材料制成。
适用范围	本口罩为一次性使用产品，用于医疗环境、公共卫生场所中的卫生护理，阻隔空气中的尘埃等颗粒的传播，防止其侵入人体，避免交叉感染。（本口罩不能作为外科或防护口罩使用）
附　件	产品技术要求
其他内容	
备　注	

审批部门：湖北省食品药品监督管理局　　批准日期：2016 年 05 月 18 日

有效期至：2021 年 05 月 15 日

（审批部门盖章）

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



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

TÜVRheinland®

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
Prüfzierungsstelle

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.

10/020 d 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

CE certificate:

7.3.ISO 13485 体系证书 (Website trackinghttps://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 Zhong

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
global service

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: 2006US609548
Issue date: Apr.11, 2020

SUNGO Technical Service Inc.
6050 W EASTWOOD AVE APT 201
CHICAGO, ILLINOIS 60630, USA
sungo.group@yahoo.com

7.5 检验报告

Test Report

GTT

检验检测报告

防伪查询网址：www.gttc.net.cn
防伪码：RAOJ-4112-24

No:200025156　　共3页 第1页

委托单位	仙桃市兴荣防护用品有限公司 地址：湖北省仙桃市彭场镇彭场大道东段46号				
客户认定信息	一次性无纺布口罩　　18个				
检验性质	委托检测	样品受理/测试开始日期	2020-02-26	报告签发日期	2020-02-29
判定依据	YY/T 0969-2013 《一次性使用医用口罩》				
综合检验结论	---				

检验检测结果	检验检测项目	判定依据	判定
	细菌过滤效率	YY/T 0969-2013	符合

备注	本报告中检验检测项目均在相应标准规定的环境条件下进行（有注明的除外）。 复印件、副本未重新加盖报告书确认章无效。 本报告检验检测地址为广州市番禺区珠江路1号。

检验检测专用章

签发：方明 工程师　方明

总部：广州市番禺区珠江路1号
花都实验室：广州市花都区狮岭镇旗岭河滨西路1号
电话：020-61994598/61994599
电话：020-37721161

检验检测报告附页

No:200025156

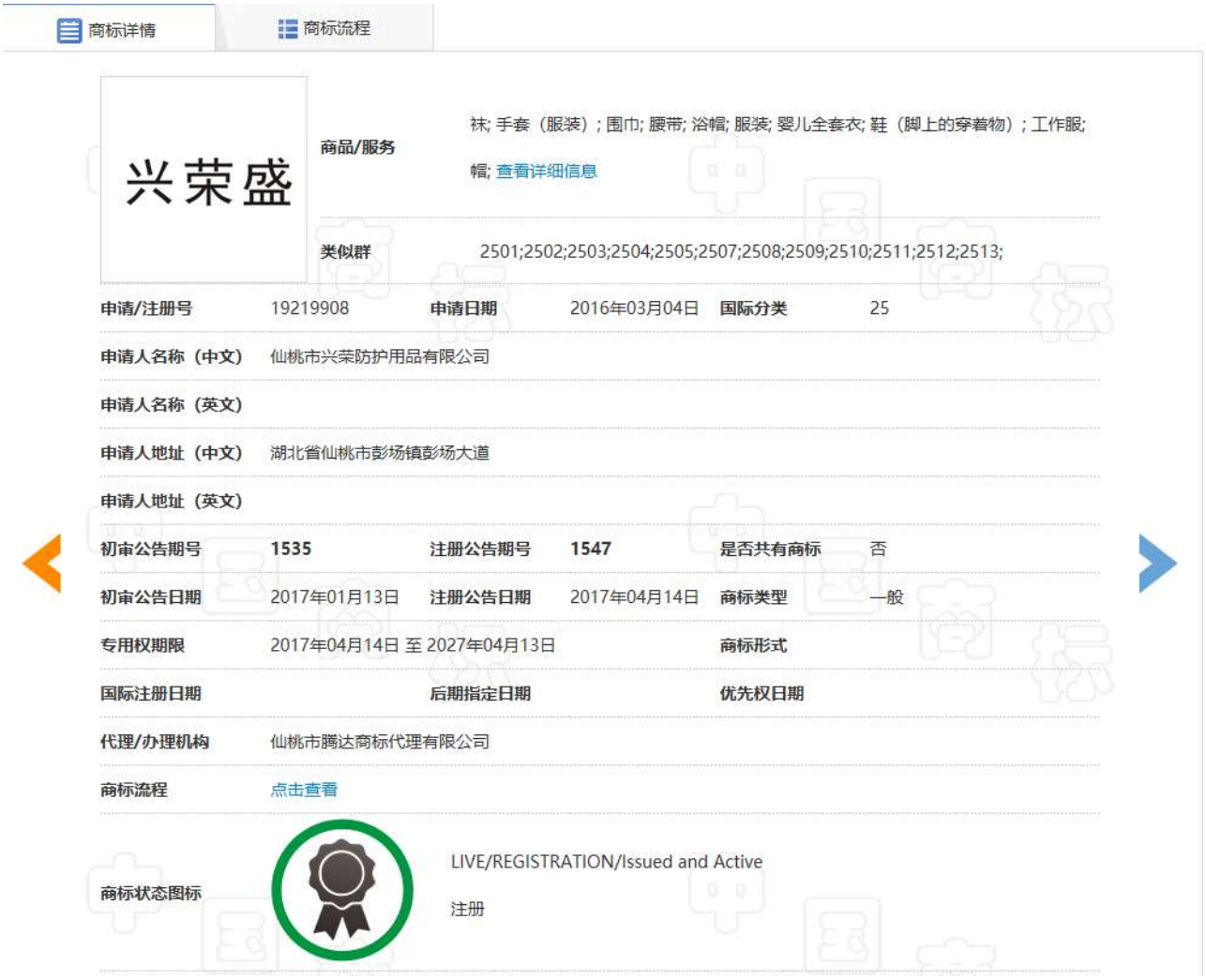
检验检测项目 (计量单位) [样品识别]	测试方法	标准值及允差	检验检测结果	判定	备注
●细菌过滤效率 (%)	YY 0469-2011 附录B 测试菌种: 金黄色葡萄球菌ATCC 6538 测试面积: 40cm^2 气体流速: 28.3L/min 平均颗粒直径: 3.0μm 阳性质控值: 1.9×10^3 CFU 阴性质控值: ＜1CFU	≥95	BFE_1 99.4 BFE_2 99.5 BFE_3 99.3	符合	
备 注	(本栏空白)				

