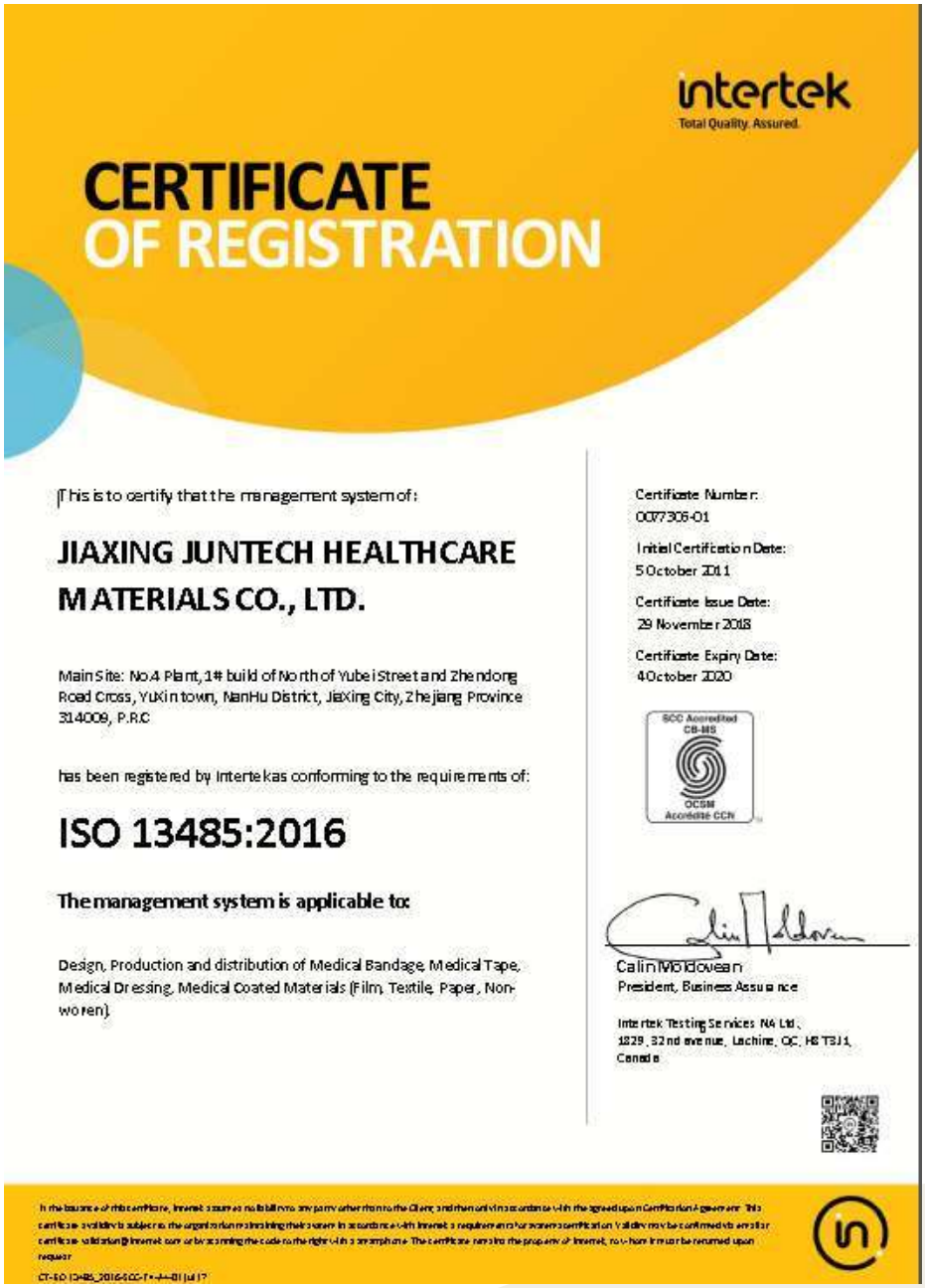
For the KN95 and N95 masks, the following details will help you better understand our KN95 mask and the approvals surrounding it:

- Our KN95 is made by Juntech. Juntech is registered with the FDA.
- Establishment listing can be viewed here: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?rid=134495
- Device listing specific to the masks: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=667326&lpcd=MSH
- That said, Juntech previously had EUA with the FDA - Emergency Use Approval. EUA allows the masks to be marketed as an acceptable equivalent and alternative to an N95 mask. Juntech was removed from the EUA list on 5/7/20, along with about 70 other manufacturers/factories. The EUA list from 5/7/20 is located here - save this to your favorites!: https://www.fda.gov/media/136663/download.
- Are our masks FDA approved? So, the short answer is yes, they are FDA approved. However, they are NOT FDA approved to sell and market as an acceptable equivalent to an N95 mask for medical use.
- Our manufacturer is reapplying for EUA. They have filtration testing that shows they meet the minimum criteria, however the FDA requires that they do their own independent testing, and it's spot testing. Meaning that when a customs declaration is made for Juntech KN95 masks arriving in the US, the FDA will intercept that shipment, independently test 10 random masks out of the shipment and release the results. This process will take time - unknown to us - could be weeks, could be months. And of course we can't guarantee the masks will pass with flying colors - we think they will, but the reality is we don't know until it happens.
- What this means is that for now, we are selling our KN95 - that do have FDA registration - as a civilian use/non-medical use mask, making no claims about equivalency to the N95. They have FDA registration but are not on the approved Emergency Use Authorization list to substitute for N95's.
- I've attached all the testing paperwork we have. These masks tested out at greater than 99.9% - far exceeding 95% (N95 and KN95 just mean greater than 95% particulate filtration). The 99.9% is a big reason why we went with Juntech in the first place. Also the EUA listing from April that had Juntech approved as an equivalent to the N95.

