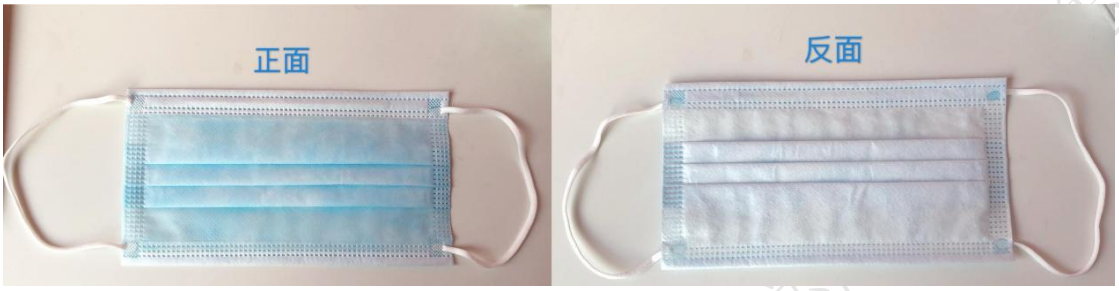
Disposable Face Mask

Packings:
Size:17.5*9.5cm
Quantity: 50/box 2000/Ctn



只供需方看

Company Profile

Established in 2001, it is a company integrating the production,sales and trade of non-woven products. We have more than 200 employees, including 10 R&D personnel, 20 professional technicians and 10 quality management staff.

With two separate factories, our company covers a total area of nearly 60,000 square meters including a Class 100,000 cleanroom and Class 10,000 laboratory.

Our products are widely used in medical protection, personal care, industrial protection, food hygiene and other fields.
We have a sound quality management system.

Our main products passed the CE certificates & ISO9001. Some products have been registered in FDA. We have also obtained registration & production license for Class II medical devices in China. Our face masks have been tested by Nelson lab in the United States to meet the highest standards of EN14683-2014 and ASTM F2100-11(2018).

We always put the quality in the first place and keep improving production technology and service level. We would work actively and try our best to provide high quality goods and the better services for overseas and domestic customers.

Certifications

一、FDA Approved

Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

has completed the FDA Establishment Registration (as manufacturer , contract manufacturer) and Device Listing with the US Food & Drug Administration, through

U.S. Agent for FDA Communications: SUNGO TECHNICAL SERVICE INC.
6050 W EASTWOOD AVE APT 201, CHICAGO, ILLINOIS 60630, USA
Telephone: +1-855-957-7779 / E-mail: sungo.group@yahoo.com

Registration Number: 3008048818
Device Listing#: See annex

SUNGO Technical Service Inc. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. SUNGO Technical Service Inc. 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. 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 certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.

FDA

Executive Director
Issued: Dec. 26 2019
Cert. No.: 2006US819518
Expiration Date: Dec. 31 2020

只供[illegible]不得作[illegible]他用途

二、NQA

Certificate of Registration

nqa

This is to certify that the Quality Management System of

XIANTAO SANDA INDUSTRIAL CO., LTD.

Unified Social Credit Code： 91429004730887731XN
Operation Address : No.46, East Section of Huangjin Avenue, Xiantao City, Hubei Province, China
Registered Address : No.46, East Section of Huangjin Avenue, Xiantao City, Hubei Province, China

applicable to

Manufacture and sales of PP non-woven series products (caps, shoes cover, sleeves, working clothing and face masks)

has been assessed and registered by NQA against the provisions of

ISO 9001:2015

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.
Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.
The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)
SNQA's website : www.snqa.com.cn

Managing Director

Certificate Number 45960

Date: 24 January 2019
Valid Until: 24 January 2022
EAC Code: 04

UKAS MANAGEMENT SYSTEMS 015

IAF

The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.
NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.
This certificate is the property of NQA and must be returned on request.

Certificate of Registration

nqa

兹证明

仙桃市三达实业有限公司

统一社会信用代码：91429004730887731XN
经营地址：湖北省仙桃市黄金大道东段 46 号
注册地址：湖北省仙桃市黄金大道东段 46 号

的质量管理体系适用于

PP 无纺布产品（帽类、鞋套、袖套、工作服、口罩）的生产和销售

已经 NQA 根据标准

ISO 9001:2015

审核和注册

注册要求组织必须按照上述标准保持其质量管理体系，并由 NQA 进行监督。
获证组织必须定期接受监督审核并经审核合格，此证书方继续有效。
本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）上查询
SNQA 查询网站：www.snqa.com.cn

Managing Director

Certificate Number 45960

Date: 24 January 2019
Valid Until: 24 January 2022
EAC Code: 04

UKAS MANAGEMENT SYSTEMS 015

IAF

The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.
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This certificate is the property of NQA and must be returned on request.

