3 Ply Medical Masks Sterile (CE, FDA cer fied)

- Non-woven multi-layer design.
- Ultra-sonic weld ensures a strongly constructed mask, eliminates holes and defects.
- Adjustable Nose Piece for better fit.
- Fluid Resistant.
- BFE ≥ 95%.

- Size: 175mm x 90mm
- Package: 20pcs/Sterile sealed bag, 150bags/ctn
- G.W: 11kg 3000pcs/ctn
- N.W: 9.5kg
- Capacity: 200k/Day
- MOQ: 50k
- Delivery date: 2 days after receipt of payment

Review Report –审查报告–검토 보고서– Rapport d'Evaluation

Form QAT_10-M04, version 00, effective since March 6th, 2020

CE Documentation Review

No. [redacted]

Holder: [redacted]

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Disposable Surgical Mask **(no sterile)**

Model(s): Ear hook

Classification: Class I (no sterile)
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. Technical File identified with the no. **TMDDMJ2003183551-AG172**
The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

Issuance date: 19 March 2020

Expiry date: 18 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

Ente Certificazione Macchine
Via Cà Bella, 243 - 40053 Valsamoggia Loc. Castello di Serravalle (Bo) Italy
☎ +39.0516705141 🖷 +39.0516705156 ✉ info@entecerma.it 🌐 www.entecerma.it

Nelson Labs.
A Sotera Health company

Sponsor:
[illegible]
CHINA

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

Test Article:	mb-sample01 mb-sample02 mb-sample03 mb-sample04 mb-sample05
Study Number:	1165455-S01
Study Received Date:	26 Mar 2019
Testing Facility:	[illegible]
Test Procedure(s):	[illegible]
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 10^3 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 F2101-14 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 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:	Smooth Side
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 Preparation:	Swatches Cut from the Material
Positive Control Average:	2.5 x 10^3 CFU
Negative Monitor Count:	<1 CFU
MPS:	3.0 µm

ilac-MRA ANAB ACCREDITED TESTING LABORATORY

Curtis Gerow For Janelle R. Bentz, M.S. — Study Director

15 Apr 2019 — Study Completion Date

Results:

Test Article	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
mb-sample01	>99.9[a]	2.9	28.5
mb-sample02	>99.9[a]	2.9	28.5
mb-sample03	>99.9[a]	2.9	28.3
mb-sample04	>99.9[a]	2.7	26.4
mb-sample05	>99.9[a]	2.4	23.9

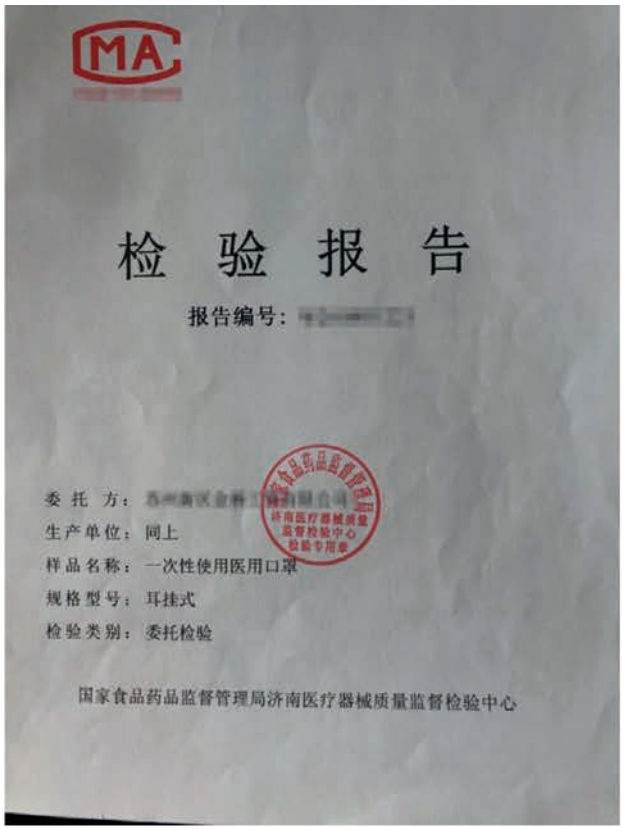
[a] There were no detected colonies on any of the Andersen sampler plates for this test article.

