

HMRoyal®

Taizhou HMRoyal medical device technology Co.,Ltd

# HMRoyal MASK PRODUCT BROCHURE

欧盟CE 美国FDA

白名单企业

**“What  
Makes us  
Different  
?”**



Taizhou HMRoyal medical device technology Co.,Ltd

Address: 6-1040Shugang Road, Taizhou Medical New & Hi-tech Industrial  
Development Zone, Jiangsu Province, China

HMRoyal<sup>®</sup>

Taizhou HMRoyal medical device technology Co.,Ltd

# CERTIFICATION

# BUSINESS LICENSE

Medical devices and mask  
are allowed to be produce.



# Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries



中国医药保健品进出口商会 | 动态更新: 取得国外标准认证或注册... | 不安全 | cccmhpie.org.cn/Pub/6325/176273.shtml

30 | CCCMHPIE 中国医药保健品进出口商会 服务产业链 | 助力国际化

English 请输入关键词进行搜索

首页 关于商会 新闻中心 行业服务 权威发布 商会会刊 企业风采 会员之家 加入商会

新闻中心 > 通知公告

### 动态更新: 取得国外标准认证或注册的医疗物资生产企业清单

2020年05月19日 中国医药保健品进出口商会

取得国外标准认证或注册的医疗物资生产企业清单

Name List of Medical Devices and Supplies Companies with Certification/Authorization from other Countries

动态更新: 2020年5月19日 下载

序号	生产企业	统一社会信用代码	国外注册认证情况
一、	医用口罩 Medical Face Masks		
378	连云港市百顺医疗用品有限公司 Lianyungang Baishun Medical Treatment Articles Co.,Ltd.	91320724791064309D	欧盟CE
379	泰州皇牌医疗器械科技有限公司 Taizhou HMRoyal Medical Device Technology Co.,Ltd.	91321291MA210AG86G	欧盟CE
380	张家港神港医疗用品有限公司 Zhanqiaqana Shengqana Medical	9132058277467958XE	欧盟CE

推荐阅读

动态更新: 取得国外标准认证或注册的非医用口罩生...  
关于12号公告有关热点关注的问与答 (之二)  
孟冬平副会长接受央视、凤凰卫视等媒体采访, 就12...  
关于12号公告热点问题的问与答  
商务部联合两部委发布12号公告, 允许海外注册防疫...  
孟冬平副会长就“5号公告”接受央视、凤凰卫视联合...  
医保商会推出中国药监部门批准上市的医疗防护物资...  
医保商会支持协办《抗疫情稳外贸系列公益直播》之...  
澄清: 关于网络传播虚假医疗产品出口资格消息的声明  
关于行书《药品植物种植及采收规范基地认定标准》



## 江苏省投资项目备案证

备案证号：泰高新发改备（2020）23号

<b>项目名称：</b>	一次性民用和医用口罩生产项目	<b>项目法人单位：</b>	泰州皇牌医疗器械科技有限公司
<b>项目代码：</b>	2020-321271-27-03-514385	<b>法人单位经济类型：</b>	有限责任公司
<b>建设地点：</b>	江苏省：泰州市 泰州医药高新区 泰州滨江工业园区大健康新材料产业集聚区7幢	<b>项目总投资：</b>	10255.59万元
<b>建设性质：</b>	新建	<b>计划开工时间：</b>	2020
<b>建设规模及内容：</b>	该项目租用泰州滨江工业园区大健康新材料产业集聚区7号厂房（总建筑面积约3608.32平方米），建设一次性医用、民用口罩生产线，以及原材料及产品库房、包装分包区、辅助生产设施（产品检测）、办公设施等。配套购置安装定制口罩机、塑封机、包装机等主要设备92台（套）。配套建设环保、安全、消防等辅助生产设施，并对公用配套工程进行改造。项目建成后形成年产63000万只成人口罩、4500万只儿童口罩、9000万只KN95口罩的生产能力。		
<b>项目法人单位承诺：</b>	对备案项目信息的真实性、合法性和完整性负责；项目符合国家产业政策；依法依规办理各项报建审批手续后开工建设；如有违规情况，愿承担相关的法律责任。		
<b>安全生产要求：</b>	要强化安全生产管理，按照相关规章制度压实项目建设单位及相关责任主体安全生产及监管责任，严防安全生产事故发生；要加强施工环境分析，认真排查并及时消除项目本身与周边设施相交相邻等可能存在的安全隐患，保障施工安全。		

泰州医药高新技术产业开发区管理委员会  
2020-03-31

### 对外贸易经营者备案登记表

统一社会信用代码: 91321291MA210AG86G  
 进出口企业代码: \_\_\_\_\_  
 备案登记表编号: 04154950

经营者中文名称	泰州皇牌医疗器械科技有限公司		
经营者英文名称	Taizhou Huangpai Medical Equipment Technology Co., Ltd.		
组织机构代码	_____	经营者类型 (由备案登记机关填写)	有限责任公司
住 所	泰州市医药高新技术产业开发区疏港路6号1040		
经营场所 (中文)	泰州市医药高新技术产业开发区疏港路6号1040		
经营场所 (英文)	1040, No. 6, Shugang Road, Taizhou Pharmaceutical High-tech Industrial Development Zone		
联系电话	15152686100	联系传真	_____
邮政编码	225300	电子邮箱	15152686100@163.com
工商登记注册日期	2020-3-12	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	许其飞	有效证件号	321281198701197610
注册资金	叁仟万元		(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  
 \_\_\_\_\_  
 \_\_\_\_\_

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。

备案登记机关  
签 章  
2020 年 04 月 07 日

### 海关进出口货物收发货人备案回执

企业名称	泰州皇牌医疗器械科技有限公司
统一社会信用代码	91321291MA210AG86G
海关备案日期	2020-04-10
海关编码	32129650B9
检验检疫备案号	3268300134
有效期	长期

2020 年 4 月 10 日

自然人、法人或者非法人组织可通过“中国海关企业进出口信用信息公示平台”  
 ( <http://credit.customs.gov.cn> ) 或者 “互联网 + 海关”  
 ( <http://online.customs.gov.cn> ) 查询海关公示的企业信息。

