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YHUK Product Certificate Document

**Type II Surgical Mask**

Date: 2020/04/25



# Inspection report

Report No.: AH2020-QSJ-00104

Name of Inspection: Disposable Surgical Mask (Non-sterile)

Purpose of examination: Entrusted inspection (emergency inspection)

## Anhui Provincial Institute for Food and Drug Control

Special seal for inspection report of Anhui Provincial Institute for Food and Drug Control



## Anhui Provincial Institute for Food and Drug Control

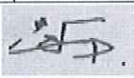
## Home Page of Test Report

Report No.: AH2020-QSJ-00104

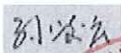
Page 1 of 3

Sample name:	Disposable Surgical Mask (Non-sterile) Sample presentation (√) Sampling ( )	Sample No.	AH2020-QSJ-00104
Trademark	/	Model and specification	17.5 X 9cm
Client	Chuzhou Market Supervision and Administration Bureau	Inspection type	Entrusted inspection (emergency inspection)
Client address	No. 105, Longpan Avenue, Chuzhou City	Product No./Batch No.	/
Production unit	Tianchang Dongan Protective Equipment Co., Ltd.	Sampling sheet No.	/
Inspected unit	Tianchang Dongan Protective Equipment Co., Ltd.	Production Date	Feb. 2, 2020
Sampling unit	/	Sample quantity	40 pcs.
Sampling site	/	Sampling basic number	/
Sampling date	/	Inspection location	Anhui Provincial Institute for Food and Drug Control
Sampling date	Feb. 10, 2020	Inspection date	Feb. 10, 2020~Feb. 16, 2020
Inspection item	4.7.1 (coliform, pseudomonas aeruginosa, staphylococcus aureus and hemolytic streptococcus)		
Inspection basis	YY/T 0969-2013 <i>Disposable Surgical Mask</i>		
Test result	<p>The tested item shall be subject to standard inspection of YY/T 0969-2013 <i>Disposable Surgical Mask</i>. Refer to report page for the result.</p> <p>Special seal for inspection report of Anhui Provincial Institute for Food and Drug Control</p> <p>(Special seal for test report or official seal of Test Unit)</p> <p>Issuing date: Feb. 16, 2020</p>		
Notes	"--" in the report indicates N/A items and "/" indicates void items.		

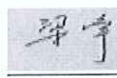
Approved by:



Reviewed by:



Mainly inspected by:


Position: Authorized signatory

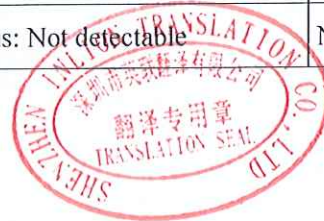
**Anhui Provincial Institute for Food and Drug Control****Home Page of Test Report**

Report No.: AH2020-QSJ-00104

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S/N	Inspection item	Standard clauses	Standard Requirements	Test result
1	Microbiological index	4.7.1	Coliform: Not detectable	Not detected
			Pseudomonas aeruginosa: Not detectable	Not detected
			Staphylococcus aureus: Not detectable	Not detected
			Hemolytic streptococcus: Not detectable	Not detected

