



湖 北 维 康

Hubei weikang

防护用品有限公司

protective equipment co., ltd,

公司简介

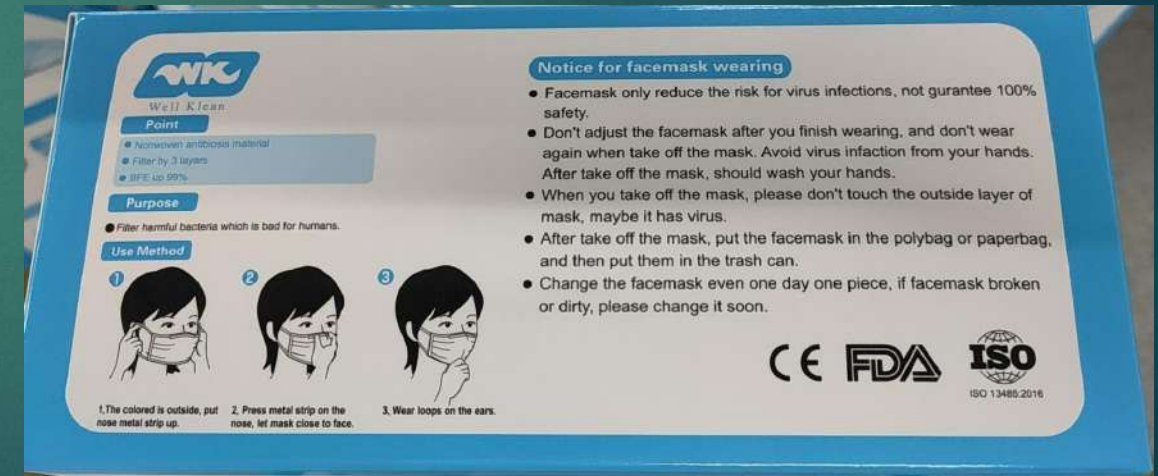
- 湖北维康防护用品有限公司是专业生产一次性无纺布制品和塑料制品的企业，位于仙桃市，素有“江汉平原之珠”和“体操之乡”之称。公司座落在汉江以南的共青县创业工业区，是长江的一条支流，靠近宜昌至黄石高速公路和**318**国道，交通便利。
- 我公司成立于**1996**年，占地**4500**平方米，现有员工**80**余人，产品主要包括一次性无纺布口罩，手术衣，防护衣，隔离衣，医用帽，鞋套以及一些塑料制品。
- 我公司产品质量优良，价格优惠，产品畅销国际市场。产品远销美国，日本，法国，韩国，新加坡，香港，台湾等二十多个国家和地区。
- 自成立以来，我们公司一直致力于为客户提供最优质，最优惠的价格，最优质的服务，并以市场为导向，不断创新。展望未来，我们将通过合理的利用逐步扩大生产规模并加强管理。信息，人才，技术和设备，通过**ISO 13485: 2016**质量认证体系标准化，我们公司竭尽全力提高产品质量和竞争能力。同时，我们拥有**CE**和**FDA**证书，以寻求更大的发展市场，我们热忱欢迎广大客户前来洽谈业务，共创辉煌！

Company Profile

- As an enterprise specializing in producing disposable non-woven products and plastic products, Hubei Weikang Protective Protective ,Co.,LTD is located in Xiantao, a city honored by the name of “Pearl of the Jiangnan Plain” and” Hometown of Gymnastics’ .Positioned in Gongqing Chuang Ye Industrial Zone at the south of Han River,a branch of Yangzi River,our company enjoys convenient transportation for it is close to Yichang-Huangshi speedway and 318 national highway.
- Our company was established in 1996.It covers 4500 square meters and have more than 80 staff.Its products mainly include disposable non-woven face mask ,surgical gown,protective gown,isolating gown,medical cap,shoecover,and some plastic.
- Our company has our products well sold in international market because of its good quality and favorable price.The products have been exporting to U.S,Japan,France,South Korea,Singapore,Hong Kong, Taiwan,etc,over 20 countries and regines.
- Since the establishment,our company has been striving to serve our customers with best quality,most favorable price and best service,and to be market-oriented and creative.Looking into the future,we will increasingly expand production scale and enhance management through reasonable utilization of information,talents,technology and equipment,standardize by ISO 13485:2016 quality certification system,our company tries its best to improve the quality of products and the competitive power.Meanwhile,we have CE and FDA certificates,in order to explore a bigger market,we warmly dear clients to negotiate business and create brilliance together!