- 1 -

### Establishment Registration & Device Listing

FDA Home Medical Devices Databases



1 result found for Owner Operator Number : 10067494

[New Search](#)

Establishment Name	Registration Number	Current Registration Yr
<a href="#">TAIZHOU HMROYAL MEDICAL DEVICE TECHNOLOGY CO.,LTD</a> CHINA	3016872040	2020
<ul style="list-style-type: none"> <li><a href="#">Respirator, Surgical - Protective Respirator</a></li> <li><a href="#">Accessory, Surgical Apparel - Disposable Face Mask; Disposable Medical Mask; Disposable Surgical Mask</a></li> </ul>		Foreign Exporter; Manufacturer
		Foreign Exporter; Manufacturer

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**CMC MEDICAL DEVICES & DRUGS SL**  
**NO. CMC/CE/2020/29042020.2**

CONFIRMED THAT CMC MEDICAL DEVICES & DRUGS S.L. Is the European Authorized Representative of  
**Taizhou HMRoyal medical device technology Co.,Ltd**  
**6-1040Shugang Road, Taizhou Medical New & Hi-tech Industrial Development Zone,**  
**Jiangsu Province, China**

The certificate remains valid until the expiration agreement of EC REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.  
 The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all above mentioned models of the medical device.

Complies with the applicable essential requirements of the council directive 93/42/EEC on medical devices as amended.

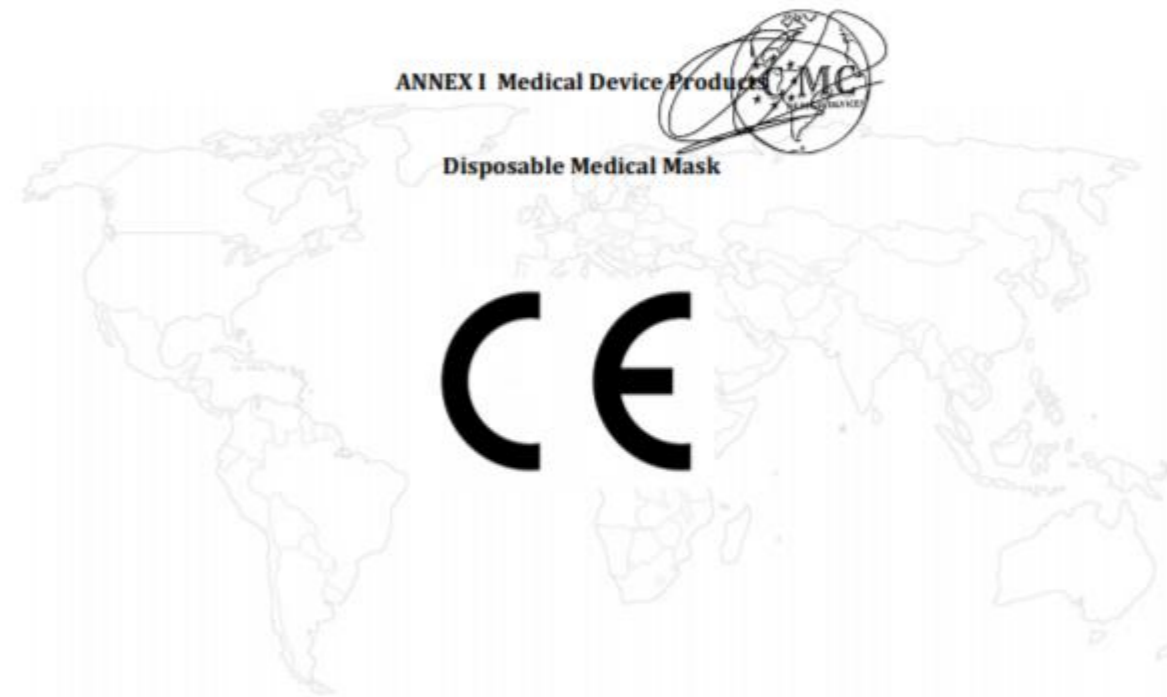
The products in Annex I was registered in Spanish MOH with number **RPS/643/2020**



Issued on: 29/04/2020

Valid until: 28/04/2021

  
 Authorized Signatory  
 CMC Medical Devices & Drugs SL



## La notificación se ha realizado correctamente.

Datos de registro	
Código de Expediente:	RPS/643/2020
Fecha Registro:	29/04/2020 13:14:05
Nº registro General:	RPS/643/2020
Oficina:	ETEL
Nº registro Oficina:	RPS/643/2020

### Registro de Responsables de Productos Sanitarios - RPS/643/2020

Datos de la notificación			
<b>Datos de registro</b>			
Nº Registro	<input type="text" value="RPS/643/2020"/>	Fecha Registro	<input type="text" value="29/04/2020"/>
<b>Datos del Responsable</b>			
Tipo de Responsable (*)	<input type="text" value="Rep. Autorizado"/>	Tipo de entidad	<input type="text" value="Empresa"/>
CIF(*)	<input type="text" value="B93316149"/>	Nombre (*)	<input type="text" value="CMC MEDICAL DEVICES &amp; DRUGS S.L."/>
Dirección(*)	<input type="text" value="C/ HORACIO LENGU Nº 18"/>		
Localidad (*)	<input type="text" value="MALAGA"/>		
Provincia(*)	<input type="text" value="Málaga"/>	CP(*)	<input type="text" value="29006"/>
Teléfono(*)	<input type="text" value="951214054"/>	Fax	<input type="text"/>
e-mail(*)	<input type="text" value="info@cmcmmedicaldevices."/>	Web	<input type="text"/>
<b>Datos del Fabricante</b>			
Nombre o Razón Social (*)	<input type="text" value="Taizhou HMRoyal medical device technology Co.,Ltd"/>		
Dirección(*)	<input type="text" value="6-1040Shugang Road, Taizhou Medical New &amp; Hi-tech Industrial Development Zone"/>		
Localidad (*)	<input type="text" value="Jiangsu"/>		
País(*)	<input type="text" value="República Popular China"/>	CP	<input type="text"/>
Teléfono(*)	<input type="text" value="008615861057111"/>	Fax	<input type="text"/>
e-mail(*)	<input type="text" value="Jolly@oursearth.com"/>	Web	<input type="text"/>

### Relación de Productos

#### Listado de Productos Sanitarios

Se encontro una fila.