211 Summit Parkway, Suite 100, Birmingham, AL 35209mit Parkway, Suite 100, Birmingham, AL 35209
(205) 823-6967 | sales@stopheartattack.com | www.stopheartattack.com/health-safety/

附件 1（ISO13485 体系认证证书）



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CERTIFICATE OF REGISTRATION

This is to certify that the management system of:

JIAXING JUNTECH HEALTHCARE MATERIALS CO., LTD.

Main Site: No.4 Plant, 1# build of North of Yubei Street and Zhendong Road Cross, YuKin town, NanHu District, JiaXing City, Zhejiang Province 314009, P.R.C

has been registered by Intertek as conforming to the requirements of:

ISO 13485:2016

The management system is applicable to:

Design, Production and distribution of Medical Bandage, Medical Tape, Medical Dressing, Medical Coated Materials (Film, Textile, Paper, Non-woven).

Certificate Number:
007306-01

Initial Certification Date:
5 October 2011

Certificate Issue Date:
29 November 2018

Certificate Expiry Date:
4 October 2020

SCC Accredited CB-MS OCSM Accredite CCN

Calin Moldovean
President, Business Assurance

Intertek Testing Services NA Ltd.,
1829, 32nd avenue, Lachine, QC, H8T3J1,
Canada

地址：浙江省嘉兴市余新镇
电话：0573-83178618
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Juntech
HEALTHCARE

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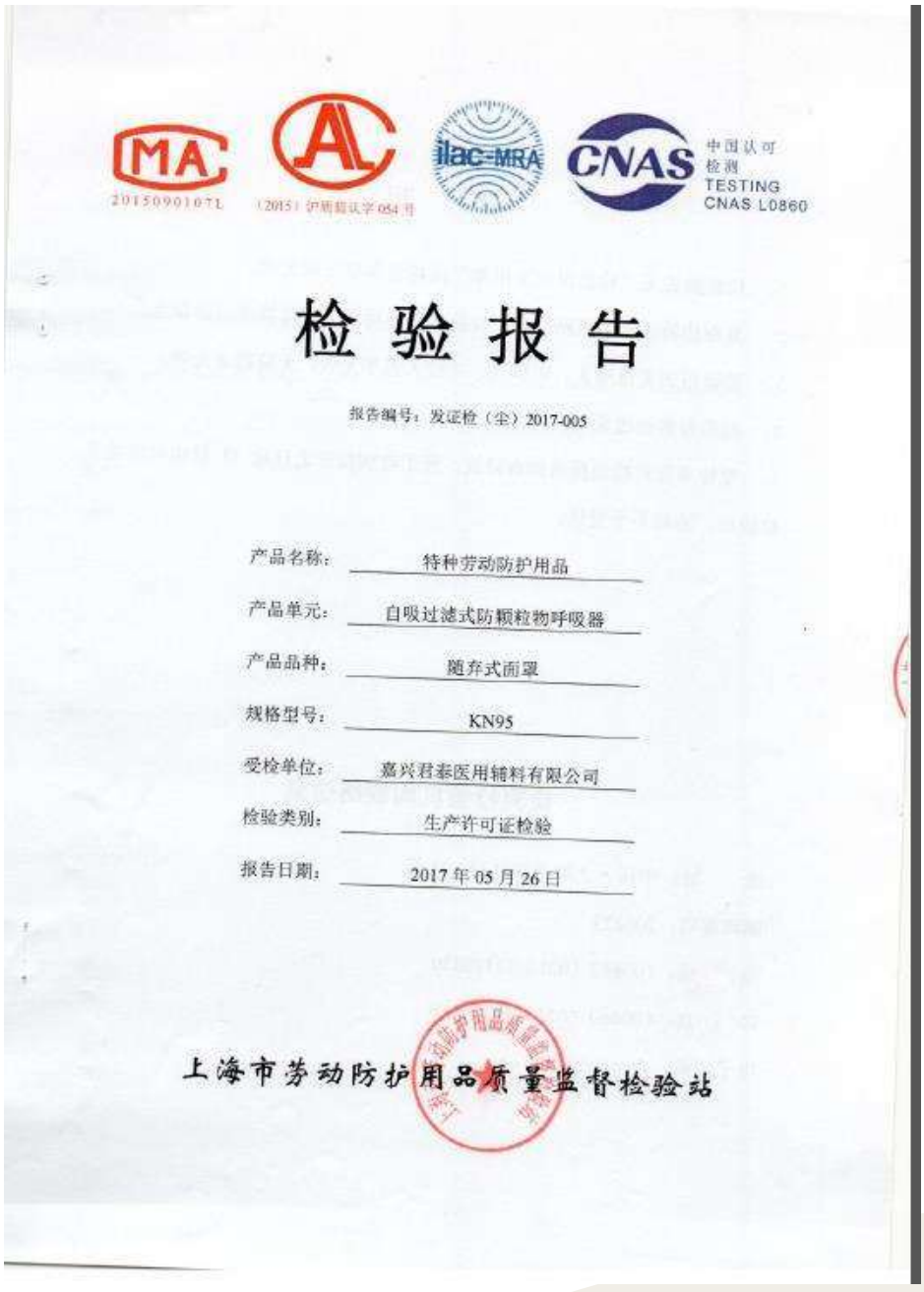