产品展示 *Products*







Disposable Medical Mask



Disposable Medical Mask

Q'ty: 2000pcs/ctn

N.W: 7KG

G.W: 8KG

MEAS: 52×38×35CM



ISO 13485:2018

VENDOR NAME: HuBei Weikang Protective Products Co.Ltd

ADD: GongQing ChuangYe Industrial Zone, YeWang Rd.
Xiantao 433000, Hubei, China

F&D Administration Registration Number 3005090771

LOT: WK20200420

MFR DATE: 20/04/2020

EXP DATE: 20/04/2022

MADE IN CHINA

厂区展示
Factory show



车间展示
production line



BFE检测报告

BFE Test Report



Sponsor:
Cindy Jiang
Hubei Weikang Protective Products Co., Ltd.
Gongqing Chuangye Industrial Zone,
Yewang Rd.
Xiantao, Hubei, 433000
CHINA

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

Test Article: WK018-238/235
3-PLY FACE MASK WITH EARLOOP
Purchase Order: WK-TEST-20180912
Study Number: 1098109-S01
Study Received Date: 17 Sep 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 1.7×10^7 colony forming units (CFU) with a mean particle size (MPS) of $3.0 \pm 0.3 \mu\text{m}$. 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: $\sim 40 \text{ cm}^2$
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 Liters per minute (L/min)
Conditioning Parameters: $85 \pm 5\%$ relative humidity (RH) and $21 \pm 5^\circ\text{C}$ for a minimum of 4 hours
Test Article Dimensions: $\sim 174 \text{ mm} \times \sim 157 \text{ mm}$
Positive Control Average: 2.5×10^7 CFU
Negative Monitor Count: < 1 CFU
MPS: $3.2 \mu\text{m}$



Janelle R. Bentz
Study Director

Janelle R. Bentz, M.S.

26 Sep 2018
Study Completion Date



801-290-7500 | nelsonlabs.com | sales@nelsonlabs.com

STP0004-001 Rev 15
Page 1 of 2

These results relate only to the test article listed on this report. Reports may not be reproduced without its written consent. Subject to ML terms and conditions at www.nelsonlabs.com



Study Number 1098109-S01
Bacterial Filtration Efficiency (BFE)
and Differential Pressure (Delta P) Final Report

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H ₂ O/cm ²)	Delta P (Pa/cm ²)
1	99.9	3.0	29.8
2	>99.9	3.1	30.3
3	99.8	3.0	29.4
4	99.9	3.0	29.1
5	99.8	2.9	28.3

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.

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STP0004-001 Rev 15
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资质证照 Certifications

页码: 1/1 (W)

营业执照

(副本) (1-1)

统一社会信用代码 91429004757013938H

名称 湖北维康防护用品有限公司

类型 有限责任公司(自然人投资或控股的法人独资)

住所 湖北仙桃市叶王路共青创业园

法定代表人 杨焕

注册资本 贰佰万圆整

成立日期 2004年06月09日

营业期限 长期

经营范围 生产和销售无纺布、无纺布制品、塑料制品、纸制品、一次性劳保用品及一次性使用医用口罩、本公司产品的进出口贸易。(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

2017年 09 月 15 日

企业信用信息公示系统网址: <http://192.0.99.148/Topics/CertificatePrint.do>

中华人民共和国国家工商行政管理总局监制 2017/9/15

医疗器械生产许可证

许可证编号:鄂食药监械生产许20170752号

企业名称:湖北维康防护用品有限公司 生产地址:湖北仙桃市叶王路共青创业园

法定代表人:杨焕 生产范围:二类:6864医用卫生材料及敷料***

企业负责人:杨焕

住所:湖北仙桃市叶王路共青创业园 发证部门:湖北省药品监督管理局

有效期限:至 2022 年 5 月 31 日 发证日期:2018 年 9 月 19 日

国家药品监督管理局制

查询网址: <http://www.hubfda.gov.cn>

中华人民共和国医疗器械注册证

注册证编号：鄂械注准 20172642433

注册人名称	湖北维康防护用品有限公司
注册人住所	湖北仙桃市叶王路共青创业园
生产地址	湖北仙桃市叶王路共青创业园
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	橡筋口罩；绑带口罩。儿童：14.5cm×9cm；成人：17.5cm×9.5cm。（卫生级别为普通级）
结构及组成	本品由非织造布、过滤纸、鼻夹、口罩带（或橡皮筋）组成；口罩由两层非织造布夹一层过滤纸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，用于普通医疗环境、公共卫生场所中的一般卫生护理。（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：2017 年 04 月 07 日

有效期至：2022 年 04 月 06 日

医疗器械
(审批专用章)

医疗器械生产产品登记表

第 1 页，共 1 页

企业名称	湖北维康防护用品有限公司			
许可证编号	鄂食药监械生产许 20170752 号			
许可证有效期限	2022 年 05 月 31 日			
生产范围	二类：6804 医用卫生材料及敷料***			
生产产品列表				
序号	产品名称	注册号	登载日期	备注
1	一次性使用医用口罩	鄂械注准 20172642433	2017 年 04 月 07 日	
发证部门（公章）： 湖北省食品药品监督管理局 2017 年 06 月 07 日				

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 20200022
Certificate NO.: 鄂仙桃食药监械出 20200022

产品名称: 一次性使用医用口罩
Product(s): Disposable medical face masks

规格型号: 橡筋口罩; 绑带口罩. 17.5*9.5CM; 14.5*9CM.
Model: Ear loop face mask; Tie on face mask. 17.5*9.5CM 14.5*9CM

产品注册或备案凭证号: 鄂械注准 20172642433
Registration certificate(s): 20172642433

生产企业: 湖北维康防护用品有限公司
Manufacturer: Hubei Weikang Protective Products Co., Ltd.