Listado de Productos Sanitarios			
Nombre Comercial	Tipo de Producto	Estado del producto	Acción
DISPOSABLE MEDICAL MASK	Clase I	Primera Comunicación	

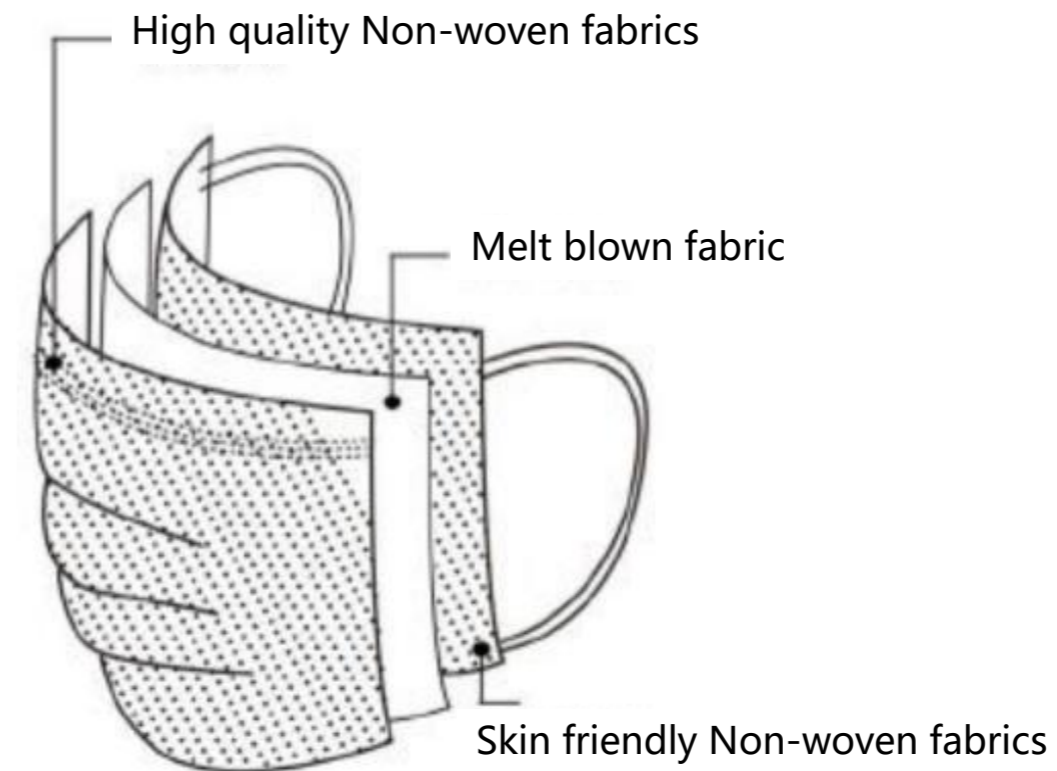
HMRoyal<sup>®</sup>

Taizhou HMRoyal medical device technology Co.,Ltd

# DISPOSABLE 3/4-PLY MASK

# DISPOSABLE MASK

HMRoyal®



**[product name]:** Disposable Mask

**[specification]:** 17.5 \* 9cm (+-3%)

**[structure and composition]:** the product is composed of mask body, nose clip and mask belt. The mask body is made of non-woven fabric and melt-blown fabric.

**[standard]:** EN 14683-2019, YY/T0969-2013, GB/T32610-2016

**[scope of application]:** it covers the user's mouth, nose and jaw, and suitable for the isolation and protection of dust and droplets in the air.

**[package]:** 50 pieces / box

**[name of manufacturer]:** Taizhou HMRoyal medical device technology Co.,Ltd

**[production address]:** 6-1040Shugang Road, Taizhou Medical New & Hi-tech Industrial Development Zone, Jiangsu Province, China

**[contact]:** 4000068600



## 50PCS/BOX

- MATERIAL: 350g wrapping paper
  - SIZE: 200\*100\*90mm
- PRINT: four-color printing
  - **OEM is available**



## 40BOXS/CARTON

- MATERIAL: five-layer carton
  - SIZE: 525\*420\*385mm
- LOADING CAPACITY: > 0.05kgf/cm<sup>2</sup>

# DISPOSABLE FACE MASK

HMRoyal®



**[STANDARD]:**  
According to GB/T32610-2016

- [TWO STYLE]:**
- WITH ear loop
  - WITH ties

# DISPOSABLE MEDICAL MASK

HMRoyal®



**[STANDARD]:**

According to EN 14683:2019

**[2 LEVELS]:**

I、II

**[TWO STYLE]:**

- WITH ear loop
- WITH ties

**[STERILIZATION]:**

- Sterile
- Non sterile

# DISPOSABLE SURGICAL MASK

HMRoyal®



**[STANDARD]:**  
According to EN 14683:2019

**[2 LEVELS]:**  
IIR

**[TWO STYLE]:**

- WITH ear loop
- WITH ties

**[STERILIZATION]:**

- Sterile
- Non sterile



# TEST REPORT (EN14683: 2019)

HMRoyal®

**BeFitLab** 百帆测试 **IAS** ACCREDITED Testing Laboratory

Report No.: BT20040201616-3 Page 1 of 8

**Customer Information:**  
Customer: Taizhou HMRoyal medical device technology Co.,Ltd  
Address: 6-1040Shugang Road, Taizhou Medical New & Hi-tech Industrial Development Zone, Jiangsu Province, China

**Sample Information:**  
Sample Name: Disposable Medical Mask  
Sample Specification: 175mmx95mm (with ear loop/with tie)  
Sample Classification: Type II R  
Sample Description: Samples in good condition  
Sampled Method: All parts were received from customer  
Receipt Date: 2020-04-02

**Testing Information:**  
Test Items: Bacterial Filtration Efficiency(BFE), etc.  
Test Reference: EN 14683: 2019  
Test Result: Please refer to the following pages