三、CE

European Commission

Verification of Conformity

Applicant:	XIANTAO SANDA INDUSTRIAL CO.,LTD
Address:	NO.46 GOLDEN AVENUE,XIANTAO,HUBEI,CHINA
Product(s):	Coverall, Lab Coat, Shoe Cover, Pillow Case, Sleeve Cover, Apron, Face Mask, Cap, Surgical Gown, Patient Gown, Isolation Gown, Bed Sheet/Bed Cover
Type(s):	See annex
Product Classification:	Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Medical Device Directive (93/42/EEC).

Standard(s) used for showing compliance with the essential requirements in the specified directive(s):

Standard(s): EN ISO 14971:2012; EN ISO 15223-1:2016; EN 1041:2013; EN ISO 10993-1:2009/AC:2010; EN ISO 10993-5:2009; EN ISO 10993-10:2013

The review result of the technical files and test report support the self declaration for the devices listed above. Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

SUNGO Cert GmbH

CE Sungo global service

Executive Director
Issued: Dec. 10 2019
Cert. No.: EU158518
Expiration Date: Dec. 9 2024

SUNGO CHINA OFFICE Tel: 021-68828052 Email:info@sungoglobal.com Website: www.sungoglobal.com
Add: 13th Floor, No.1500 Century Avenue, Shanghai 200122, P.R.China

四、Nelson Test Report

Nelson Labs
A Sotera Health company

Sponsor:
Mingmin Hu
Xiantao Sanda Industrial, Co., Ltd.
No. 46 HuangJin Ave. (East Section)
Xiantao, Hubei Province, 433000
CHINA

Latex Particle Challenge Final Report

Test Article: SD20180308-1
SD20180308-2
SD20180308-3
SD20180308-4
SD20180308-5
Study Number: 1033510-S01
Study Received Date: 23 Mar 2018
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 05
Deviation(s): None

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, dried, and passed through the test article. The particles that passed through the test article were enumerated using a laser particle counter.

Three one-minute counts were performed, with the test article in the system, and the results averaged. Three one-minute control counts were 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 average 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, 23% relative humidity (RH) at 1040; 20°C, 25% RH at 1403
Average Filtration Efficiency: 98.8%
Standard Deviation: 0.09

Study Director Brandon L. Williams — Study Completion Date 04 Apr 2018

1033510-S01

These results relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NL terms and conditions at www.nelsonlabs.com.

Results:

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	172	14,013	98.8
2	131	11,853	98.9
3	140	12,677	98.9
4	175	13,246	98.7
5	159	13,458	98.8

Nelson Labs
A Sotera Health company

Sponsor:
Mingmin Hu
Xiantao Sanda Industrial, Co., Ltd.
No. 46 HuangJin Ave. (East Section)
Xiantao, Hubei Province, 433000
CHINA

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

Test Article: SD20180308-1
SD20180308-2
SD20180308-3
SD20180308-4
SD20180308-5
Study Number: 1033509-S01
Study Received Date: 23 Mar 2018
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 15
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 - 2.7 x 10^8 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 F2101-14, EN 14683:2014, Annex B, and AS4381:2015.

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 was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C and AS4381:2015.

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: ~160 mm x ~156 mm
Positive Control Average: 2.5 x 10^8 CFU
Negative Monitor Count: <1 CFU
MPS: 2.9 µm

Study Director Janelle R. Bentz, M.S. — Study Completion Date 02 APR 2018

1033509-S01

These results relate only to the test article listed in this report. Reports may not be reproduced except in their entirety. Subject to NL terms and conditions at www.nelsonlabs.com.