CMA 20150901071L　CAL (2015) 沪质监认字054号　ilac-MRA　CNAS 中国认可 检测 TESTING CNAS L0860

检 验 报 告

报告编号：发证检（尘）2017-005

产品名称：特种劳动防护用品

产品单元：自吸过滤式防颗粒物呼吸器

产品品种：随弃式面罩

规格型号：KN95

受检单位：嘉兴君泰医用辅料有限公司

检验类别：生产许可证检验

报告日期：2017 年 05 月 26 日

上海市劳动防护用品质量监督检验站

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检 验 报 告

No. 发证检（尘）2017-005　　共 7 页　第 1 页

产品名称	特种劳动防护用品	产品单元	自吸过滤式防颗粒物呼吸器
产品品种	随弃式面罩	规格型号	KN95
受检单位名称	嘉兴君泰医用辅料有限公司		
受检单位生产地址	浙江省嘉兴市南湖区余新镇余北大街与镇东路东北侧 1 幢四号厂房		
样品数量	36 个	样品等级	合格品
出厂编号	/	生产日期	2017 年 03 月 01 日
送 样 人	肖先德	样品编号	YP2017-0449
到样日期	2017 年 04 月 28 日	检验日期	2017 年 05 月 08 日至 2017 年 05 月 26 日
样品描述	样品为随弃式面罩，有呼气阀；样品完好。		
样品照片			
检验依据	GB 2626-2006《呼吸防护用品　自吸过滤式防颗粒物呼吸器》 （X）XK02-001《特种劳动防护用品产品生产许可证实施细则》		
检验结论	按照 GB 2626-2006 标准和特种劳动防护用品产品实施细则对自吸过滤式防颗粒物呼吸器产品进行检验，检验结果符合该标准和实施细则规定（随弃式面罩，KN95）的要求，判定该样品为合格。 检验单位： 签发日期：2017 年 05 月 26 日		
备　注	/		

批准：童遂放　职务：常务副站长　　审核：王桂芬　　主检：钱瑞琳

地址：浙江省嘉兴市余新镇
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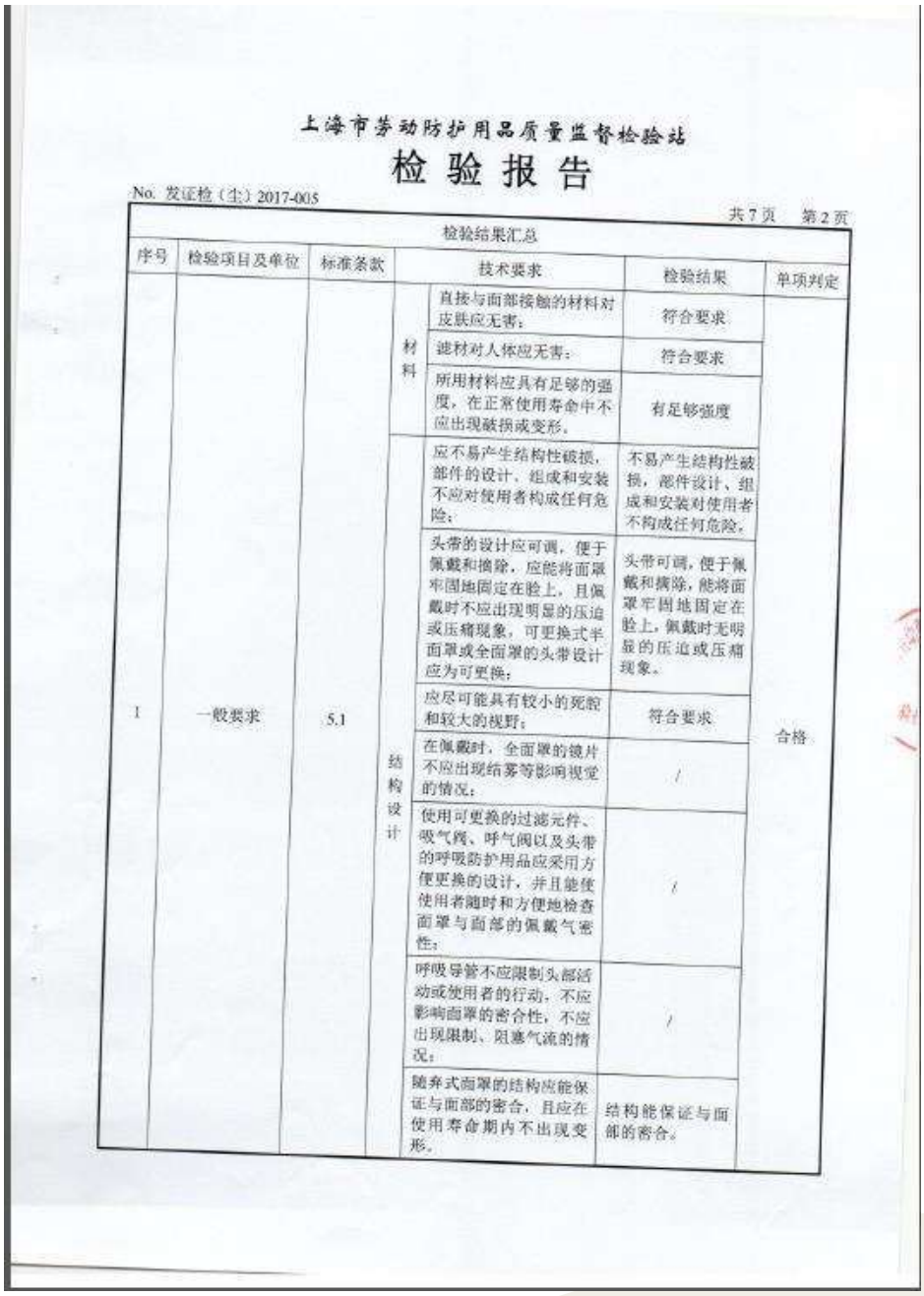