生产企业住所: 湖北仙桃市叶王路共青创业园
Address of manufacturer: Gongqing Chuangye Industrial Zone, Yewang Road, Xiantao City, Hubei Province

生产许可或备案凭证号: 鄂食药监械生产许 20170752 号
Manufacturing License(s): 鄂食药监械生产许 20170752

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: 2022 年 3 月 24 日
This certification valid until: Mar 24th 2022

备注:
Remark:



对外贸易经营者备案登记表

备案登记表编号: 03598202
统一社会信用代码: 91429004757013938H
进出口企业代码: _____

经营者中文名称	湖北维康防护用品有限公司		
经营者英文名称	HUBEI WEIKANG PROTECTIVE PRODUCTS CO.LTD		
组织机构代码	_____	经营者类型 (由备案登记机关填写)	私营有限责任公司
住 所	湖北仙桃市叶王路共青创业园		
经营场所 (中文)	湖北仙桃市叶王路共青创业园		
经营场所 (英文)	Gongqing Chuangye Industrial Zone, YeWang Rd. Xiangtao, Hubei.		
联系电话	0728-3274141	联系传真	0728-3274155
邮政编码	433000	电子邮箱	xiantaoweikang@163.com
工商登记注册日期	2004-6-30	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	杨焕	有效证件号	429004199004072558
注册资金	贰佰万元	(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/ 个体工商户负责人姓名	_____	有效证件号	_____
企业资产/个人财产	_____	(折美元)	

备注 变更法人	_____
------------	-------

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户负责人签字、盖章。





This is to certify that the Quality Management System of

Hubei Weikang Protective products Co., Ltd.

Unified Social Credit Code : 91429004757013938H

Operation Address : Gongqing Chuangye Industrial Zone, Yewang Road, Xiantao City, Hubei Province, China

Registered Address : Gongqing Chuangye Industrial Zone, Yewang Road, Xiantao City, Hubei Province, China

applicable to

Non-sterile Production and sales of disposable medical mask (within the scope of license qualification); production and sales of disposable medical non-woven products (clothes, sleeve covers, shoe covers, hats) (exported to Europe and America)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

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

42327

Date:

28 July 2016

Reissue Date:

06 November 2018

Valid Until:

06 November 2021

EAC Code:

04/14



兹证明

湖北维康防护用品有限公司

统一社会信用代码: 91429004757013938H

经营地址: 湖北仙桃市叶王路共青创业园

注册地址: 湖北仙桃市叶王路共青创业园

的质量管理体系适用于

非灭菌: 一次性使用医用口罩的生产和销售 (许可资质范围内); 一次性医用无纺布制品 (衣服、袖套、鞋套、帽子) 的生产和销售 (出口欧美)

已经 NQA 根据标准

ISO 13485: 2016

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

42327

Date:

28 July 2016

Reissue Date:

06 November 2018

Valid Until:

06 November 2021

EAC Code:

04/14



nqa.

Compliance Report

Applicant: HUBEI WEIKANG PROTECTIVE PRODUCTS CO., LTD
Address: GongQing ChuangYe Garden, Yewang Rd. Xiantao Hubei, China

Product: Face Mask (Non-Sterile)
Type: 17.5cm*9.5cm, 14.5cm*9cm, 12.5cm*8.5cm

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 Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affixes 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.

This report is not a certificate of conformity.

No. 03204
Initial Issue Date: 22 Apr 2020

Signer

This report is the property of NQA and should be returned to NQA upon request.

File No: CE-TCF-001



EC Declaration of Conformity

Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC



Manufacturer

Manufacturer: HUBEI WEIKANG PROTECTIVE PRODUCTS CO., LTD
Address: GongQing ChuangYe Garden, Yewang Rd. Xiantao Hubei, China

Product

Name: Face Mask

Type: 17.5cm*9.5cm, 14.5cm*9cm, 12.5cm*8.5cm

Classification : I
Rule: According to Rule 1

We confirm our product can meet the requirement of Medical Device Directive and the following harmonized standards.