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	99.3	3.1	30.4
2	99.4	3.0	29.5
3	99.4	3.3	32.4
4	99.3	3.0	29.6
5	99.7	3.2	31.6

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

仅供参考，不得作为其他用途

五、Europr EN14683 Test Report

Your notice of	Your reference	Date
03-05-2018		26-06-2018

Analysis Report 18.02617.01

Required tests :

EN 14683 (2014)	**EN 14683 - annex B (2014)**	**Bacterial filtration efficiency**
EN 14683 (2014)	**EN 14683 - annex C (2014)**	**Surgical masks - Breathability (differential pressure)**
EN 14683 (2014)	**EN 14683 - §5.2.5 (2014)**	**Microbial cleanliness on masks**

Identification number	Information given by the client	Date of receipt
T1810792	Type II Surgical Mask Lot NR. 181629	02-05-2018

Yvette Register

Order responsible

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The results of the analysis cover the received samples. Centexbel is not responsible for the representativeness of the samples.
In assessing compliance with the specifications, we did not take into account the uncertainty on the test results.

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GENT • Technologiepark 7 • BE-9052 Zwijnaarde, Belgium • phone +32 9 220 41 51 • fax +32 9 220 49 55 • gent@centexbel.be
GRÂCE-HOLLOGNE • Rue du Travail 5 • BE-4460 Grâce-Hollogne, Belgium • phone +32 4 296 82 00 • g-h@centexbel.be
KORTRIJK • Etienne Sabbelaan 49 • BE-8500 Kortrijk, Belgium • phone +32 56 281828 • fax +32 56 281830 • info@vkc.be
VAT BE 0459.218.289 • IBAN BE44 2100 4729 6545 • BIC GEBABEBB

Reference: **T1810792 - Type II Surgical Mask**
Lot NR. 181629

Bacterial filtration efficiency

Date of ending the test	31-05-2018
Standard used	EN 14683 - annex B (2014)
Product standard	EN 14683 (2014)
Mask description	Non woven masks – 3 ply (blue outside/white inside)
Number of tested masks :	5
BFE Area tested :	± 46 cm²
Masks conditioning :	21 ± 5°C and 85 ± 5% RH
Side of the mask in contact with the bacterial challenge :	Inner side
Challenge bacterial strain used :	*Staphylococcus aureus* ATCC6538
Bacterial challenge per test :	2200 ± 500 CFU
Total test time :	1 min. delivering challenge + 1 min. without challenge (air flow continuing)
Flow rate :	28.3 l/min.
Positive control	Tests performed with no filter material in the air stream
Negative control	Test performed without challenge

Performed in the microbiological lab under the responsibility of Yvette Register

Results

B = Bacterial filtration efficiency (%)

$$B = \frac{(C - T)}{C} X\ 100$$

With C = mean of the total plate counts for the positive control runs
T = total count for the tested mask

# Mask	B (%)
1	99.7
2	> 99.9
3	99.9
4	99.8
5	99.9

Mean particle size of the bacterial challenge aerosol : 3.0 µm

Controls

Mean positive controls	2395 CFU
Negative control	< 1

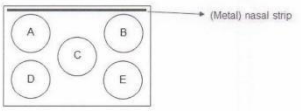
Performed in the microbiological lab under the responsibility of Yvette Register

Reference: **T1810792 - Type II Surgical Mask**
Lot NR. 181629

Surgical masks - Breathability (differential pressure)

Date of ending the test	30-05-2018
Standard used	EN 14683 - annex C (2014)
Product standard	EN 14683 (2014)
Mask description	Non woven masks – 3 ply (blue outside/white inside)
Number of tested masks :	5
Number of areas per mask	5 (see figure)
Dimension of the areas :	Disc whose diameter is 2.5 cm
Surface areas :	4.9 cm²
Flow rate :	8 l/min.
Direction of the air flow :	From the inside of the mask to the outside
Masks conditioning :	21 ± 5°C and 85 ± 5% RH

Figure : Distribution of the areas in the mask



Results **Δ P**

Performed in the microbiological lab under the responsibility of Yvette Register

只供需方参考 不得作为其他用途

	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	29.7	30.2	34.6	31.0	28.9
Area B	26.5	31.0	28.3	29.9	27.5
Area C	28.9	34.6	27.7	27.1	29.3
Area D	27.9	25.5	23.2	25.5	24.6
Area E	22.8	23.6	23.6	24.0	26.9
Average Δ P (Pa/cm²)	**27.2**	**29.0**	**27.5**	**27.5**	**27.4**

INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947

Performed in the microbiological lab under the responsibility of Yvette Register

Reference: **T1810792 - Type II Surgical Mask**
Lot NR. 181629

Microbial cleanliness on masks

Date of ending the test	05-06-2018
Standard used	EN 14683 - §5.2.5 (2014)
Product standard	EN 14683 (2014)
Number of tested masks	5
Extraction liquid	Peptone 1g/l, NaCl 5g/l & Tween 20 2g/l
Extraction volume	300 ml
Extraction time	5 min.
Counting technique	Membrane filtration
Filtration volume	100 ml
Culture media	TSA (Tryptic Soy Agar) SDA (Sabouraud Dextrose Agar with chloramphenicol)
Incubation conditions	3 days at 30°C (TSA) 7 days at 20-25°C (SDA)