Written by: Ayzi Gul Inspected by: Yanli Li Approved by: Shaoen Zhai  
Date: 2020-05-25 Date: 2020-05-25 Date: 2020-05-25

**INTERNATIONAL TESTING SERVICE**  
**BTT**  
CERTIFICATION

**BEFITLAB TEST TECHNOLOGY COMPANY LIMITED**  
Member of International Standards Certification (ISC) Group

BEFITLAB TEST TECHNOLOGY COMPANY LIMITED  
www.befitlab.com Tel:021-59100859 Email: info@befitlab.com

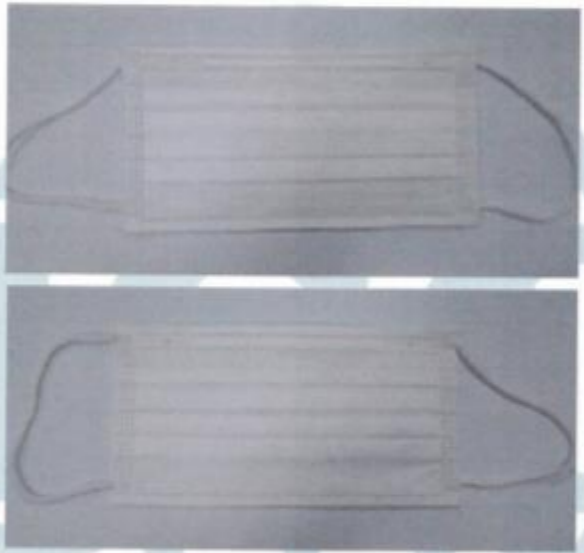
**BeFitLab** 百帆测试

Report No.: BT20040201616-3 Page 2 of 8

**1. Sample List**

Manufacturer	Sample Name	Specification	Material	Lot
Taizhou HMRoyal medical device technology Co.,Ltd	Disposable Medical Mask	175mmx95mm (with ear loop/with tie)	Nonwoven Fabric+Meltblown Nonwoven Fabric	20200314

**2. Sample Photos**



**BEFITLAB TEST TECHNOLOGY COMPANY LIMITED**  
www.befitlab.com Tel:021-59100859 Email: info@befitlab.com

# TEST REPORT (EN14683: 2019)

**BeFitLab** 百帆测试

## Test Report

Report No.: BT20040201616-3 Page 3 of 8

**Appendix 1: Bacterial Filtration Efficiency(BFE)**

**1.1.Reference Standard Item:** EN 14683-5.2.2 BFE

**1.2.Environmental Condition:** 23°C, 60%RH

**1.3.Strain, Medium and Reagent information:**  
 Staphylococcus Aureus (ATCC6538);  
 Peptone Agar Medium (20191205);  
 Peptone Liquid Medium (1085071);  
 PH7.0 Sodium Chloride-peptone Buffer (1071461);

**1.4.Test Parameters:**

Air flow rate (double way)	57 L/min
Mean particle diameter of bacterial aerosol	(3.0±0.3)µm

**1.5.Result:**


Determination of bacterial suspension concentration									
Plate 1(CFU)		Plate 2(CFU)			Dilution level		Concentration(CFU/mL)		
58		60			10 <sup>-4</sup>		5.9×10 <sup>5</sup>		
Groups	Plate 1	Plate 2	Plate 3	Plate 4	Plate 5	Plate 6	Total	BFE	
Negative	r	0	0	0	0	0	0	/	
Control	p	0	0	0	0	0	0	/	
Positive	r	173	58	70	275	349	97	1022	
Control 1	p	227	63	77	465	824	111	1767	
Positive	r	202	27	102	256	348	130	1065	
Control 2	p	281	28	118	409	816	157	1809	
Sample 1	r	0	0	0	0	1	0	1	99.94%
	p	0	0	0	0	1	0	1	
Sample 2	r	0	0	1	0	0	1	2	99.89%
	p	0	0	1	0	0	1	2	
Sample 3	r	0	0	0	0	5	0	5	99.72%
	p	0	0	0	0	5	0	5	
Sample 4	r	0	0	0	1	2	0	3	99.83%
	p	0	0	0	1	2	0	3	
Sample 5	r	0	0	0	3	0	0	3	99.83%
	p	0	0	0	3	0	0	3	

**BeFitLab** 百帆测试

## Test Report

Report No.: BT20040201616-3 Page 4 of 8

**1.6. Sample after Test:**



About 12 cm\*12cm

**Appendix 2: Differential Pressure (Delta P)**

**2.1.Reference Standard Item:** EN 14683-5.2.3 Breathability

**2.2.Environmental Conditions:** 22.3°C, 51%RH

**2.3.Test Parameters:**

Air flow rate (double way)	8 L/min
Sample Diameter	φ25 mm
Test area	4.9 cm <sup>2</sup>

**2.4.Result:**

NO.	Position 1 (Pa)	Position 2 (Pa)	Position 3 (Pa)	Position 4 (Pa)	Position 5 (Pa)	Average (Pa)	Delta P (Pa/cm <sup>2</sup> )
Sample 1	98.7	109.0	95.8	110.3	98.4	102.4	20.91
Sample 2	90.4	116.2	115.4	118.4	98.0	107.7	21.98
Sample 3	102.3	105.3	99.1	95.7	107.0	101.9	20.79
Sample 4	120.6	88.9	98.1	91.0	92.1	98.1	20.03
Sample 5	119.1	106.9	99.8	112.5	108.2	109.3	22.31

**2.5. Sample after Test:**

# TEST REPORT (EN14683: 2019)

BeFitLab 百帆测试

## Test Report

Report No.: BT20040201616-3 Page 5 of 8



Test location of sample

**Appendix 3: Splash resistance**

**3.1.Reference Standard Item:** EN14683-5.2.4 Splash resistance; ISO 22609; 2004

**3.2.Environmental Condition:** 22.3℃, 51%RH

**3.3.Test Parameters:**

Pressure (KPa)	Velocity (cm/s)	Time (s)
16.0	550	0.66

**3.4. Sample after Test:**



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BeFitLab 百帆测试

## Test Report

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Picture : 16.0 KPa Sample after Test

**3.5.Result:**  
The samples were tested under pressure of 16.0kPa, no synthetic blood penetration on the medial side.

**Appendix 4: Microbial cleanliness**

**4.1.Reference Standard Item:** EN 14683-5.2.5 Microbial cleanliness (Bioburden); EN ISO 11737-1:2018

**4.2. Reagents:**  
SDA (Lot No:180912)  
TSA (Lot No:20190613)  
Sodium chloride-peptone buffer (Lot No:180820)

**4.3. Sample preparation:**  
5 samples were randomly selected for the experiment.

**4.4. Test method:**  
Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5g/l NaCl and 2 g/l Tween 20). The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0.45 μm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30℃ and 7 days at 25℃ for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts.

