Aoshang ASTM Level3 Earloop 3Ply and 4Ply Surgical Mask FDA 510K：K210030

Tab #6 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K210030

1. Date of Preparation: 03/09/2021

2. Sponsor Identification

Tianjin Aoshang Outdoor Equipment Co., Ltd.
C-1-106, No.23 Xiangtan Road, Hongqiao District, Tianjin

Establishment Registration Number: 3016716690.

Contact Person: Xiaoning Zhang
Position: QS Engineer
Tel: +86-22-87702678
Fax: +86-22-87702677
Email: zhangning860222@163.com

3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

Mid-Link Consulting Co., Ltd.
P.O. Box 120-119, Shanghai, 200120, China

Tel: +86-21-22815850,
Fax: 360-925-3199
Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: Medical surgical mask
Common Name: Surgical mask

Regulatory Information
Classification Name: Mask, Surgical
Classification: II;
Product Code: FXX;
Regulation Number: 21CFR 878.4040
Review Panel: General Hospital

Indication for use:
The Medical Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These surgical masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device, provided non-sterile.

Device Description:
The Medical Surgical Masks are single use, flat-pleated masks that are provided in blue. The Medical Surgical Masks are available in two types, which are Level 2 and Level 3 based on ASTM F2100-19. The outer and inner layers of the mask are made of spunbond polypropylene. The middle filter layer of Level 2 mask is made of one layer of meltblown polypropylene filter, and the middle filter layer of Level 3 mask is made of two layers of meltblown polypropylene filter. The nose clip is made of polyethylene (PE) and iron. Users can adjust the nose clip according to the shape of the bridge of the nose, and fix the mask on the bridge of the nose to prevent the mask from falling off.

The Level 2 masks are ear-loop masks. The Level 3 masks are available in two types, ear-loop and Tie-on. The ear loops for Level 2 and Level 3 masks are made of spandex. The ties are made of spunbond polypropylene. The ear loops/ties are held in place over the users' mouth and nose by two ear loops/ties welded to the mask.

5. Identification of Predicate Devices

Predicate Device 1
510(k) Number: K201479
Product Name: DemeMASK Surgical Mask

Predicate Device 2
510(k) Number: K153496

Product Name: Disposable Surgical Face Mask

6. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was same/similar to the predicate devices. The test results demonstrated that the proposed device complies with the following standards:

- 16 CFR Part 1610 Standard for the Flammability of Clothing Textiles;
- ASTM F1862/F1862M-17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity)
- ASTM F2299/F2299M-03 (2017) Standard Test Method for Determining the Initial Efficiency of Material Used in medical Face Masks to Penetration by Particulates using Latex Spheres
- ASTM F2101: 2019 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus
- ASTM F2100: 2019 Standard Specification for Performance of Materials Used in Medical Face Masks
- EN 14683: 2019, Annex C, Medical face masks- Requirements and test methods
- ISO 10993-5:2009 Biological evaluation of medical device- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical device- Part 10: Tests for irritaion and skin sensitization

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Summary of Technological characteristics

Table 1 Comparison of Medical Surgical Masks

ITEM	Proposed Device K210030	Predicate Device 1 K201479	Predicate Device 2 K153496	Remark
Product Code	FXX	FXX	FXX	Same
Regulation No.	21 CFR 878.4040	21 CFR 878.4040	21 CFR 878.4040	Same
Class	II	II	II	Same
Indication for Use	The Medical Surgical Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These surgical masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device provided non-sterile.	The Disposable Surgical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.	Same
Mask style	Flat-pleated	Flat-pleated	Flat-pleated	Same
ASTM F2100 Level	Level 2 and Level 3	Level 3	Level 2	Similar
Design feature	Level 2: Ear loop Level 3: Ear loop and Tie-on	Ear loop and Tie-on	Ear loop and Tie-on	Similar
Color	Blue	Blue	Blue	Same
Dimension	17.5cm×9.5cm	17.5cm×9.5cm	17.5cm×9.5cm	Same
Sterility	Non-Sterile	Non-Sterile	Non-Sterile	Same
Use	Single Use, Disposable	Single Use, Disposable	Single Use, Disposable	Same
Particulate filtration efficiency	Level 2 mask: average 99.71% Level 3 mask: average 99.93%	≥99%	98.46%	Different
Bacterial filtration efficiency	Level 2 mask: average 99.7% Level 3 mask: average 99.9%	≥99%	98.7%	Different
Differential	Level 2 mask: average	3.6mmH_2O/cm^2	4.2mmH_2O/cm^2	Different