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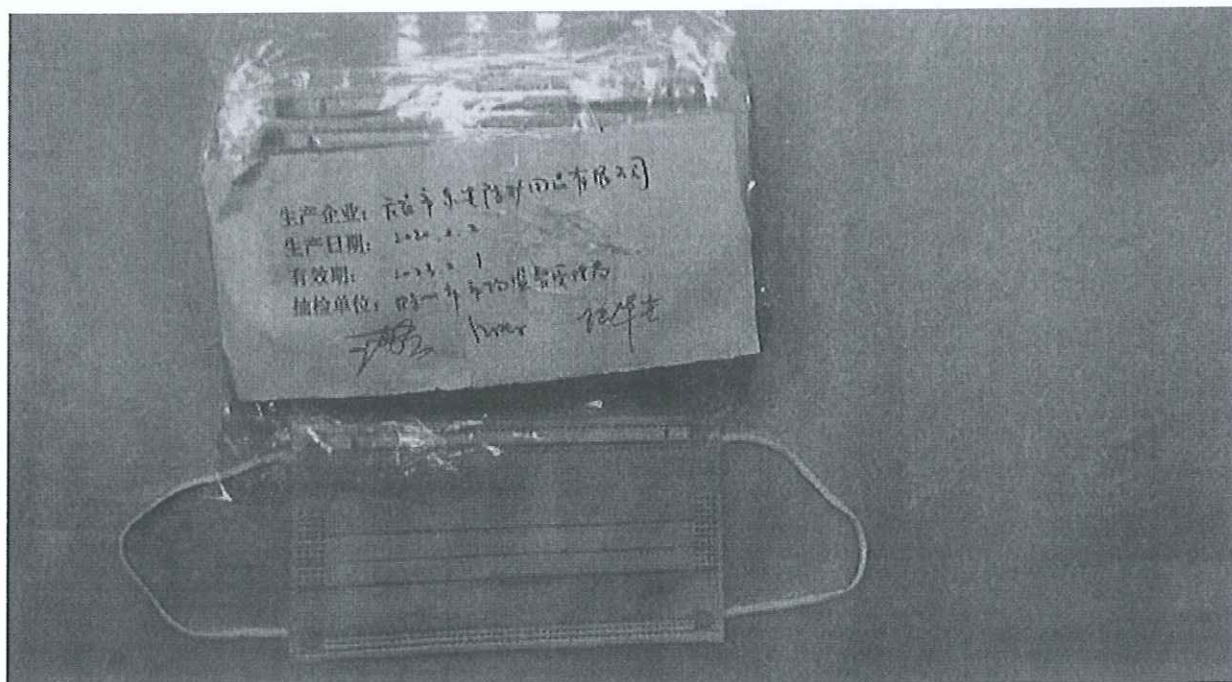
## Anhui Provincial Institute for Food and Drug Control

## Home Page of Test Report

Report No.: AH2020-QSJ-00104

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## Photos and explanations



## Sample description

/

## Model specifications or other instructions

17.5X9cm







170015143957

# 检 验 报 告

报 告 编 号: AH2020-QSJ-00104

检 品 名 称: 一次性使用医用口罩 (非无菌)

检 验 目 的: 委托检验 (应急检验)

安徽省食 药 品 检 验 研 究 院





# 安徽省食品药品检验研究院

## 检验报告首页

报告编号: AH2020-QSJ-00104

共 3 页 第 1 页

样品名称	一次性使用医用口罩 (非无菌)	样品编号	AH2020-QSJ-00104
	送样 (√)      抽样 ( )		
商 标	/	型号规格	17.5×9cm
委托方	滁州市市场监督管理局	检验类别	委托检验(应急检验)
委托方地址	滁州市龙蟠大道105号	产品编号/批号	/
生产单位	天长市东安防护用品有限公司	抽样单编号	/
受检单位	天长市东安防护用品有限公司	生产日期	2020.2.2
抽样单位	/	样品数量	40只
抽样地点	/	抽样基数	/
抽样日期	/	检验地点	安徽省食品药品检验研究院
收样日期	2020/02/10	检验日期	2020/02/10~2020/02/16
检验项目	4.7.1(大肠菌群、绿脓杆菌、金黄色葡萄球菌、溶血性链球菌)		
检验依据	YY/T 0969-2013《一次性使用医用口罩》		
检验结论	所检项目参照YY/T 0969-2013《一次性使用医用口罩》标准检验结果见报告 (检验报告专用章或检验单位公章) 签发日期: 2020/2/16		
备注	报告中“—”表示不适用项, “/”表示空白项。		

样品

报告

( )



批 准:

审 核:

主 检:

职

务:

授权签字人



# 安徽省食品药品检验研究院

## 检 验 报 告

报告编号: AH2020-QSJ-00104

共 3 页 第 2 页

序号	检验项目	标准条款	标准要求	检验结果
1	微生物指标	4.7.1	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