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

National Medical Administration certificate



检 验 报 告

报告编号：

委 托 方：

生产单位：同上

样品名称：一次性使用医用口罩

规格型号：耳挂式

检验类别：委托检验

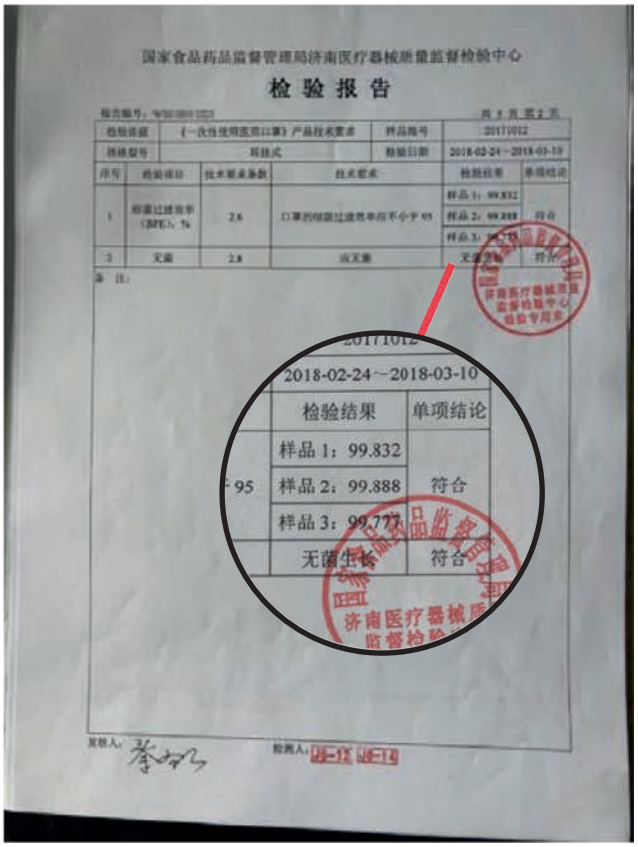
国家食品药品监督管理局济南医疗器械质量监督检验中心

国家食品药品监督管理局济南医疗器械质量监督检验中心

检验报告首页

样品名称	一次性使用医用口罩	样品编号	W2018011221
采样方式	委样		
商标	/	规格型号	耳挂式
委托方		检验类别	委托检验
委托方地址		产品编号/批号	20171012
生产单位		抽样单编号	—
受检单位		生产日期	2017 年 10 月 12 日
抽样单位	—	样品数量	21 枚 +1 包材料
抽样地点	—	抽样基数	—
抽样日期	—	检验地点	本检验中心实验室
收样日期	2018-1-12	检验日期	2018-1-29~2018-3-10
检验项目	全项目。		
检验依据	《一次性使用医用口罩》产品技术要求		
检验结论	被检样品符合《一次性使用医用口罩》产品技术要求		
备注	1）报告中的"—"表示此项不适用，报告中"/"表示此项空白。		

批准：　　职务：主任



国家食品药品监督管理局济南医疗器械质量监督检验中心

检验报告

检验依据	《一次性使用医用口罩》产品技术要求		样品编号	20171012
规格型号	耳挂式		检验日期	2018-02-24~2018-03-10
序号	检验项目	技术要求条款	技术要求	检验结果	单项结论
1	细菌过滤效率（BFE），%	2.6	口罩的细菌过滤效率应不小于 95	样品 1：99.832 样品 2：99.888 样品 3：99.777	符合
2	无菌	2.8	应无菌	无菌生长	符合