pressure	2.8mmH_2O/cm^2 Level 3 mask: average 4.0 mmH_2O/cm^2 EN 14683	MIL-M-36954C	MIL-M-36954C	
Flammability	Class 1	Class 1	Class 1	Same
Fluid resistance	Level 2: Pass at 120mmHg Level 3: Pass at 160mmHg	Pass at 160mmHg	Pass at 120mmHg	Similar
Label/Labeling	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Complied with 21 CFR part 801	Same
Patient Contacting Material				
Outer facing layer	Spunbond Polypropylene	Spunbond Polypropylene	Spunbond Polypropylene	Different
Middle layer	Meltblown Polypropylene Filter	Meltblown Polypropylene Filter	Meltblown Polypropylene Filter	
Inner facing layer	Spunbond Polypropylene	Spunbond Polypropylene	Spunbond Polypropylene	
Nose clip	PE and Iron	Galvanized wire coated with polyethylene	Malleable aluminum wire	
Ear loop	Spandex	Spandex and Nylon – Not made from natural rubber latex	Polyester	
Ties	Spunbond Polypropylene	Spandex and Nylon – Not made from natural rubber latex	Spun-bond polypropylene	
Biocompatibility	ISO 10993-5 and ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing, and non-irritating.	ISO 10993-5 and ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing, and non-irritating.	ISO 10993-5 and ISO 10993-10; Under the conditions of the study, the proposed device extract was determined to be non-cytotoxic, non-sensitizing, and non-irritating.	Same

Similar - ASTM F2100 Level

The proposed devices are available in two types, which are Level 2 and Level 3 based on ASTM F2100-19. The proposed Level 2 mask can be covered by the predicate device K201479 and proposed Level 3 mask can be covered by the predicate device K153496. Thus, this difference will not affect the safety and effectiveness between the proposed device and the two predicate devices.

Similar - Design feature

The proposed Level 2 masks are ear-loop masks. The proposed Level 3 masks are available in two types, ear-loop and Tie-on. The design features of the two levels of masks for the proposed device can be covered by the design features of the two predicate devices. Thus, this difference will not affect the safety and effectiveness between the proposed device and the two predicate devices.

Different - Particulate filtration efficiency

The test result for particulate filtration efficiency for the proposed device is different from the two predicate devices. However, the test result for the proposed device can meet the requirements of level 2 mask and Level 3 mask. Thus, this difference will not affect the safety and effectiveness between the proposed device and the two predicate devices.

Different - Bacterial filtration efficiency

The test result for bacterial filtration efficiency for the proposed device is different from the two predicate devices. However, the test result for the proposed device can meet the requirements of level 2 mask and Level 3 mask. Thus, this difference will not affect the safety and effectiveness between the proposed device and the two predicate devices.

Different - Differential pressure

The test result for differential pressure for the proposed device is different from the two predicate devices. However, the test result for the proposed device can meet the requirements of level 2 mask and Level 3 mask based on ASTM F2100-19. Thus, this difference will not affect the safety and effectiveness between the proposed device and the two predicate devices.

Similar - Fluid resistance

The proposed devices are available in two types, which are Level 2 and Level 3 based on ASTM F2100-19. The test result for the proposed device can meet the requirements of level 2 mask and Level 3 mask. Thus, this difference will not affect the safety and effectiveness between the proposed device and the two predicate devices.