**4.5. Statistical method:**  
Count according to the principle of colony count.

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www.befitlab.com Tel:021-59100859 Email: info@befitlab.com

# TEST REPORT (EN14683: 2019)

**BeFitLab**  
百帆测试

## Test Report

Report No.: BT20040201616-3 Page 7 of 8

**4.6. Results of the test:**

Sample number	Weight g	Aerobic cfu/100ml	Fungal cfu /100ml	Total Bioburden cfu /sample	Total Bioburden cfu /g
1	3.1	13	5	54	17.4
2	3.1	19	3	66	21.3
3	3.1	14	1	45	14.5
4	3.1	21	4	75	24.2
5	3.2	15	2	51	15.9

**Appendix 5: Summary of performance requirements**

**5.1.Reference Standard Item:** EN 14683-5.2.5 Microbial cleanliness (Bioburden)

**5.2.Performance requirements:**

Table 1 — Performance requirements for medical face masks

Test	Type I*	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm <sup>2</sup> )	< 40	< 40	< 60
Splash resistance pressure (kPa)	Not required	Not required	≥ 16.0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

\* Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

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**BeFitLab**  
百帆测试

## Test Report

Report No.: BT20040201616-3 Page 8 of 8

**5.3.Results:**

Test Item	Test Result
Bacterial Filtration Efficiency(BFE)	Sample 1: 99.94%
	Sample 2: 99.89%
	Sample 3: 99.72%
	Sample 4: 99.83%
	Sample 5: 99.83%
Differential Pressure (Delta P)	Sample 1: 20.91 Pa/cm <sup>2</sup>
	Sample 2: 21.98 Pa/cm <sup>2</sup>
	Sample 3: 20.79 Pa/cm <sup>2</sup>
	Sample 4: 20.03 Pa/cm <sup>2</sup>
	Sample 5: 22.31Pa/cm <sup>2</sup>
Splash resistance	The samples were tested under pressure of 16.0kPa, no synthetic blood penetration on the medial side.
Microbial cleanliness	18.66 cfu/g

**5.4. Conclusion:**  
Compliance with the performance requirements of Type IIR.

\*\*\*\*\* End \*\*\*\*\*

**Notice Items:**

1. It is not valid if the report without our stamp.
2. This report must not be altered, increased or deleted.
3. The report is just responsible for the tested sample.
4. The sample(s) information was/were submitted and identified on behalf of the client.
5. Any questions on the report should be put forward within fifteen days since the date on which you receive the report, and overdue is inadmissible.
6. The report must not be partially duplicated except in full, without prior written approval of the company.
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**BEFITLAB TEST TECHNOLOGY COMPANY LIMITED**  
www.befitlab.com Tel:021-59100859 Email: info@befitlab.com

# TEST REPORT (GB/T32610-2016)

HMRoyal®



中国认可  
国际互认  
检测  
TESTING  
CNAS L6760

## 检测报告

报告编号: HAPTX20041168

第 1 页 共 4 页

申请公司 泰州皇牌医疗器械科技有限公司  
地址 泰州市医药高新技术产业开发区疏港路 6 号 1040

### 样品信息

序号	样品名称
01	一次性普通防护口罩
02	一次性普通防护口罩

样品品牌 HMRoyal

\*以上信息内容由申请人提供并确认

样品接受日期 2020-04-08

样品检测日期 2020-04-08—2020-04-26

### 检测要求

根据客户要求,  
(1) 按照 GB/T 32610-2016 标准部分条款要求对 01 样品测试以下项目: 甲醛, pH 值, 可分解致癌芳香胺染料, 口罩带及口罩带与口罩体的连接处断裂强力, 外观, 吸气阻力, 呼气阻力;  
(2) 依据 GB/T 32610-2016 附录 A 测试 02 样品的过滤效率 (盐性)。

### 检测结果

见后续页

签

发: Paul Chen  
授权签字人

签发日期: 2020-04-26



验证报告网址: 认监委验证平台 yz.cnca.cn



中国认可  
国际互认  
检测  
TESTING  
CNAS L6760

## 检测报告

报告编号: HAPTX20041168

第 2 页 共 4 页

检测结论 01 样品经检验, 所测项目符合 GB/T 32610-2016 产品标准的规定要求, 检验合格, 判定如下:

序号	检测项目	要求	检测方法	01	单项 评定
1	甲醛 (mg/kg)	≤20	GB/T 2912.1-2009	ND	符合
2	pH 值	4.0-8.5	GB/T 7573-2009	6.1	符合
3	可分解致癌芳香胺染料 (mg/kg)*	禁用 (≤20)	GB/T 17592-2011	ND	符合
4	口罩带及口罩带与口罩体的连接处断裂强力/N	≥20	GB/T 32610-2016	31	符合
5	外观	口罩表面不应有破损、油污污渍、变形及其他明显的缺陷	GB/T 32610-2016	符合	符合

备注: (1) 1mg/kg=1ppm=0.0001%  
(2) ND=未检出  
(3) 甲醛的最低检测限为 16 mg/kg  
(4) \*项目检测信息详见检测结果  
(5) 1-5 项目数据来源于报告 HAPTX20040264

### 1. 过滤效率的检测结果 (单位: %)

检测方法 依据 GB/T 32610-2016 附录 A 进行测定, (流量: 85L/min)

测试项目	02
过滤效率	盐性: 91

# TEST REPORT (GB/T32610-2016)

HMROYAL®



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## 检测报告



中国认可  
国际互认  
检测  
TESTING  
CNAS L6760

报告编号: HAPT X20041168

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### 2.可分解致癌芳香胺染料的检测结果(单位: mg/kg)