检验检测专用章

———本报告结束———

7.6. 商标注册证

Trademark Registration Certificate



商标详情 商标流程

兴荣盛

商品/服务	袜; 手套（服装）; 围巾; 腰带; 浴帽; 服装; 婴儿全套衣; 鞋（脚上的穿着物）; 工作服; 帽; 查看详细信息
类似群	2501;2502;2503;2504;2505;2507;2508;2509;2510;2511;2512;2513;

申请/注册号	19219908	申请日期	2016年03月04日	国际分类	25
申请人名称（中文）	仙桃市兴荣防护用品有限公司				
申请人名称（英文）					
申请人地址（中文）	湖北省仙桃市彭场镇彭场大道				
申请人地址（英文）					
初审公告期号	1535	注册公告期号	1547	是否共有商标	否
初审公告日期	2017年01月13日	注册公告日期	2017年04月14日	商标类型	一般
专用权期限	2017年04月14日 至 2027年04月13日			商标形式	
国际注册日期		后期指定日期		优先权日期	
代理/办理机构	仙桃市腾达商标代理有限公司				
商标流程	点击查看				
商标状态图标		LIVE/REGISTRATION/Issued and Active 注册			

7.7 中华人民共和国医疗器械产品出口销售证明 People's Republic of China Certificate for exportation of medical products

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号：鄂仙桃食药监械出 20190080
Certificate NO.：鄂仙桃食药监械出 20190080

产品名称：一次性医用口罩
Product(s): Disposable Surgical Face Mask

规格型号：橡筋口罩， 尺寸 （12cm*7cm, 14.5cm*9cm, 17.5cm*9.5cm）
绑带口罩， 尺寸 （12cm*11cm, 13cm*12cm, 14cm*13cm）
Model: Face Mask with earloop, size (12cm*7cm, 14.5cm*9cm, 17.5cm*9.5cm)
Face Mask with tie on, size (12cm*11cm, 13cm*12cm, 14cm*13cm)

产品注册或备案凭证号：鄂械注准 20162642286
Registration certificate(s)：鄂械注准 20162642286

生产企业：仙桃市兴荣防护用品有限公司
Manufacturer: Xiantao Xingrong Protective Products Co., Ltd

生产企业住所：仙桃市彭场镇彭场大道
Address of manufacturer: Pengchang Ave, Xiantao, Hubei

生产许可或备案凭证号：鄂食药监械生产许 20180815 号
Manufacturing License(s)：鄂食药监械生产许 20180815 号

兹证明上述产品已准许在中国生产和销售。
This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至：2021 年 5 月 15 日
This certification valid until: May 15th 2021