Results

# Mask	Mask weight (g)	CFU*/mask		Microbial cleanliness	
		Aerobic microbial count (bacteria)	*Fungi count (SDA)*	*Σ CFU/mask*	*Σ CFU/g*
1	2.64	6	<3	< 9	< 4
2	2.60	9	<3	< 12	< 5
3	2.63	6	<3	< 9	< 4
4	2.58	18	9	27	11
5	2.63	12	3	15	6

* CFU : Colony Forming Unit

INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947

Performed under accreditation in the microbiological lab under the responsibility of Yvette Register

EN14683 Type IIR

Your notice of	Your reference	Date
03-05-2018		26-06-2018

Analysis Report 18.02617.02

Required tests :

EN 14683 (2014)	**EN 14683 - annex B (2014)**	**Bacterial filtration efficiency**
EN 14683 (2014)	**EN 14683 - annex C (2014)**	**Surgical masks - Breathability (differential pressure)**
EN 14683 (2014)	**EN 14683 - §5.2.5 (2014)**	**Microbial cleanliness on masks**
EN 14683 (2014)	**ISO 22609 (2004)**	**Surgical masks - Splash Test**

Identification number	Information given by the client	Date of receipt
T1810793	Type II R Surgical Mask Lot NR. 181629	02-05-2018

Yvette Register

Order responsible

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The results of the analysis cover the received samples. Centexbel is not responsible for the representativeness of the samples.
In assessing compliance with the specifications, we did not take into account the uncertainty on the test results.

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KORTRIJK • Etienne Sabbelaan 49 • BE-8500 Kortrijk, Belgium • phone +32 56 281828 • fax +32 56 281830 • info@vkc.be
VAT BE 0459.218.289 • IBAN BE44 2100 4729 6545 • BIC GEBABEBB

INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTE-LOI DU 30 JANVIER 1947

Reference: **T1810793 - Type II R Surgical Mask**
Lot NR. 181629

Bacterial filtration efficiency

Date of ending the test	31-05-2018
Standard used	EN 14683 - annex B (2014)
Product standard	EN 14683 (2014)
Mask description	Non woven masks – 3 ply (blue outside/white inside)
Number of tested masks :	5
BFE Area tested :	± 46 cm²
Masks conditioning :	21 ± 5°C and 85 ± 5% RH
Side of the mask in contact with the bacterial challenge :	Inner side
Challenge bacterial strain used :	*Staphylococcus aureus* ATCC6538
Bacterial challenge per test :	2200 ± 500 CFU
Total test time :	1 min. delivering challenge + 1 min. without challenge (air flow continuing)
Flow rate :	28.3 l/min.
Positive control	Tests performed with no filter material in the air stream
Negative control	Test performed without challenge

Performed in the microbiological lab under the responsibility of Yvette Register

Results

B = Bacterial filtration efficiency (%)

$$B = \frac{(C - T)}{C} \; X \; 100$$

With C = mean of the total plate counts for the positive control runs
T = total count for the tested mask

# Mask	B (%)
1	> 99.9
2	99.9
3	99.9
4	99.6
5	99.9

Mean particle size of the bacterial challenge aerosol : 3.0 µm

Controls

Mean positive controls 2395 CFU
Negative control < 1

INRICHTING ERKEND BIJ TOEPASSING VAN DE BESLUITWET VAN 30 JANUARI 1947 / ETABLISSEMENT RECONNU PAR APPLICATION DE L'ARRÊTÉ LOI DU 30 JANVIER 1947

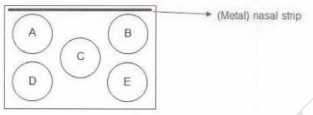
Reference: T1810793 - Type II R Surgical Mask
Lot NR. 181629

Surgical masks - Breathability (differential pressure)

Date of ending the test 30-05-2018
Standard used EN 14683 - annex C (2014)
Product standard EN 14683 (2014)