上海市劳动防护用品质量监督检验站

检 验 报 告

No. 发证检（尘）2017-005

共 7 页　第 2 页

检验结果汇总

序号	检验项目及单位	标准条款	技术要求		检验结果	单项判定
1	一般要求	5.1	材料	直接与面部接触的材料对皮肤应无害；	符合要求	合格
				滤材对人体应无害；	符合要求	
				所用材料应具有足够的强度，在正常使用寿命中不应出现破损或变形。	有足够强度	
			结构设计	应不易产生结构性破损，部件的设计、组成和安装不应对使用者构成任何危险；	不易产生结构性破损，部件设计、组成和安装对使用者不构成任何危险。	
				头带的设计应可调，便于佩戴和摘除，应能将面罩牢固地固定在脸上，且佩戴时不应出现明显的压迫或压痛现象，可更换式半面罩或全面罩的头带设计应为可更换；	头带可调，便于佩戴和摘除，能将面罩牢固地固定在脸上，佩戴时无明显的压迫或压痛现象。	
				应尽可能具有较小的死腔和较大的视野；	符合要求	
				在佩戴时，全面罩的镜片不应出现结雾等影响视觉的情况；	/	
				使用可更换的过滤元件、吸气阀、呼气阀以及头带的呼吸防护用品应采用方便更换的设计，并且能使使用者随时和方便地检查面罩与面部的佩戴气密性；	/	
				呼吸导管不应限制头部活动或使用者的行动，不应影响面罩的密合性，不应出现限制、阻塞气流的情况；	/	
				随弃式面罩的结构应能保证与面部的密合，且应在使用寿命期内不出现变形。	结构能保证与面部的密合。	

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上海市劳动防护用品质量监督检验站

检 验 报 告

No. 发证检（尘）2017-005　　共7页　第3页

检验结果汇总

序号	检验项目及单位	标准条款	技术要求		检验结果		单项判定
2	外观检查	5.2	样品的表面不应破损、变形和有明显的其他缺陷；		无破损、变形和其他缺陷。		合格
			部件材料和结构应能耐受正常使用条件及可能遇到的温度和湿度预处理；		符合要求		
			头带应可调，可更换式面罩的头带设计应为可更换；		头带可调		
			全面罩的镜片在佩戴时不应出现结雾等影响视觉的情况；		/		
			经温度湿度预处理后，部件不应脱落、损坏和变形；		无脱落、损坏和变形。		
			标识和制造商提供的各种信息。		有此类信息		
3	过滤效率（%）	5.3	KN类	KN90：≥90.0 KN95：≥95.0 KN100：≥99.97	KN95（最低值）		KN95合格
					未处理	98.0	
					温度湿度预处理	97.7	
					机械强度预处理	/	
			环境温度：25℃±5℃ 相对湿度：30％±10％		环境温度：22℃ 相对湿度：36％		
			KP类	KP90：≥90.0 KP95：≥95.0 KP100：≥99.97	最低值		
					未处理	/	
					温度湿度预处理	/	
					机械强度预处理	/	
			环境温度：25℃±5℃		/		