Different - Patient Contacting Material

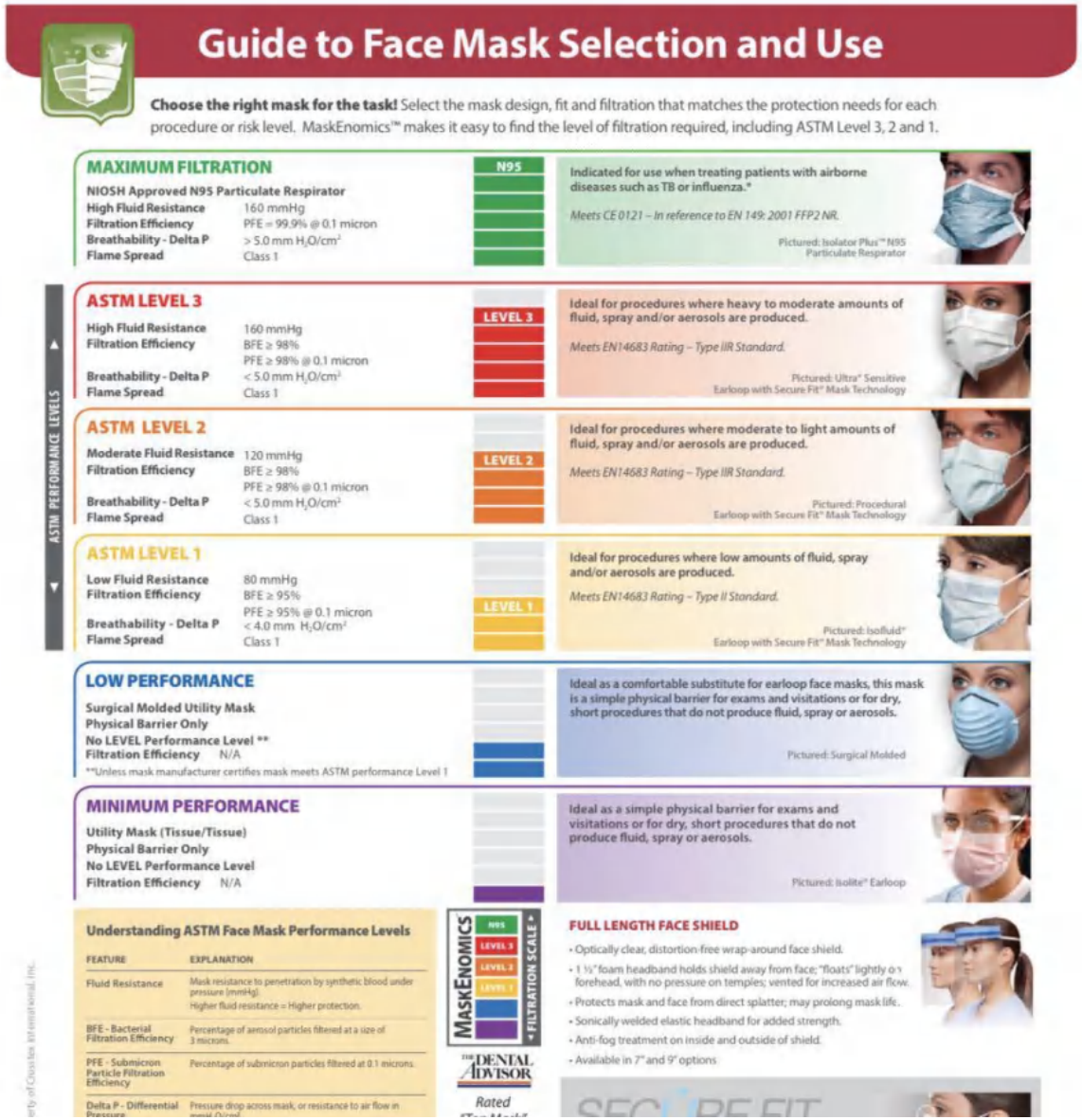
The patient contacting material for the proposed device is different from the two predicate devices. However, biocompatibility test has been performed on the proposed device and the results does not show any adverse effect. Thus, this difference will not affect the safety and effectiveness between the

proposed device and the two predicate devices.