备注：
Remark:

湖北省药品监督管理局
2019 年 7 月 4 日

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 Pengchang 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	28.8
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: 10 Dec 2014

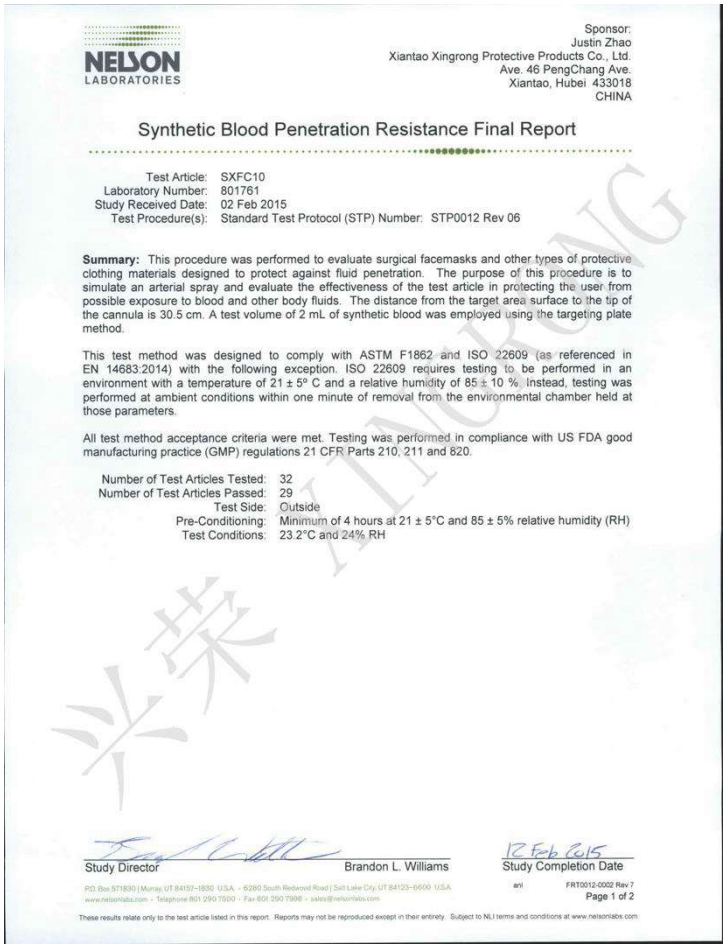
The filtration efficiency percentages were calculated using the following equation:

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

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: 801761
Study Received Date: 02 Feb 2015
Test Procedure(s): Standard Test Protocol (STP) Number: STP0012 Rev 06

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.

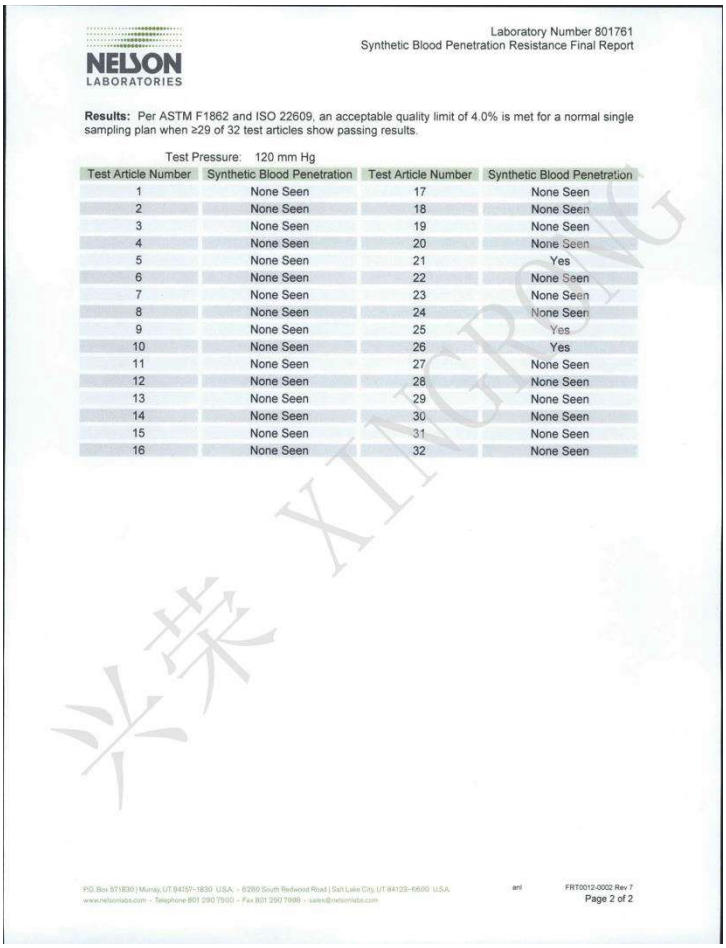
This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2014) with the following exception. ISO 22609 requires testing to be performed in an environment with a temperature of 21 ± 5° C and a relative humidity of 85 ± 10 %. Instead, testing was performed at ambient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

12 Feb 2015
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

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 / Hailian Xuan (Authorized Signatory)

3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
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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%.