检测方法 依据 GB/T 17592-2011, 采用 GC-MS 进行测定。

检测项目	CAS No.	MDL	限量	01
4-氨基联苯	92-67-1	5	20	ND
联苯胺	92-87-5	5	20	ND
4-氯邻甲苯胺	95-69-2	5	20	ND
2-萘胺	91-59-8	5	20	ND
邻氨基偶氮甲苯	97-56-3	5	20	ND
对氯苯胺	106-47-8	5	20	ND
2,4-二氨基苯甲醛	615-05-4	5	20	ND
4,4'-二氨基二苯甲烷	101-77-9	5	20	ND
3,3'-二氯联苯胺	91-94-1	5	20	ND
3,3'-二甲氧基联苯胺	119-90-4	5	20	ND
3,3'-二甲基联苯胺	119-93-7	5	20	ND
3,3'-二甲基-4,4'-二氨基联苯基甲烷	838-88-0	5	20	ND
2-甲氧基-5-甲基苯胺(p-克利肟)	120-71-8	5	20	ND
4,4'-亚甲基-二-(2-氯苯胺)	101-14-4	5	20	ND
4,4'-二氨基二苯醚	101-80-4	5	20	ND
4,4'-二氨基二苯硫醚	139-65-1	5	20	ND
邻甲苯胺	95-53-4	5	20	ND
2,4-二氨基甲苯	95-80-7	5	20	ND
2,4,5-三甲基苯胺	137-17-7	5	20	ND
邻氨基苯甲醛	90-04-0	5	20	ND
5-硝基-邻甲苯胺	99-55-8	5	20	ND
4-氨基偶氮苯	60-09-3	5	20	ND
2,4-二甲基苯胺	95-68-1	5	20	ND
2,6-二甲基苯胺	87-62-7	5	20	ND

备注: (1) 1mg/kg=1ppm=0.0001%

(2) MDL=方法检出限

(3) ND=未检出 (<MDL)



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## 检测报告



中国认可  
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检测  
TESTING  
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报告编号: HAPT X20041168

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### 3.呼吸阻力的检测结果(单位: Pa)

检测方法 依据 GB/T 32610-2016 进行测定。(通气量: 85L/min)

测试项目	01
呼气阻力	未预处理
	1#23 2#20
吸气阻力	未预处理
	1#25 2#32

备注: GB/T 32610-2016 不在 CMA,CNAS 认证能力范围内

样品照片:



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# TEST REPORT (YY/T0969-2013)

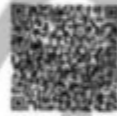
HMRoyal®



171021110579

## 检验检测报告

TEST REPORT



STFWT20206726

产品名称  
Product Name 一次性使用口罩

委托单位  
Trust Unit 泰州皇牌医疗器械科技有限公司

生产单位  
Manufacturer 泰州皇牌医疗器械科技有限公司

检验检测类别  
Test Category 委托送样检验

SPC 江苏省特种安全防护产品质量监督检验中心  
JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

## 检验检测报告

Test Report

STFWT20206726

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Page 1 of 2

产品名称 Product Name	一次性使用口罩	规格型号 Specification Type	—
委托单位 Trust Unit	泰州皇牌医疗器械科技有限公司	商 标 Trademark	HMRoyal
生产单位 Manufacturer	泰州皇牌医疗器械科技有限公司	电 话 Tel	15261092111
样品数量 Sample Quantity	20 只	样品等级 Sample Grade	—
检验检测类别 Test Category	委托送样检验	送样日期 Sample Receiving Date	2020-03-27
样品状态 Samples Conditions	符合检测要求		
检验检测及判定依据 Document and Decide Accordance	YY/T 0969-2013 《一次性使用医用口罩》		
检验检测结论 Test Conclusion	样品经检验，所检项目符合 YY/T0969-2013 标准规定的要求。 签发日期：2020-03-29 Signature Date		
备 注 Remarks	本报告检验结论仅对所检项目得出，不代表未经检验的项目功能符合要求。 本报告仅对来样负责。		

批准： 审核： 主 检：

Approver Examiner Major tester

# TEST REPORT (YY/T0969-2013)

HMRoyal®

检 验 检 测 结 果  
Testing Results

STFWT20206726 共 2 页 第 2 页  
Page 2 of 2

序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment
1	外观	—	口罩外观应整洁, 形状完好, 表面不得有破损、污渍。	口罩外观整洁, 形状完好, 表面未有破损、污渍。	合格
2	结构与尺寸	—	口罩佩戴好后, 应能罩住佩戴者的鼻、口至下颌。	口罩佩戴好后, 能罩住佩戴者的鼻、口至下颌。	合格
3	鼻夹	—	1、口罩上应配有鼻夹, 鼻夹由可塑性材料制成。 2、鼻夹长度应不小于 8.0cm。	1、口罩上配有鼻夹, 鼻夹由可塑性材料制成。 2、鼻夹长度: 9.7cm、9.6cm、9.7cm。	合格
4	口罩带	—	1、口罩带应佩戴方便。 2、每根口罩带与口罩体连接点处的断裂强力应不小于 10N。	1、口罩带佩戴方便。 1 <sup>#</sup> : 试样断裂强力不小于 10N 2 <sup>#</sup> : 试样断裂强力不小于 10N 3 <sup>#</sup> : 试样断裂强力不小于 10N	合格
5	通气阻力	Pa/cm <sup>2</sup>	口罩两侧面进行气体交换的通气阻力应不大于 49 Pa/cm <sup>2</sup>	4 <sup>#</sup> : 32 5 <sup>#</sup> : 34 6 <sup>#</sup> : 31	合格
6	细菌过滤效率/% (BFE)	—	≥95	98.2	合格