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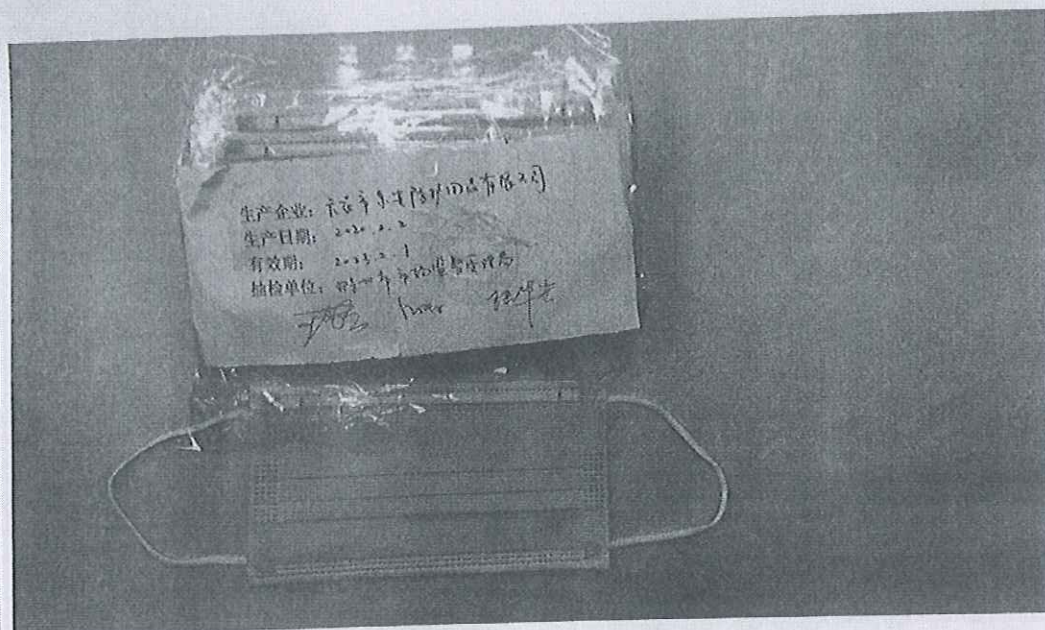
# 安徽省食品药品检验研究院

## 检 验 报 告 照 片 页

报告编号: AH2020-QSJ-00104

共 3 页 第 3 页

照片和说明

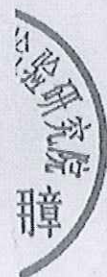


样品描述

/

型号规格或其它说明

17.5×9cm





170015143957

## Inspection Report

Report No.: AH2020-QSJ-00066

Name of Inspection: Disposable Surgical Mask

Purpose of examination: Entrusted inspection (emergency inspection)

Special seal for inspection report of Anhui Provincial Institute for Food and Drug Control

Anhui Provincial Institute for Food and Drug Control

Special seal for inspection report of Anhui Provincial Institute for Food and Drug Control





## Description

- I. The report is invalid in case of being obliterated, increased or deleted and failing to be affixed with special seal for inspection report of our institute on the first page and perforation.
- II. The duplicate test report is invalid without Special Seal for Test and Detection.
- III. The data and conclusions presented in this report are the test results of the items inspected of the samples.
- IV. In case of any objection against inspection report, such objection shall be raised in written within the time limit specified in the relevant document of the state as of the date when the report is received and won't be accepted in case of exceeding the time limit (unless otherwise specified).
- V. Without written consent from our institute, the inspection report is forbidden to be used for advertising, etc., or the consequence shall be borne voluntarily.
- VI. Contact information

Postal code: 230051

Organization address: Junction between Baohe Avenue and Urumchi Road, Hefei City

Tel.: 0551-63710010

Address of food inspection institute: No. 13, Yan'an Road, Hefei City

Tel.: 0551-63356518

Reinspection and complaint telephone number: 0551-63710067

Website: [www.ahifdc.org.cn](http://www.ahifdc.org.cn)

Special seal for inspection report of Anhui Provincial Institute for Food and Drug Control





# Anhui Provincial Institute for Food and Drug Control

## Home Page of Test Report

Report No.: AH2020-QSJ-00066

Page 1 of 3

Sample name:	Disposable Surgical Mask	Sample No.	AH2020-QSJ-00066
	Sample presentation (√) Sampling ( )		
Trademark	/	Model and specification	17.5 X 9.5cm
Client	Chuzhou Market Supervision and Administration Bureau	Inspection type	Entrusted inspection (emergency inspection)
Client address	No. 105, Longpan Avenue, Chuzhou City	Product No./Batch No.	/
Production unit	Tianchang Dongan Protective Equipment Co., Ltd.	Sampling sheet No.	/
Inspected unit	Tianchang Dongan Protective Equipment Co., Ltd.	Production Date	Feb. 2, 2020
Sampling unit	/	Sample quantity	100
Sampling site	/	Sampling basic number	/
Sampling date	/	Inspection location	Anhui Provincial Institute for Food and Drug Control
Sampling date	Feb. 3, 2020	Inspection date	Feb. 3, 2020~Feb. 7, 2020
Inspection item	4.1, 4.2, 4.3.1, 4.3.2, 4.5, 4.6		
Inspection basis	YY/T 0969-2013 <i>Disposable Surgical Mask</i>		
Test result	<p>The tested item shall be subject to standard inspection of YY/T 0969-2013 <i>Disposable Surgical Mask</i>. Refer to report page for the result.</p> <p>Special seal for inspection report of Anhui Provincial Institute for Food and Drug Control (Special seal for test report or official seal of Test Unit) Issuing date: Feb. 7, 2020</p>		
Notes	"--" in the report indicates N/A items and "/" indicates void items.		