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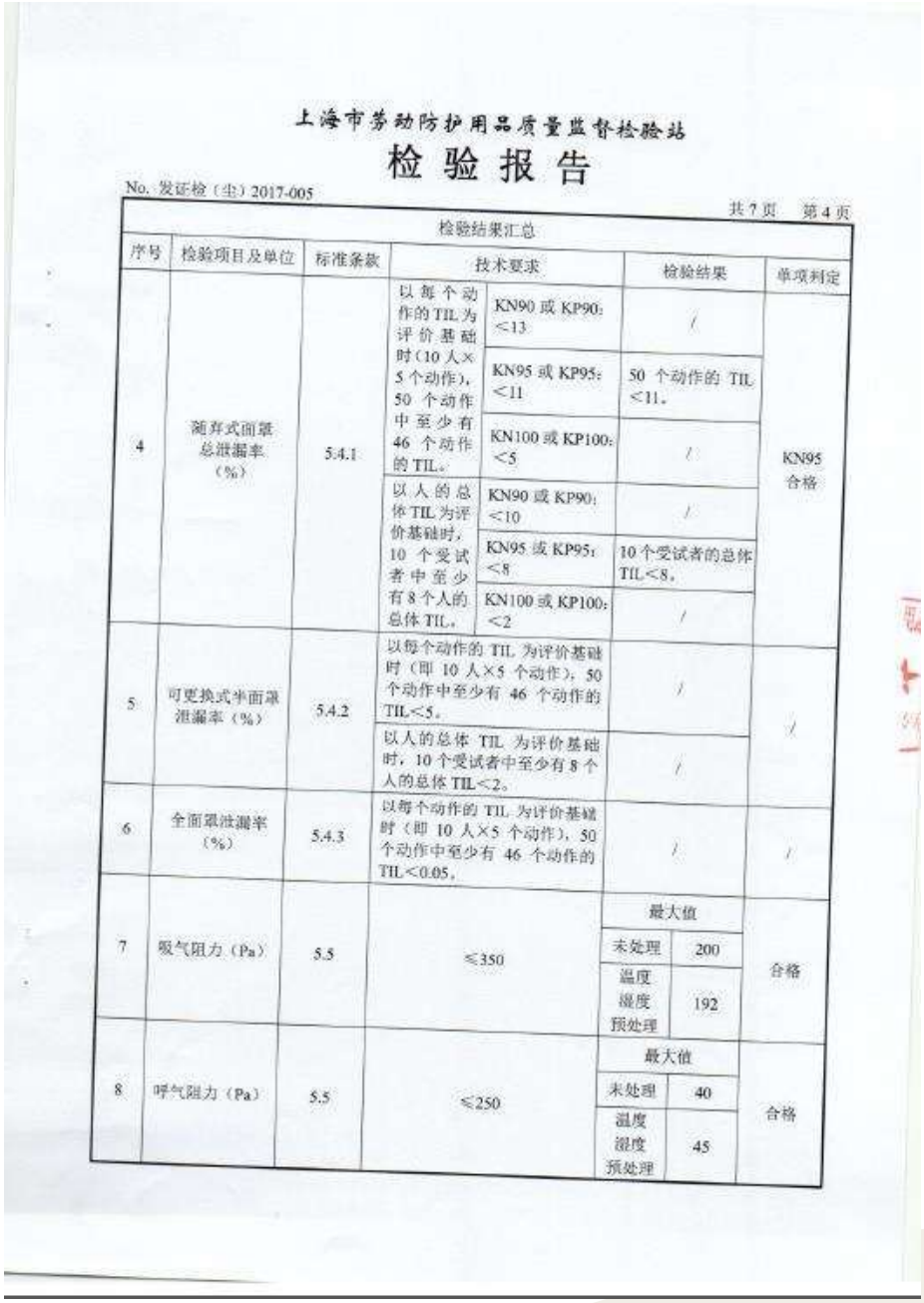

上海市劳动防护用品质量监督检验站

检 验 报 告

No. 发证检（尘）2017-005

共7页 第4页

检验结果汇总

序号	检验项目及单位	标准条款	技术要求		检验结果	单项判定
4	随弃式面罩总泄漏率（%）	5.4.1	以每个动作的TIL为评价基础时（10人×5个动作），50个动作中至少有46个动作的TIL。	KN90或KP90：≤13	/	KN95合格
				KN95或KP95：≤11	50个动作的TIL≤11。	
				KN100或KP100：≤5	/	
			以人的总体TIL为评价基础时，10个受试者中至少有8个人的总体TIL，	KN90或KP90：≤10	/	
				KN95或KP95：≤8	10个受试者的总体TIL≤8。	
				KN100或KP100：≤2	/	
5	可更换式半面罩泄漏率（%）	5.4.2	以每个动作的TIL为评价基础时（即10人×5个动作），50个动作中至少有46个动作的TIL≤5。		/	/
			以人的总体TIL为评价基础时，10个受试者中至少有8个人的总体TIL≤2。		/	
6	全面罩泄漏率（%）	5.4.3	以每个动作的TIL为评价基础时（即10人×5个动作），50个动作中至少有46个动作的TIL≤0.05。		/	/
7	吸气阻力（Pa）	5.5	≤350	最大值		合格
				未处理	200	
				温度湿度预处理	192	
8	呼气阻力（Pa）	5.5	≤250	最大值		合格
				未处理	40	
				温度湿度预处理	45	