样品图片



以下空白

注 意 事 项

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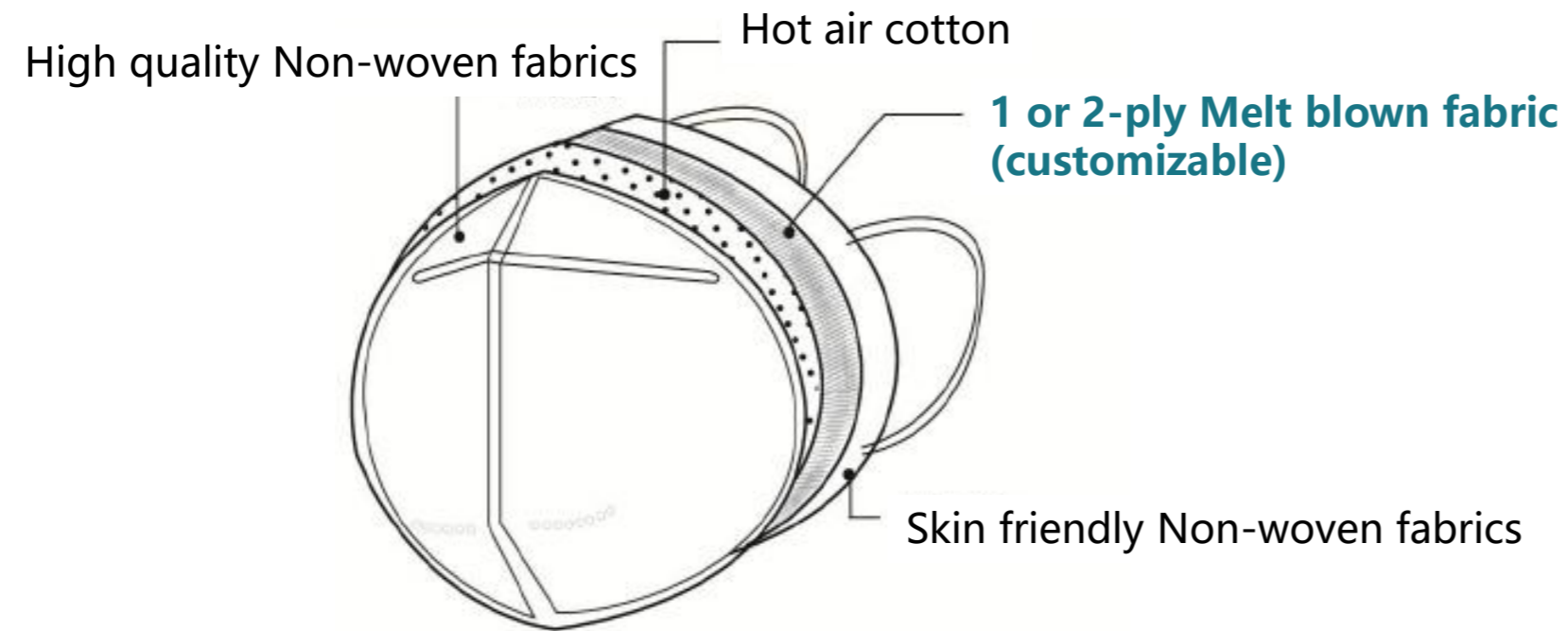
HMRoyal<sup>®</sup>

Taizhou HMRoyal medical device technology Co.,Ltd

# PROTECTIVE MASK

# PROTECTIVE MASK (4/5-PLY)

HMRoyal®



**[product name]:** Protective Mask KN95

**[specification]:** 19cm \* 16.5cm

**[structure and composition]:** the product is composed of mask body, nose clip and mask belt. The mask body is made of PP non-woven fabric, melt-blown fabric, antibacterial cotton, skin-friendly non-woven fabric.

**[Standard]:** According to GB2626-2006 = **EN 149:2001 = N95**

**[scope of application]:** it covers the user 's mouth, nose and jaw, provide the wearer with suction protection, for non-oily particulate matter filter efficiency of 95% or higher.

**[package]:** 25 pieces / box

# PACKING

HMRoyal®



## 25PCS/BOX

- MATERIAL: 350g wrapping paper
- SIZE: 130\*130\*130mm
- PRINT: four-color printing
- OEM is available



## 40BOXES/CARTON

- MATERIAL: five-layer carton
- SIZE: 667\*536\*278mm
- LOADING CAPACITY: > 0.05kgf/cm<sup>2</sup>

# PACKING

HMRoyal®



# KN95 PROTECTIVE MASK

HMRoyal®



**[STANDARD]:**

According to [GB2626-2006](#)

**[TWO STYLE]:**

- WITH ear loop
- WITH ties

# FFP2 MASK

HMRoyal®



**[STANDARD]:**  
According to EN149:2001

- [TWO STYLE]:**
- WITH ear loop
  - WITH ties

# TEST REPORT (GB2626-2006)

HMRoyal®





## 检验检测报告

### TEST REPORT



STFWT20205325

产品名称 自吸过滤式防颗粒物呼吸器  
 Product Name 自吸过滤式防颗粒物呼吸器

委托单位 Taizhou HMRoyal Medical Device Technology Co., Ltd.  
 Trust Unit 泰州皇牌医疗器械科技有限公司

生产单位 Taizhou HMRoyal Medical Device Technology Co., Ltd.  
 Manufacturer 泰州皇牌医疗器械科技有限公司

检验检测类别 Commissioned sample inspection  
 Test Category 委托送样检验




江苏省特种安全防护产品质量监督检验中心  
 JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS

## 检验检测报告

### Test Report

STFWT20205325 共 4 页 第 1 页  
Page 1 of 4

产品名称 Product Name	自吸过滤式防颗粒物呼吸器	规格型号 Specification Type	—
委托单位 Trust Unit	泰州皇牌医疗器械科技有限公司	商标 Trademark	HMRoyal
生产单位 Manufacturer	泰州皇牌医疗器械科技有限公司	电话 Tel	15261092111
样品数量 Sample Quantity	50 只	样品等级 Sample Grade	KN95
检验检测类别 Test Category	委托送样检验	送样日期 Sample Receiving Date	2020-03-18
样品状态 Samples Conditions	符合检测要求 Meet the testing requirements		
检验检测及判定依据 Document and Decide Accordance	GB 2626-2006 《呼吸防护用品 自吸过滤式防颗粒物呼吸器》		
检验检测结论 Test Conclusion	样品经检验，所检项目符合 GB 2626-2006 标准规定的 KN95 级要求。 签发日期: 2020-03-26 Signatium Date: 		
备注 Remarks	标记“—”的检测项目表示不予单项评价或不具备单项评价条件。 本报告检验结论仅对所检项目得出，不代表未经检验的项目或功能符合要求。 本报告仅对来样负责。		

批准: 陈敏 审核: 吴高亮 主检: 蔡燕文  
 Approver Examiner Major tester

# TEST REPORT (GB2626-2006)

Structure:  
 a) Structural damage did not occur easily and the design, composition and installation of the components didn't pose any danger to the user;  
 b) The design of the headband is adjustable for easy wearing and removing, and the mask were firmly fixed on the face, and there was no obvious pressure or tenderness when wearing it;  
 c) It had a smaller dead space and a larger field of vision.