EN ISO 14971:2012
EN ISO 15223-1:2016
EN 1041:2008
EN ISO 10993-1:2018
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN 14683:2013

Signature

Date :





Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

HUBEI WEIKANG PROTECTIVE PRODUCTS CO.LTD
Gongqing Chuangye Industrail Zone, Yewang Rd. Xiantao City,
CN-42 CHINA

has completed the FDA Establishment Registration (as 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: sungogroup@yahoo.com

Registration Number: 3005090771
Device Listing#: See annex

SUNGO Technical Services, Inc. will confirm that the 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. SUNGO Technical Services, 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. The user 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 Services 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.



SUNGO CHINA OFFICE Tel: 021-68828052 Email: Shage2008@126.com Website: www.sungoglobal.com
Add: 13th Floor, No.1500 Century Avenue, Shanghai 200122, P.R.China



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

HUBEI WEIKANG PROTECTIVE PRODUCTS CO.LTD
Gongqing Chuangye Industrail Zone, Yewang Rd. Xiantao City,
CN-42 CHINA

The facility registration and device listing information:

Registration Number: 3005090771		
Device Listing No.	Product Code	Product Name(s)
D009883	LYU	Surgical Apparel Accessory
D009884	FXO	Surgical Suit
D009885	OEa	Non-surgical Isolation Gown
D009895	NTX	Nursing Pad
D009896	FME	Examination Gown
D009897	BWP	Shoe Cover
D009898	FXP	Operation-room Shoe Cover
D387280	CKR	DISPOSABLE FACE MASK
E290132	KHA	Isolation Mask; Scavenging Mask
E290133	FFY	Surgical Cap
E290134	FYE	Surgical Dress

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 807.59, "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 an attestation of registration, nor does the U.S. Food and Drug Administration recognize an attestation of registration, SUNGO Technical Service Inc. is not affiliated with the U.S. Food and Drug Administration.

Reference Number: 2006US250558
Issue date: Apr.08, 2020





检验检测报告

Test Report

(2019) WSZ FHL 第0983号

产品名称 一次性使用医用口罩
Product Name
委托单位 湖北维康防护用品有限公司
Applicant
生产单位 湖北维康防护用品有限公司
Manufacturer
检验检测类别 委托检验
Test Type

浙江国检检测技术有限公司
Zhejiang Guojian Testing Technology Jiangsu Co.,Ltd

检验检测报告

Test Report

[2019] WSZ FHL 第0983号

共 2 页 第 1 页

产品名称 Product name	一次性使用医用口罩	规格型号 Specification	17.5*9.5cm
		商 标 Brand	—
委托单位/地址/联系电话 Applicant/Add/Tel	湖北维康防护用品有限公司/湖北省仙桃市叶王路共青创业园维康防护用品有限公司/13339708561		
生产单位/地址/联系电话 Manufacturer/Add/Tel	湖北维康防护用品有限公司/湖北省仙桃市叶王路共青创业园维康防护用品有限公司/13339708561		
样品等级 Sample grade	—	样品编号 Sample number	GW 0983-2019
样品数量 Sample quantity	20 个	样品接收日期 Receiving date of sample	2019 年 11 月 19 日
检验检测类别 Test type	委托检验	批号/货号 Batch number/ Article number	—
检验检测日期 Test date	2019/11/19~2019/12/04	检验检测地点 Test site	本公司检验室
样品状态 Sample state	符合检验检测要求		
检验检测依据 Test standard(s)	YY/T 0969-2013 《一次性使用医用口罩》		
检验检测项目 Test items	细菌过滤效率、通气阻力、微生物指标		
检验检测结论 Test conclusion	样品经检验，所检项目符合 YY/T 0969-2013 标准规定的要求。具体检验结果详见第2页。 签发日期 2019年12月4日		
备 注 Note	样品信息由委托方提供，本报告仅对来样负责 报告有效期为 1 年		

批准: 朱 杨 祥 审核: 李 如 明 主 检: 杨 莹

检验检测结果

Test Result

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序号 Number	检验检测项目 Test item	单 位 Unit	技 术 要 求 Technical requirement	检验检测结果 Test result	单项评价 Single Item decision
1	通气阻力	Pa/cm ²	口罩两侧面进行气体交换的通气阻力应不大于 49。	11.3 12.6 11.8	合 格
2	细菌过滤效率	—	≥95%	97.5%	合 格
3	微生物指标	—	—	—	合 格
	细菌菌落总数	cfu/g	≤100	<20	
	真菌菌落总数	cfu/g	不得检出	第 3 天 <20 第 5 天 <20 第 7 天 <20	
	大肠菌群	—	不得检出	未检出	
	绿脓杆菌	—	不得检出	未检出	
	金黄色葡萄球菌	—	不得检出	未检出	
	溶血性链球菌	—	不得检出	未检出	
备注	— 以下空白 —				



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*Be looking forward to
cooperation with your company!*