Approved by: Reviewed by: Mainly inspected by: Position: Authorized signatory

Special seal for inspection report of Anhui Provincial Institute for Food and Drug Control



# Anhui Provincial Institute for Food and Drug Control

## Home Page of Test Report

Report No.: AH2020-QSJ-00066

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S/N	Inspection item	Standard clauses	Standard Requirements	Test result
1	Appearance	4.1	The mask appearance shall be clean and the shape shall be good, without the damage and stain on the surface.	Qualified
2	Structure and size	4.2	After the mask is worn, it shall be able to cover the wearer's mouth, nose and lower jaw.	Qualified
			17.5cm $\pm$ 5%	17.7 cm ~ 17.8 cm
			9.5cm $\pm$ 5%	9.2 cm
3	Nasal splint	4.3.1	The mask should be provided with nasal splint, which is made from the plastic materials.	Qualified
		4.3.2	The length of nasal splint shall be no less than 8.0cm.	10.4cm ~ 10.6cm
4	Bacterial filtration efficiency (BFE)	4.5	The bacterial filtration efficiency shall not less than 95%.	100%
5	Ventilation resistance	4.6	The ventilation resistance at two sides for gas exchange shall not higher than 49Pa/cm <sup>2</sup> .	30 Pa/cm <sup>2</sup> ~ 38 Pa/cm <sup>2</sup>

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Special seal for inspection report of Anhui Provincial Institute for Food and Drug Control



## Anhui Provincial Institute for Food and Drug Control

## Home Page of Test Report

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## Photos and explanations



## Sample description

/

## Model specifications or other instructions

17.5X9.5cm

Special seal for inspection report of Anhui Provincial Institute for Food and Drug Control







170015143957

# 检 验 报 告

报 告 编 号: AH2020-QSJ-00066

检 品 名 称: 一次性使用医用口罩

检 验 目 的: 委托检验(应急检验)

安徽省食品药品检验研究院



## 说 明

- 一、本报告涂改、增加、删减和未在内页第一页及骑缝加盖  
我院检验报告专用章无效。
- 二、复制检验报告未重新加盖我院检验报告专用章无效。
- 三、本检验报告所出具的数据和结论，是对来样所检项目的  
检验结果。
- 四、如对本检验报告有异议，请于收到报告之日起在国家有  
关文件规定的时间期限内以书面形式提出，逾期不予受  
理（另有规定除外）。
- 五、未经我院书面同意，本检验报告不得用于广告等宣传，  
否则后果自负。

### 六、联系方式

邮编：230051

单位地址：合肥市包河大道与乌鲁木齐路交界处

电话：0551-63710010

食品检验所地址：合肥市延安路13号

电话：0551-63356518

复检及投诉电话：0551-63710067

网址：[www.ahifdc.org.cn](http://www.ahifdc.org.cn)





# 安徽省食品药品检验研究院

## 检验报告首页

报告编号: AH2020-QSJ-00066

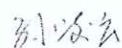
共 3 页 第 1 页

样品名称	一次性使用医用口罩	样品编号	AH2020-QSJ-00066
	送样 (√)      抽样 ( )		
商 标	/	型号规格	17.5×9.5cm
委托方	滁州市市场监督管理局	检验类别	委托检验(应急检验)
委托方地址	滁州市龙蟠大道105号	产品编号/批号	/
生产单位	天长市东安防护用品有限公司	抽样单编号	/
受检单位	天长市东安防护用品有限公司	生产日期	2020.2.2
抽样单位	/	样品数量	100
抽样地点	/	抽样基数	/
抽样日期	/	检验地点	安徽省食品药品检验研究院
收样日期	2020/02/03	检验日期	2020/02/03~2020/02/07
检验项目	4.1、4.2、4.3.1、4.3.2、4.5、4.6		
检验依据	YY/T 0969-2013《一次性使用医用口罩》		
检验结论	所检项目参照YY/T 0969-2013《一次性使用医用口罩》标准检验,结果见报告单。 (检验报告专用章或检验单位公章) 签发日期: 2020/2/7		
备注	报告中“—”表示不适用项,“/”表示空白项。		