9. Conclusion

The conclusion drawn from the non-clinical tests demonstrates that the subject device in 510(K) submission K210030, the Medical surgical mask is as safe, as effective, and performs as well as or better than the legally marketed predicate devices cleared under K201479 and K153496.

Nelson Lab Testing Reports



Our products have passed the ASTM F2100 Testing From Nelson Lab. The BFE and PFE are all over 99.5%. Our products is
real ASTM Level3 medical masks. Please find the detail of the reports in the following pages.

Manufacture:
TianJin Aoshang
Outdoor Equipment Co.,Ltd.
C-1-106, No.23 Xiangtan Road,
Hongqiao District, Tianjin,
CHINA

Sponsor:
Cai Lin
CNU International, Inc.
2721 44th Dr., Apt.1902
Long Island City, NY 11101

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

Test Article:	Lot #101
Study Number:	1289137-S01
Study Received Date:	16 Apr 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 18
Deviation(s):	None

Summary: The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 µm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-19 and EN 14683:2019, Annex B.

The Delta P test is performed to determine the breathability of test articles 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 complies with EN 14683:2019, Annex C and ASTM F2100-19.

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 Test Area:	~40 cm^2
BFE Flow Rate:	28.3 Liters per minute (L/min)
Delta P Flow Rate:	8 L/min
Conditioning Parameters:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours
Test Article Dimensions:	~172 mm x ~166 mm
Positive Control Average:	2.5 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	2.8 µm

Reid Jones electronically approved for
Study Director James Luskin

15 May 2020 20:14 (+00:00)
Study Completion Date and Time

Results:

Test Article Number	Percent BFE (%)
1	99.6
2	99.7
3	99.7
4	99.7
5	99.8

Test Article Number	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	2.6	25.2
2	2.5	24.8
3	2.8	27.3
4	2.8	27.4
5	2.6	25.6

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

Manufacture:
TianJin Aoshang
Outdoor Equipment Co., Ltd
C-1-106, No.23 Xiangtan Road,
Hongqiao District, Tianjin,
China

Sponsor:
Cai Lin
CNU International, Inc.
2721 44th Dr., Apt.1902
Long Island City, NY 11101

Latex Particle Challenge Final Report

Test Article:	Lot #101 Lot #AS002	
Study Number:	1289138-S01.1 Amended	
Study Received Date:	16 Apr 2020	
Study Completion Date:	16 May 2020	
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.	
Test Procedure(s):	Standard Test Protocol (STP) Number:	STP0005 Rev 07
Deviation(s):	Quality Event (QE) Number(s):	QE22125

Summary: This procedure was performed to evaluate the non-viable particle filtration efficiency (PFE) of the test article. Monodispersed polystyrene latex spheres (PSL) were nebulized (atomized), dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

A one-minute count was performed, with the test article in the system. A one-minute control count was performed, without a test article in the system, before and after each test article and the counts were averaged. Control counts were performed to determine the average number of particles delivered to the test article. The filtration efficiency was calculated using the number of particles penetrating the test article compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. 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
Area Tested:	91.5 cm^2
Particle Size:	0.1 µm
Laboratory Conditions:	21°C, 25% relative humidity (RH) at 0940; 21°C, 23% RH at 1100
Average Filtration Efficiency:	99.73%
Standard Deviation:	0.051

Christopher Acker electronically approved for Curtis Gerow
Study Director

26 May 2020 23:28 (+00:00)
Amended Report Date and Time

Deviation Details: Controls and sample counts were conducted for one minute instead of an average of three one minute counts. This change shortens the total test time for each sample but will still provide an accurate determination of the particle counts. An equilibrate is a dwell period where the challenge is being applied to the test article for a certain period of time before test article counts are counted. The equilibrate period was reduced from 2 minutes to a minimum of 30 seconds which is sufficient time to clear the system of any residual particles, and establish a state of stable equilibrium before sample counts are taken. Test method acceptance criteria were met, results are valid.