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上海市劳动防护用品质量监督检验站

检 验 报 告

No. 发证检（尘）2017-005　　共7页　第5页

检验结果汇总

序号	检验项目及单位	标准条款	技术要求		检验结果		单项判定
9	呼气阀气密性	5.6.1	检测半面罩，各样品均不得出现下述情况之一： 1）抽气流速已经达到500 mL/min时，系统负压达不到1180 Pa； 2）呼气阀恢复至常压时间＜20 s。		最低值		合格
					未处理	＞40 s	
					温度湿度预处理	＞40 s	
			环境湿度：＜75 %		环境湿度：52 %		
10	呼气阀盖	5.6.2	随弃式面罩的呼气阀在承受10 N的轴向拉力，持续10 s时，不应出现滑脱、断裂和变形。		无滑脱、断裂和变形。		合格
			可更换式面罩的呼气阀在承受50 N的轴向拉力，持续10 s时，不应出现滑脱、断裂和变形。		/		
11	死腔（%）	5.7	以吸入气中二氧化碳体积分数表示时，结果平均值应≤1。		0.8		合格
			环境温度：16℃～32℃		环境温度：23℃		
12	视野	5.8	半面罩	下方视野≥60°	69°		合格
			全面罩 大眼窗	总视野≥70 %	/		
				双目视野≥80 %	/		
			全面罩 双眼窗	总视野≥70 %	/		
				双目视野≥20 %	/		
13	头带	5.9	随弃式面罩的每条头带、带扣及其他调节部件在承受10 N，持续时间10 s的拉力时，不应出现滑脱或断裂。		未处理	无滑脱和断裂	合格
					温度湿度预处理	无滑脱和断裂	
			可更换式半面罩的每条头带、带扣及其他调节部件在承受50 N，持续时间10 s的拉力时，不应出现滑脱或断裂。		未处理	/	
					温度湿度预处理	/	

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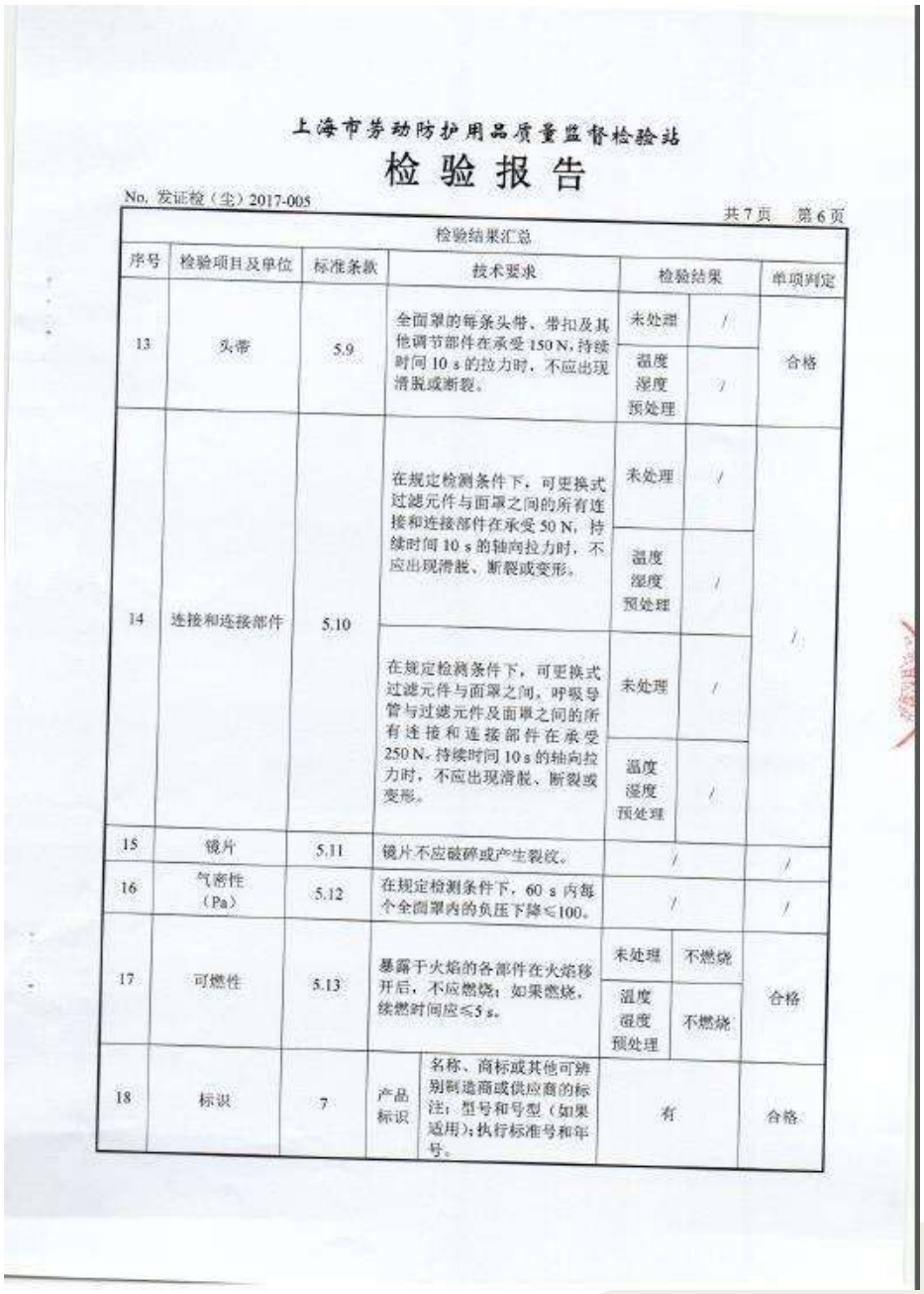