Material:  
 a) Materials in direct contact with the face should be harmless.  
 b) Filter material should be harmless to human body.  
 c) The materials used should have sufficient strength and should not be damaged or deformed during normal service life.  
 Structure:  
 a) Structural damage shall not occur easily and the design, composition and installation of the components shall not pose any danger to the user;  
 b) The design of the headband should be adjustable for easy wearing and removing, and the mask should be firmly fixed on the face, and there should be no obvious pressure or tenderness when wearing it;  
 c) It should have a smaller dead space and a larger field of vision as much as possible;  
 d) The structure of the disposable mask should be able to ensure close contact with the face, and should not deform during the service life

The surface of the sample shall not be damaged, deformed or have other obvious defects. The material and structure of every part shall be able to withstand normal operating conditions and possible temperature, humidity and mechanical impact. The headband shall be adjustable

The total inspiratory resistance of each sample shall not be greater than 350 and the total expiratory resistance shall not be greater than 250

序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment			
1	General requirements 一般要求	—	材料: a) 直接与面部接触的材料应无害; b) 滤材应对人体无害; c) 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。 结构: a) 不应产生结构性破损, 部件的设计、组成和安装不对使用者构成任何危险; b) 头带的设计应可调, 便于佩戴和摘除, 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; c) 应尽可能具有较小的死腔和较大的视野; d) 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: a) 不易产生结构性破损, 部件的设计、组成和安装未对使用者构成任何危险; b) 头带的设计可调, 便于佩戴和摘除, 能将面罩牢固地固定在脸上, 且佩戴时未出现明显的压迫或压痛现象; c) 具有较小的死腔和较大的视野;	合格 Qualified			
2	Appearance inspection 外观检查	—	样品表面不应破损、变形和有明显的其它缺陷, 部件材料和结构应能够耐受正常使用条件及可能遇到的温度、湿度和机械冲击, 头带应可调。	符合要求	合格 Qualified			
3	Respiratory resistance 呼吸阻力	Pa	每个样品的总吸气阻力应不大于 350, 总呼气阻力应不大于 250	试样编号		实测值	合格 Qualified	
				总吸气阻力 未预处理	1#	123.4		No pretreatment
					2#	130.4		
				预处理	5#	127.9		After pretreatment
					6#	134.6		
				总呼气阻力 未预处理	3#	104.6		No pretreatment
4#	105.9							
预处理	7#	110.4	After pretreatment					
	8#	109.6						
4	Field of vision 视野	—	Lower field of vision ≥ 60°	63°	合格 Qualified			
5	Dead space 死腔	—	二氧化碳体积分数应不大于 1% The volume fraction of carbon dioxide shall not be greater than 1%	二氧化碳体积分数为 0.4% The volume fraction of Carbon dioxide is 0.4%	合格 Qualified			

## 检验检测结果 Testing Results

STFWT20205325

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序号 Serial	检验检测项目 Test Items	单位 Unit	技术要求 Requirement	检验检测结果 Results	单项评价 Individual Judgment					
6	Filtration efficiency/% NaCl particles 过滤效率% (NaCl 颗粒物)	—	KN95: ≥95.0	试样编号		实测值	合格 Qualified			
				未预处理	9#	初始 98.4 加载 97.7		合格 Qualified		
					10#	初始 97.9 加载 97.2				
				11#		初始 97.3 加载 96.7				
					12#	初始 98.4 加载 98.0				
				13#		初始 97.9 加载 97.3				
					14#	初始 98.0 加载 97.5				
				15#		初始 98.1 加载 97.5				
					16#	初始 98.2 加载 97.6				
				17#		初始 98.3 加载 97.6				
					18#	初始 97.9 加载 97.3				
				温度湿度处理		19#			初始 97.8 加载 97.3	
					20#	初始 98.0 加载 97.4				
						21#			初始 97.8 加载 97.3	
					22#	初始 97.9 加载 97.3				
						23#			初始 97.5 加载 96.9	
				7	Headband 头带	—			面罩的每条头带、带扣及其他调节部件在承受 10N 拉力且持续 10s 时, 不应出现滑脱或断裂。 未预处理: 1#面罩的每条头带、带扣及其他调节部件在承受 10N 拉力且持续 10s 后, 未出现滑脱或断裂。 预处理后: 5#面罩的每条头带、带扣及其他调节部件在承受 10N 拉力且持续 10s 后, 未出现滑脱或断裂。	合格 Qualified

No pretreatment:  
 1# Each headband, buckle and other adjusting parts of the mask did not slip or break under 10N tension for 10s.  
 After pretreatment:  
 5# Each headband, buckle and other adjusting parts of the mask did not slip or break under 10N tension for 10s.



# FACTORY ENVIRONMENT

# FACTORY ENVIRONMENT

HMRoyal®



**Class 100,000 clean room**

# MASK EQUIPMENT

HMRoyal®



Daily production capacity:  
more than **1 million** pieces

5 semi-automatic disposable mask production lines,  
and 5 semi-automatic protective mask production lines

**UV transfer room (mask is transferred from the production clean room to the packaging clean room through UV sterilization)**



# MATERIAL INVENTORY

HMRoyal®

- **Melt blown fabric** (BFE $\geq$ 95% / BFE $\geq$ 99%) depend on customer requirement.
- **High quality Non-woven fabrics**
- **Hot air cotton**



HMRoyal<sup>®</sup>

Taizhou HMRoyal medical device technology Co.,Ltd

THANK YOU