Results:

Test Article Number	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	37	11,150	99.67
2	25	11,517	99.78
3	28	11,327	99.75
4	27	11,426	99.76
5	37	11,711	99.68

Amendment Justification: To reflect the sponsor's original request, the contact information was updated.

Sponsor:
TianJin Aoshang Outdoor Equipment Co., Ltd
C-1-106, No. 23 Xiangtan Road
Hongqiao District, Tianjin,
CHINA

Synthetic Blood Penetration Resistance Final Report

Test Article:	Lot#102
Purchase Order:	AS20200625
Study Number:	1317678-S01
Study Received Date:	08 Jul 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0012 Rev 09
Deviation(s):	None

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 14683:2019 and AS4381:2015) 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:	31
Test Side:	Outside
Pre-Conditioning:	Minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity (RH)
Test Conditions:	23.8°C and 21% RH

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: 160 mmHg (21.3 kPa)

Test Article Number	Synthetic Blood Penetration
1-2, 4-32	None Seen
3	Yes

Christopher Acker electronically approved for James Luskin
Study Director

08 Sep 2020 22:30 (+00:00)
Study Completion Date and Time

Nelson Labs
A Sotera Health company

Manufacturer
TianJin Aoshang Outdoor Equipment Co., Ltd.
C-1-106,No.23 Xiangtan Road, Hongqiao District, Tianjin, CHINA

Sponsor:
USA Importer/ Distributor:
CNU International, Inc.
2721 44th Dr., Apt.1902
Long Island City, NY 11101

Flammability of Clothing Textiles Final Report

Test Article:	Lot #101
Study Number:	1289140-S01.1 Amended
Study Received Date:	16 Apr 2020
Study Completion Date:	24 Apr 2020
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0073 Rev 06
Deviation(s):	None

Summary: This procedure was performed to evaluate the flammability of plain surface clothing textiles by measuring the ease of ignition and the speed of flame spread. The parameter of time is used to separate materials into different classes, thereby assisting in a judgment of fabric suitability for clothing and protective clothing material. The test procedure was performed in accordance with the test method outlined in 16 CFR Part 1610 (a) *Step 1 - testing in the original state*. Step 2 - *Refurbishing and testing after refurbishing*, was not performed. 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 Article Side Tested:	Outside Surface
Orientation:	Machine

Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

Class	Plain Surface Textile Fabric
1	Burn time ≥3.5 seconds
2	Not applicable to plain surface textile fabrics
3	Burn time <3.5 seconds

The 16 CFR Part 1610 standard specifies that 10 replicates are to be tested if, during preliminary testing, only 1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this study.

ilac-MRA ANAB ACCREDITED ISO/IEC 17025 TESTING LABORATORY

Trang Truong for
Study Director

Curtis Gerow, B.S.

04May2020
Amended Report Date

1289140-S01

Results:

Replicate Number	Time of Flame Spread
1	DNI
2	DNI
3	DNI
4	DNI
5	DNI

DNI = Test Article did not ignite

Amendment Justification: The sponsor information was changed to reflect both the distributor and manufacturer.