上海市劳动防护用品质量监督检验站

检 验 报 告

No. 发证检（尘）2017-005　　共7页　第6页

检验结果汇总

序号	检验项目及单位	标准条款	技术要求	检验结果		单项判定
13	头带	5.9	全面罩的每条头带、带扣及其他调节部件在承受150 N，持续时间10 s的拉力时，不应出现滑脱或断裂。	未处理	/	合格
				温度湿度预处理	/	
14	连接和连接部件	5.10	在规定检测条件下，可更换式过滤元件与面罩之间的所有连接和连接部件在承受50 N，持续时间10 s的轴向拉力时，不应出现滑脱、断裂或变形。	未处理	/	/
				温度湿度预处理	/	
			在规定检测条件下，可更换式过滤元件与面罩之间，呼吸导管与过滤元件及面罩之间的所有连接和连接部件在承受250 N，持续时间10 s的轴向拉力时，不应出现滑脱、断裂或变形。	未处理	/	
				温度湿度预处理	/	
15	镜片	5.11	镜片不应破碎或产生裂纹。	/		/
16	气密性（Pa）	5.12	在规定检测条件下，60 s内每个全面罩内的负压下降≤100。	/		/
17	可燃性	5.13	暴露于火焰的各部件在火焰移开后，不应燃烧；如果燃烧，续燃时间应≤5 s。	未处理	不燃烧	合格
				温度湿度预处理	不燃烧	
18	标识	7	产品标识	名称、商标或其他可辨别制造商或供应商的标注；型号和号型（如果适用）；执行标准号和年号。	有	合格

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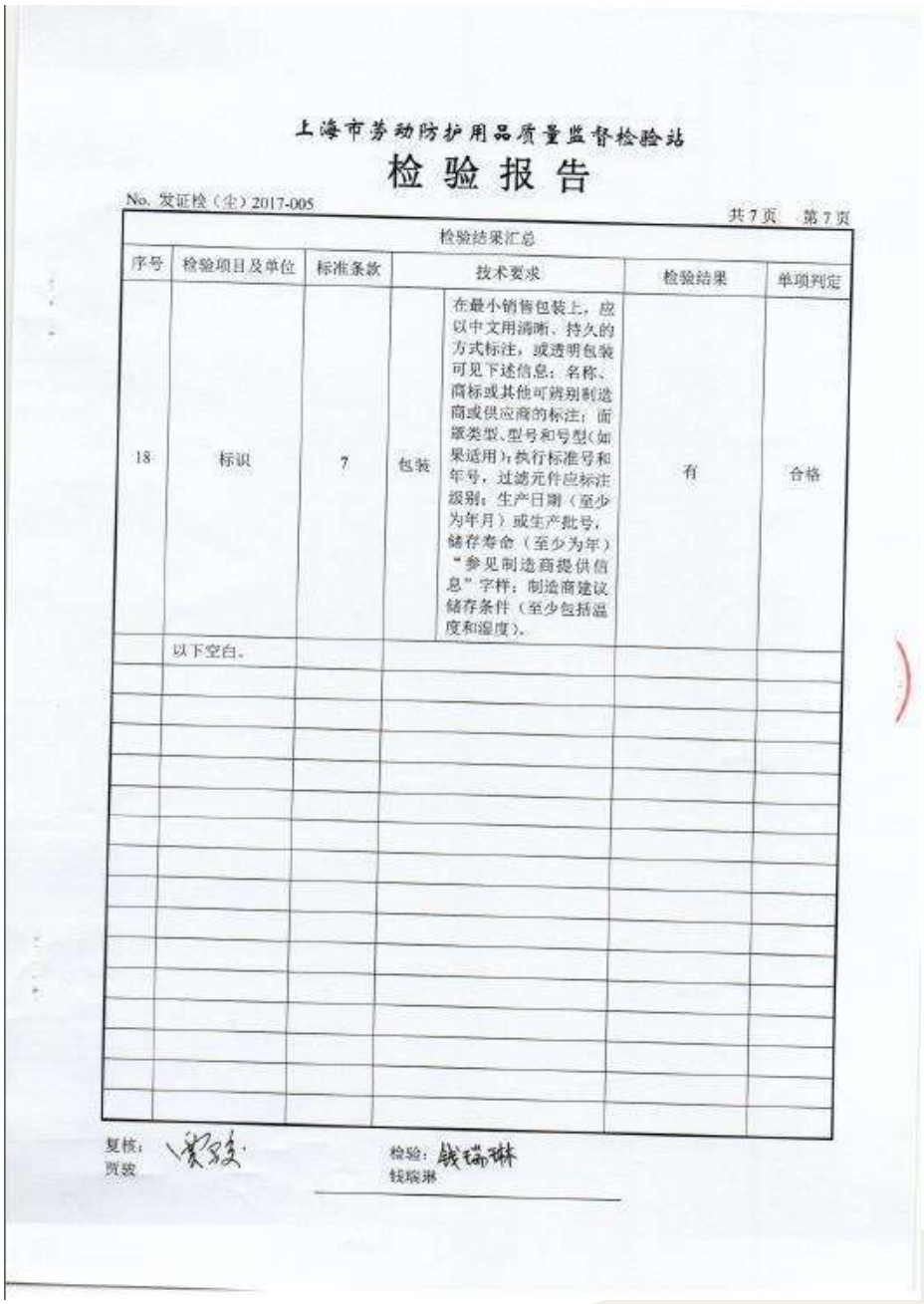