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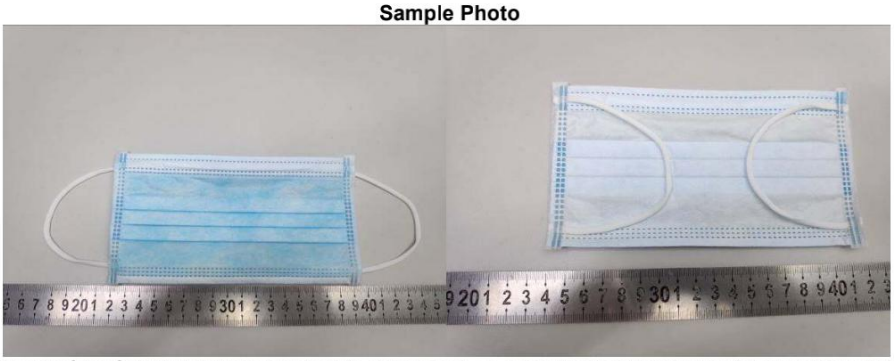
Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

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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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)

3rd Building,No.889,Yishan Road,Xuhui District Shanghai,China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn
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) 64958763 e sgs.china@sgs.com

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 △P (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

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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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17x10x8

MEDI SANTÉ

Disposable medical Mask
For Kids 4-12 Years Old
Masque jetable médical
Pour enfants âgés de 4 -12 ans

MEDI SANTÉ

Disposable medical Mask
For Kids 4-12 Years Old
Masque jetable médical
Pour enfants âgés de 4 -12 ans

EN14683-2019 Type Ⅱ CE

Instruction:

Step 1: Placez le masque face à la bande pince-nez vers le haut, avec le coté bleu vers l'exterieur, le coté blanc vers l'intérieur et accrochez-le aux deux oreilles

Peel off the package, take out the Mask.

Step 2: Appuyez sur le pince-nez avec votre main, tirez le masque sur votre bouche et votre menton, verifiez que les bords sont bien fixés

Cover the mask on the nose and mouth, and pull the straps around both ears.

Step 3: Appuyez légèrement sur le pince-nez pour vous assurer qu'il est fixé à la base du nez pour une proctéctio

Fix metal nosepiece to mode the nose area, check air tightness, cover the mouth and nose with both hands,and exhale to prevent air leakage. Readjust nosepiece if air leaks around the nose.

Masque jetable médical d'enfant
TYPE II

ATTENTION

1. Veuillez utiliser dans la période de validité.
2. Pour une utilisation unique, veuillez jeter conformément aux réglementations après utilisation.
3. Ne pas utiliser si l'emballage est endommagé.
4. N'utilisez pas le produit si vous y êtes allergique.
5. Le masque n'élimine pas le risque de contracter une maladie ou une infection.
6. Le fait de ne pas utiliser et entretenir correctement ce produit peut entraîner des maladies, voire la mort.
7. Veuillez vous référer aux instructions avant utilisation.
8. Si le masque est endommagé, souillé ou la respiration devient difficile, quittez la zone contaminée et remplacez le par un nouveau masque.
9. Conserver dans une pièce bien ventilée avec un niveau d'humudité inférieur à 80%.

6 900258 406859

Made in China EN14683-2019 Type Ⅱ CE

MEDI SANTÉ

50 Masks / Masques

BFE ≥98%
3–Layer

Disposable medical Mask
For Kids 4-12 Years Old
Masque jetable médical
Pour enfants âgés de 4 -12 ans

EN14683-2019 Type Ⅱ CE

Pediatric / Pédiatrique

Composition: 70% tissu non tissé soufflé par fusion,30%tissu non tissé
Main structure and Compositon: Non-woven fabric 70%,
Melt Blown: 30%
Product Size:145mmx90mm

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

REF **XR001**
LOT **Lot number:20201028**
MFG Date:2020-10-28
Expiry Date:2025-10-27

EC REP Luxus Lebenswelt GmbH
Kochstr.1,47877,Willich,Germany

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

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