Certificate Of Rigistration

统一社会信用代码
91120106340881035 5

营业执照

（副本）

扫描二维码登录"国家企业信用信息公示系统"了解更多登记、备案、许可、监管信息。

名　　称　天津奥尚户外装备有限公司

类　　型　有限责任公司

法定代表人　韩晓斌

经营范围　一般项目：产业用纺织制成品制造；第一类医疗器械生产；第一类医疗器械批发；第一类医疗器械零售；第二类医疗器械批发；第二类医疗器械零售；医护人员防护用品批发；医护人员防护用品零售；特种劳动防护用品生产；特种劳动防护用品销售；劳动保护用品销售；劳保用品批发；劳动保护用品生产；服装制造；服装服饰批发；服装服饰零售；服饰制造；日用杂品制造；日用百货批发；针纺织品批发；塑料制品制造；塑料制品批发；珠宝首饰批发；金属制日用品制造；羽毛(绒)及制品制造；户外用品零售；箱包制造；鞋帽批发；缝制机械制造；金属制品批发；金属链条及其他金属制品制造；体育用品及器材批发；文具用品批发；纸制品制造；五金产品批发；工艺品及收藏品零售（象牙及其制品除外）；工艺美术品及礼仪用品制造（象牙及其制品除外）；工艺美术品及收藏品批发（象牙及其制品除外）；玻璃纤维及制品制造；玻璃纤维增强塑料制品制造；家用纺织制成品制造；面料纺织印染加工；毛皮制品加工；皮革制品制造；医用口罩批发；医用口罩零售；日用口罩（非医用）销售；日用口罩（非医用）生产。（除依法须经批准的项目外，凭营业执照依法自主开展经营活动）。许可项目：医用口罩生产；医护人员防护用品生产（Ⅱ类医疗器械）；第二类医疗器械生产；第三类医疗器械经营；第三类医疗器械生产；货物进出口；技术进出口。（依法须经批准的项目，经相关部门批准后方可开展经营活动，具体经营项目以相关部门批准文件或许可证件为准）。

注册资本　叁佰万元人民币

成立日期　二0一五年五月十九日

营业期限　2015年05月19日至2065年05月18日

住所　天津市红桥区湘潭道23号C-1-106

登记机关　天津市红桥区市场监督管理局

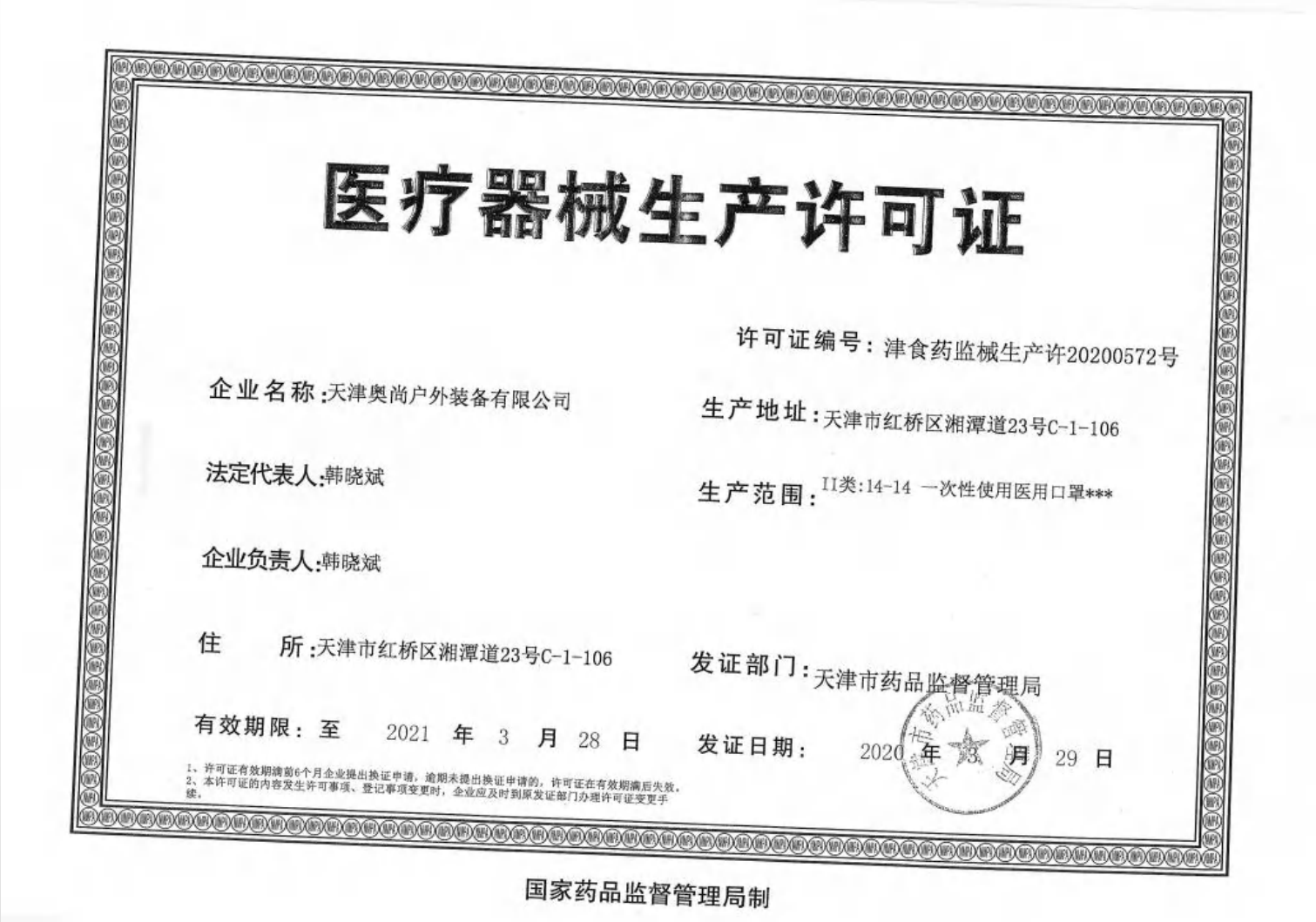
2020 年 02 月 17 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