Mask description Non woven masks – 3 ply (blue outside/white inside)
Number of tested masks : 5
Number of areas per mask 5 (see figure)
Dimension of the areas : Disc whose diameter is 2.5 cm
Surface areas : 4.9 cm²
Flow rate : 8 l/min.
Direction of the air flow : From the inside of the mask to the outside
Masks conditioning : 21 ± 5°C and 85 ± 5% RH

Figure : Distribution of the areas in the mask



Results Δ P

	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5
Area A	33.0	39.1	34.0	34.2	37.7
Area B	31.6	34.4	35.4	34.0	36.7
Area C	34.2	33.2	35.2	30.4	34.6
Area D	32.2	33.6	32.2	32.6	30.6
Area E	31.6	32.6	31.6	32.4	30.6
Average Δ P (Pa/cm²)	**32.5**	**34.6**	**33.7**	**32.7**	**34.0**

Reference: T1810793 - Type II R Surgical Mask
Lot NR. 181629

Microbial cleanliness on masks

Date of ending the test 01-06-2018
Standard used EN 14683 - §5.2.5 (2014)
Product standard EN 14683 (2014)

Number of tested masks 5
Extraction liquid Peptone 1g/l, NaCl 5g/l & Tween 20 2g/l
Extraction volume 300 ml
Extraction time 5 min.
Counting technique Membrane filtration
Filtration volume 100 ml
Culture media TSA (Tryptic Soy Agar)
SDA (Sabouraud Dextrose Agar with chloramphenicol)
Incubation conditions 3 days at 30°C (TSA)
7 days at 20-25°C (SDA)

Results

# Mask	Mask weight (g)	CFU*/mask		Microbial cleanliness	
		Aerobic microbial count (bacteria)	*Fungi count (SDA)*	*Σ CFU/mask*	*Σ CFU/g*
1	3.04	3	<3	< 6	< 2
2	2.99	6	3	9	4
3	3.00	<3	<3	< 6	< 2
4	2.97	3	<3	< 6	< 3
5	3.02	6	<3	< 9	< 3

* CFU : Colony Forming Unit

只供需方参考，不得作为其他用途

Certifications

营业执照

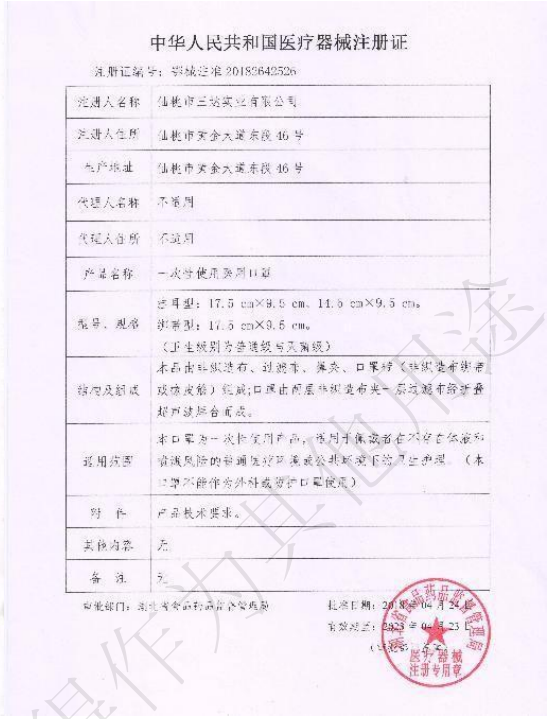
(副本) (1-1)

统一社会信用代码 91429004730887731XN

名　　称　仙桃市三达实业有限公司
类　　型　有限责任公司(自然人投资或控股)
住　　所　仙桃市黄金大道东段46号
法定代表人　黄达祥
注 册 资 本　壹佰玖拾玖万圆整
成 立 日 期　2001年10月19日
营 业 期 限　2011年10月08日至2031年10月08日
经 营 范 围　无纺布制品、棉织品服装的生产及销售；经营本企业货物进出口、技术进出口（法律、行政法规禁止的项目除外；法律、行政法规限制的项目取得许可后方可经营）。