批 准:



审 核:



主 检:



职 务:

授权签字人



# 安徽省食品药品检验研究院

## 检验报告

报告编号: AH2020-QSJ-00066

共3页 第2页

序号	检验项目	标准条款	标准要求	检验结果
1	外观	4.1	口罩外观应整洁, 形状完好, 表面不得有破损、污渍	符合要求
2	结构与尺寸	4.2	口罩佩戴好后, 应能罩住佩戴者的口、鼻至下颌	符合要求
			17.5cm $\pm$ 5%	17.7 cm $\sim$ 17.8 cm
			9.5cm $\pm$ 5%	9.2 cm
3	鼻夹	4.3.1	口罩上应配有鼻夹, 鼻夹由可塑性材料制成	符合要求
		4.3.2	鼻夹长度应不小于 8.0cm	10.4cm $\sim$ 10.6cm
4	细菌过滤效率 (BFE)	4.5	口罩的细菌过滤效率应不小于 95%	100%
5	透气阻力	4.6	口罩两侧面进行气体交换的透气阻力应不大于 49 Pa/cm <sup>2</sup>	30 Pa/cm <sup>2</sup> $\sim$ 38 Pa/cm <sup>2</sup>

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# 安徽省食品药品检验研究院 检验报告

报告编号: AH2020-QSJ-00066

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照片和说明

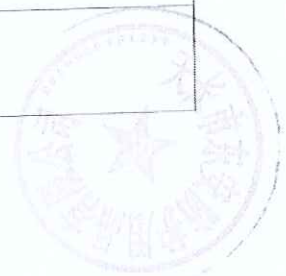


样品描述

1

型号规格或其它说明

17.5x9.5cm



# **EC Declaration of conformity**

Council Directive 93/42/EEC&2007/47/EC on Medical Devices Directive

**TIANCHANG DONGAN PROTECTIVE EQUIPMENT CO.,LTD**  
Hongmiao Village, Tiancha Road,  
Tianchang City, China

Certify that the product described is in conformity with the  
Medical Devices Directive 93/42/EEC&2007/47/EC as amended

**Product Name:**

Disposable Medical Face Mask

**Product Model:**

17.5cm×9.5cm,17.5×9cm,17.5×8.5 ,17×8.5cm,17×9cm,17×9.5cm,  
16.5×9.5cm,16.5×9cm,17×9.5cm,16.5×9.5cm,16.5×9cm,  
16.5×8.5cm,14×9.5cm,14×8.5cm,12.5×8.5cm

Applied normative documents: EN 14683:2019 Type II

Applied Quality Management System: EN ISO 13485:2016

It bears the mark



Evaluation has been carried out in accordance with test reports made by  
EUROPEAN QUALITY TEST CO., LTD.

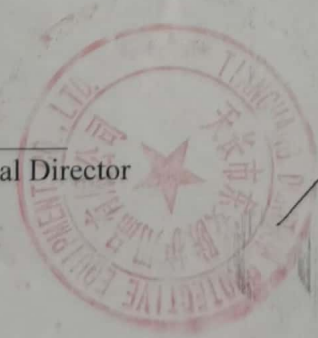
No. of test report: ENC2003121GZ66E1

Issue date: 18.03.2020

Expiration date: 17.03.2025

Signature of General Director

A handwritten signature in black ink, appearing to be 'Zhang Jie' (张杰), is written over a red circular stamp.



扫描全能王 创建





Confirms that the Management System of:

***Tianchang Dongan Protective Equipment CO., LTD.***

Hongmial Village, Tiancha Road, Tianchang City, China

Conforms to the requirements of:

***ISO 13485:2016***

Scope of Registration:

***The Production and Sale of Surgical Gown, Surgical Pack, Surgical Drape,  
Nonwoven Medical Face Mask with Ear loop, Nonwoven Medical Face Mask with Tie,  
Surgical Cap, Shoe Covers, Bed Cover, Bed Sheet, Under pad, Knit Cuffs, Sterilization Pouch,  
Medical Crepe Paper, Bandages Clip for Medical Device, Sterile Wound Dressing***

Certificate Number: C00027-1  
Registration Date: July 06, 2019  
Expiration Date: June 30, 2020



A handwritten signature in black ink, reading 'Drew D. Dysinger'.

**Drew D. Dysinger**  
President

AVU Registrations, Inc.  
5279 N. Isabella Rd.  
Rosebush, MI 48878