市场主体应当于每年1月1日至6月30日通过国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制

Medical Products Manufacturing Certificate



医疗器械生产许可证

许可证编号：津食药监械生产许20200572号

企业名称：天津奥尚户外装备有限公司

生产地址：天津市红桥区湘潭道23号C-1-106

法定代表人：韩晓斌

生产范围：II类:14-14 一次性使用医用口罩***

企业负责人：韩晓斌

住　　所：天津市红桥区湘潭道23号C-1-106

发证部门：天津市药品监督管理局

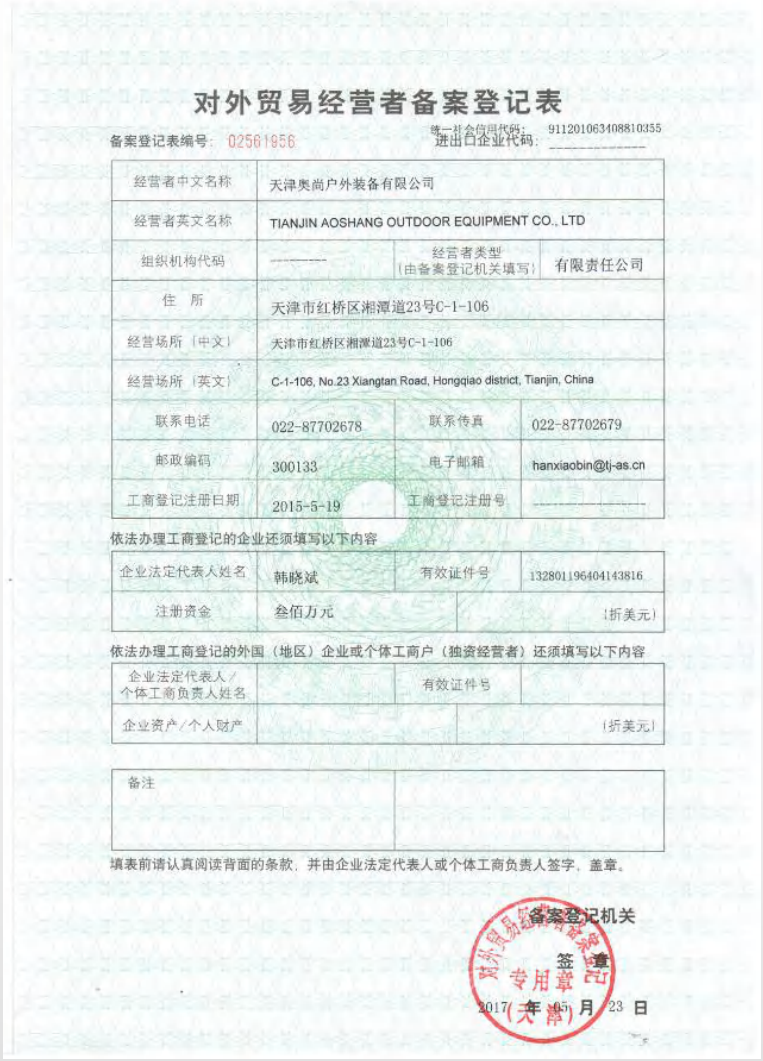
有效期限：至　2021　年　3　月　28　日

发证日期：　2020　年　3　月　29　日

1、许可证有效期满前6个月企业提出换证申请，逾期未提出换证申请的，许可证在有效期满后失效。
2、本许可证的内容发生许可事项、登记事项变更时，企业应及时到原发证部门办理许可证变更手续。

国家药品监督管理局制

Import And Export Certificate



对外贸易经营者备案登记表

备案登记表编号：02561956　　统一社会信用代码：91120106340881035S

进出口企业代码：

经营者中文名称	天津奥尚户外装备有限公司		
经营者英文名称	TIANJIN AOSHANG OUTDOOR EQUIPMENT CO., LTD		
组织机构代码	————	经营者类型（由备案登记机关填写）	有限责任公司
住　所	天津市红桥区湘潭道23号C-1-106		
经营场所（中文）	天津市红桥区湘潭道23号C-1-106		
经营场所（英文）	C-1-106, No.23 Xiangtan Road, Hongqiao district, Tianjin, China		
联系电话	022-87702678	联系传真	022-87702679
邮政编码	300133	电子邮箱	hanxiaobin@tj-as.cn
工商登记注册日期	2015-5-19	工商登记注册号	————

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	韩晓斌	有效证件号	132801196404143816
注册资金	叁佰万元		（折美元）

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人／个体工商负责人姓名		有效证件号	
企业资产／个人财产			（折美元）

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字，盖章。

备案登记机关

签　章

2017 年 05 月 23 日

FDA REGISTRATION

2020

CERTIFICATE OF REGISTRATION

This certifies that:

TIANJIN AOSHANG OUTDOOR EQUIPMENT CO., LTD.
C-1-106, No.23 Xiangtan Road,
Hongqiao District,
TianJin Tianjin, CN 300133

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	**10065770**
Device Classification Name:	**FACE MASK (EXCEPT N95 RESPIRATOR) FOR GENERAL PUBLIC/HEALTHCARE PERSONNEL PER IIE GUIDANCE**
Product Code:	**QKR**
Official Correspondent and U.S. Agent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp 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 certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Registrar Corp is not affiliated with the U.S. Food and Drug Administration.

Registrar Corp
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director
Registrar Corp
Dated: April 6, 2020

2020

CERTIFICATE OF REGISTRATION

This certifies that:

CNU INTERNATIONAL INC
2721 44th Drive
Apt.1902
Long Island City , NY 11101

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:	**10067286**
Official Correspondent:	**Registrar Corp** 144 Research Drive, Hampton, Virginia, 23666, USA Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

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

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David Lennarz
Executive Director
Registrar Corp
Dated: April 6, 2020