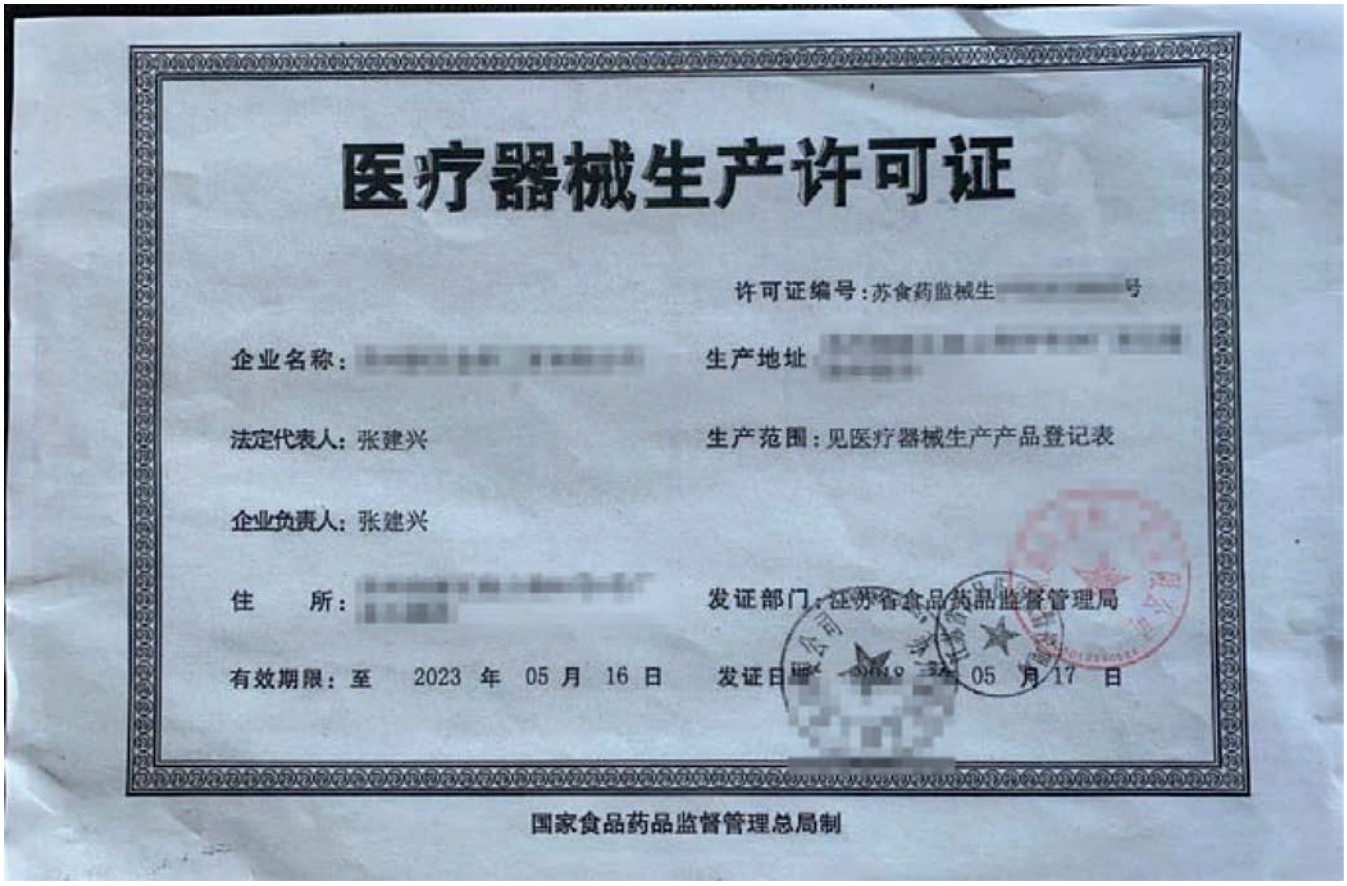
2018-02-24~2018-03-10

	检验结果	单项结论
95	样品 1：99.832	
	样品 2：99.888	符合
	样品 3：99.777	
	无菌生长	符合

济南医疗器械质量监督检验中心

检验人：　　检测人：

Medical Manufacturer license



医疗器械生产许可证

许可证编号：苏食药监械生[redacted]号

企业名称：[redacted]

生产地址[redacted]

法定代表人：张建兴

生产范围：见医疗器械生产产品登记表

企业负责人：张建兴

住　　所：[redacted]