登记机关　仙桃市工商行政管理局　年 月 日　2016 04 07

企业信用信息公示系统网址：　中华人民共和国国家工商行政管理总局监制



中华人民共和国医疗器械注册证

注册证编号：鄂械注准20182642526

注册人名称	仙桃市三达实业有限公司
注册人住所	仙桃市黄金大道东段46号
生产地址	仙桃市黄金大道东段46号
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用医用口罩
型号、规格	折叠型：17.5 cm×9.5 cm、14.5 cm×9.5 cm。 挂带型：17.5 cm×9.5 cm。 （耳带规则为普通级与儿童级）
结构及组成	本品由非织造布、过滤布、鼻夹、口罩绳（非织造布使用或熔喷布）组成；口罩由两层非织造布夹一层过滤布经超声波封合而成。
适用范围	本口罩为一次性使用产品，适用于佩戴者在公共场所等普通风险的普通医疗环境或公共场所下的个人防护。（本口罩不能作为外科或医护口罩使用）
附　件	产品技术要求。
其他内容	无
备　注	无

审批部门：湖北省食品药品监督管理局　批准日期：2018 年 04 月 24 日　有效期至：2023 年 04 月 23 日

医疗器械生产许可证

许可证编号：鄂食药监械生产许20180809号

企业名称：仙桃市三达实业有限公司　　生产地址：仙桃市黄金大道东段46号（整个厂区）

法定代表人：黄达祥　　生产范围：二类：6864医用卫生材料及敷料。***

企业负责人：黄达祥

住　　所：仙桃市黄金大道东段46号　　发证部门：湖北省食品药品监督管理局

有效期限：至　2023　年5　月31　日　　发证日期：　2018　年6　月1　日

国家食品药品监督管理总局制

仅供售卡客户使用，不得作为其他用途

中华人民共和国医疗器械注册证

注册证编号：鄂械注准 20182642526

注册人名称	仙桃市三达实业有限公司
注册人住所	仙桃市黄金大道东段 46 号
生产地址	仙桃市黄金大道东段 46 号
代理人名称	不适用
代理人住所	不适用
产品名称	一次性使用医用口罩
型号、规格	挂耳型：17.5 cm×9.5 cm、14.5 cm×9.5 cm。 绑带型：17.5 cm×9.5 cm。 （卫生级别为普通级与灭菌级）
结构及组成	本品由非织造布、过滤布、鼻夹、口罩带（非织造布绑带或橡皮筋）组成;口罩由两层非织造布夹一层过滤布经折叠超声波焊合而成。
适用范围	本口罩为一次性使用产品，适用于佩戴者在不存在体液和喷溅风险的普通医疗环境或公共环境下的卫生护理。（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	无
备　注	无

审批部门：湖北省食品药品监督管理局　　批准日期：2018 年 04 月 24 日

有效期至：2023 年 04 月 23 日

（审批部门盖章）

湖北省食品药品监督管理局 医疗器械注册专用章

JOFO

东营俊富集团

东营俊富净化科技有限公司

JOFO GROUP

DONGYING JOFO FILTRATION TECHNOLOGY CO., LTD

产 品 检 测 报 告

TEST PHYSICAL PROPERTIES

产品名称/Product：BFE-25　　测试日期/Test Date：2020.02.02

批号/Lot No：200202　　检测仪器：TSI 8130

客户代号/Customer：XTSD

测试项目 Item	单位 Unit	测试标准 Method	检测结果
克重 Basic Weight	g/m2	25g/m²±10%	24.9
外观 Appearance	------	无明显褶皱、污渍	合格
流量 Flow	LPM	32.0	32.0
阻力 Resistance	mmH2O	R≤2.5	2.4
效率 Efficiency	%	BFE≥95	BFE≥95
结论 Conclusion	本批产品合格		

备注：

以上提到的性能检测数据只适用于本批产品，这些数值不能看作是此类产品的性能指标。货架期：一年（自生产之日起）

NOTE:

The physical properties mentioned above represent this lot of non-woven fabric. These values should not be considered as specification values of this type of material . Shelf time: 1 year (From date of manufacture).

东营俊富净化科技有限公司

品管部

本单编号：QJF04-PG-41　　版号：C0

只供零方备考，不得作为其他用途

六、Export Certificate

对外贸易经营者备案登记表

备案登记表编号：01974576　　进出口企业代码：420073088731X

经营者中文名称			
经营者英文名称	]a Industrial Co.,Ltd.		
组织机构代码	73088731X	经营者类型（由备案登记机关填写）	有限责任公司
住　所			
经营场所（中文）			
经营场所（英文）	, China		
联系电话			
邮政编码			
工商登记注册日期	2001-10-19	工商登记注册号	4290042111762

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			
注册资金			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 变更经营地址	

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。

对外贸易经营者备案登记专用章（湖北仙桃）

备案登记机关

签　章

2015　年　06　月　23　日