上海市劳动防护用品质量监督检验站

检验报告

No. 发证检（尘）2017-005

共7页 第7页

检验结果汇总

序号	检验项目及单位	标准条款	技术要求		检验结果	单项判定
18	标识	7	包装	在最小销售包装上，应以中文用清晰、持久的方式标注，或透明包装可见下述信息：名称、商标或其他可辨别制造商或供应商的标注；面罩类型、型号和号型（如果适用）；执行标准号和年号，过滤元件应标注级别；生产日期（至少为年月）或生产批号，储存寿命（至少为年）“参见制造商提供信息”字样；制造商建议储存条件（至少包括温度和湿度）。	有	合格
	以下空白。					

复核：贾波

检验：钱瑞琳

钱瑞琳

地址：浙江省嘉兴市余新镇
电话：0573-83178618
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Appendix A: Authorized Respirators

Updated: April 10, 2020

The Authorized Respirators

Authorized respirators should be used in accordance with CDC's recommendations. For the m
recommendations on optimizing respirator use, please visit CDC's webpage: Strategies for
Optimizing the Supply of N95 Respirators.

Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China

Manufacturer	Respirator Model(s)	Country of Manufacture
Juntech (Jiaxing) Healthcare Materials Co. Ltd	KN95	China

ıost current CDC

附件 5（TUV ASTM F2100 BFE 检测报告）

Test Report No.: 721639960
Report Date: 9 July 2018

SUBJECT	Microbiological Test
TEST LOCATION	TÜV SÜD China TÜV SÜD Products Testing (Shanghai) Co., Ltd. B-3/4, No.1999 Du Hui Road, Minhang District Shanghai 201108, P.R. China
CLIENT NAME	Jiaxing Juntech Healthcare Material Co., Ltd.
CLIENT ADDRESS	No 8 of Zhengdong Rd, Yuxin Town, Nanhu District, Jiaxing, Zhejiang, China
TEST PERIOD	06-June-2018~26-June-2018

Prepared By

(Chen Rui)
Report Drafter

Authorized By

(Shen Li)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested. (3) The test report shall not be reproduced except in full without the written approval of the laboratory. (4) Without the agreement of the laboratory, the client is not authorized to use the test results for unapproved propaganda.

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Bacterial Filtration Efficiency (BFE) Test

1. Purpose

   For evaluating the Bacterial Filtration Efficiency (BFE) of medical face mask material.

2. Sample description was given by the client

   PM 2.5 mask, Lot: 752561

3. References

   ASTM F2100-2011
   ASTM F2101-2014

4. Apparatus and materials

   4.1 *Staphylococcus aureus* ATCC 6538
   4.2 Peptone water
   4.3 Tryptic Soy Broth(TSB)
   4.4 Tryptic Soy Agar(TSA)
   4.5 Bacterial filtration efficiency test apparatus
   4.6 Six-stage viable particle Anderson sampler
   4.7 Flow meters

5. Test specimen

   5.1 As requested by client, take a total of 10 test specimens.
   5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)℃ and (85±5)% relative humidity.

6. Procedure

   6.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
   6.2 Adjust the flow rate throuth the Anderson sampler to 28.3 L/min.
   6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
   6.4 Perform a positive control run without a test specime to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated form the results of these positive control plates.
      6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
      6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
      6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
      6.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
   6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen in contact with the challenge.
   6.6 Repeat the challenge procedure for each test specimen.
   6.7 Repeat a positive control afer completion of the sample set.
   6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
   6.9 Incubate agar plates at (35±2)℃ for (48±4)h.

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6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacturer of Anderson sampler. The filtration efficiency percentages are calculated as follows:

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

Where:

C= average plate count total for positive controls

T= plate count total for sample

8. Test results

Test Items*		Test Results	Test Methods
Bacterial Filtration Efficiency(BFE)(%) *Staphylococcus aureus* ATCC 6538	1	>99.9	ASTM F2101-2014
	2	>99.9	
	3	>99.9	
	4	>99.9	
	5	>99.9	
	6	>99.9	
	7	99.9	
	8	>99.9	
	9	99.9	
	10	>99.9	

Note: 1: Control average: 2322 CFU.

2: Mean particle size:3.1 μm.

3: Testing side: faceside of specimen.

4: Testing area: 39.5cm².

5:* denotes this test was carried out by external laboratory assessed as competent.

-END OF THE TEST REPORT-

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附件 3（原料第三方检测报告）

NELSON LABORATORIES

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

Test Article:	MB-BFE99
Purchase Order:	1511021NLS01
Study Number:	859427-S01.1 Amended
Study Received Date:	23 Nov 2015
Study Completion Date:	09 Dec 2015
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0004 Rev 12

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 1.7 - 2.7 x 10^3 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:	Less Patterned Side
BFE Area Tested:	~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
Positive Control Average:	2.0 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.0 µm

ANAB ACCREDITED TESTING LABORATORY

Janelle Bentz
Study Director
Janelle R. Bentz, M.S.

25 Feb 2016
Amended Report Date

859427-S01

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NELSON LABORATORIES

Study Number 859427-S01.1 Amended
Bacterial Filtration Efficiency (BFE)
and Differential Pressure (Delta P) Final Report

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	99.8	2.5	24.6
2	>99.9	2.3	22.7
3	99.9	2.4	24.0

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

Amendment Justification: At the request of the sponsor, the sponsor contact information was changed.

附件 4（产品检测报告）

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