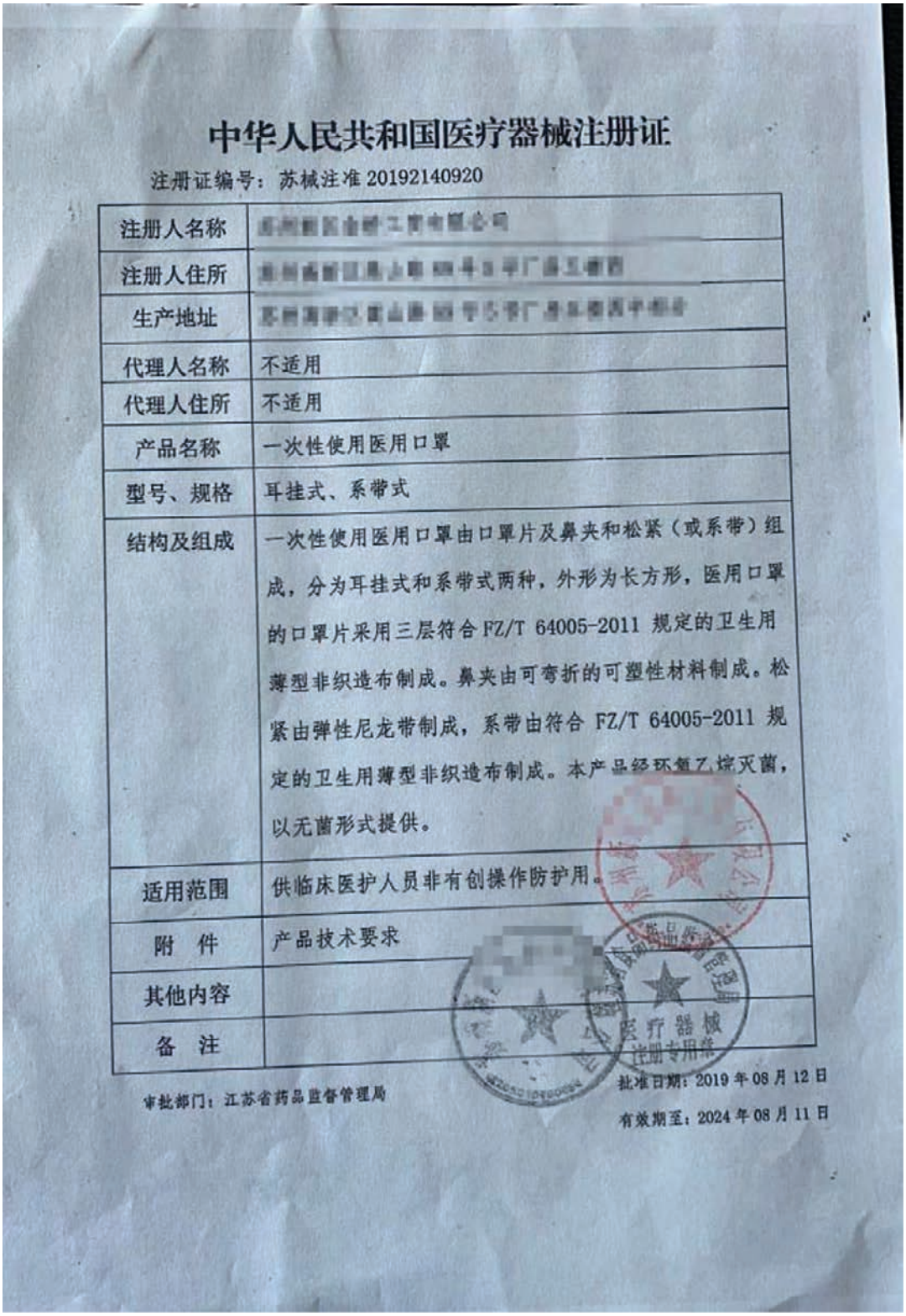
发证部门：江苏省食品药品监督管理局

有效期限：至　2023 年 05 月 16 日

发证日期：[redacted] 05 月 17 日

国家食品药品监督管理总局制

Product registration for medical masks



中华人民共和国医疗器械注册证

注册证编号：苏械注准 20192140920

注册人名称	[redacted]
注册人住所	[redacted]
生产地址	[redacted]
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	耳挂式、系带式
结构及组成	一次性使用医用口罩由口罩片及鼻夹和松紧（或系带）组成，分为耳挂式和系带式两种，外形为长方形，医用口罩的口罩片采用三层符合 FZ/T 64005-2011 规定的卫生用薄型非织造布制成。鼻夹由可弯折的可塑性材料制成。松紧由弹性尼龙带制成，系带由符合 FZ/T 64005-2011 规定的卫生用薄型非织造布制成。本产品经环氧乙烷灭菌，以无菌形式提供。
适用范围	供临床医护人员非有创操作防护用。
附　件	产品技术要求
其他内容	
备　注	

审批部门：江苏省药品监督管理局

批准日期：2019 年 08 月 12 日

有效期至：2024 年 08 月 11 日


STERILE EO
产品名称 一次性使用医用口罩
规格
数量
毛重 净重
体积 55X40X32
生产日期
失效日期
生产批号
灭菌批号


一次性使用医用口罩