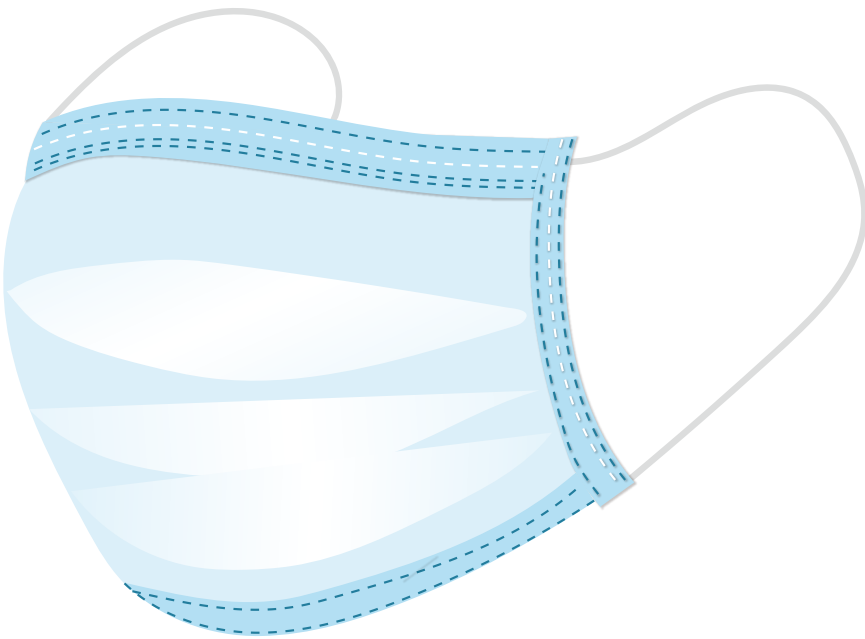




**WASTON**  
M E D I C A L

**PROFESSIONAL  
RELIABLE**



# Leading Disposable Medical Face Mask

Professional Medical Device Manufacture

Health is Important

# COMPANY INTRODUCTION

Established in the year of 2002, Changzhou Waston Medical Appliance Co., Ltd. is one of the leading designers and manufacturers of medical devices in China.

Located in the city of Changzhou, 180 kilometers to the west of Shanghai, our company covers an area of 200 Mu (30 acre), with 50,000 m<sup>2</sup> of standard workshops and 10,000 m<sup>2</sup> of cleanroom included.

Recently, COVID-19 epidemic has spread worldwide. As a professional medical device manufacturer with social responsibility, we've set up the face mask production lines since January 2020, in order to meet the emergency requirements in China and overseas. Now our daily production volume is over 5 million pieces. On the basis of professional management, strict control of raw material, we're devoted to providing disposable medical face masks and disposable protective face masks in high quality to clients in both China and overseas, to prevent themselves from affect of the COVID-19.



# PRODUCTS AND PACKAGING

Medical face mask



Surgical Face Mask



Disposable Medical Face Mask

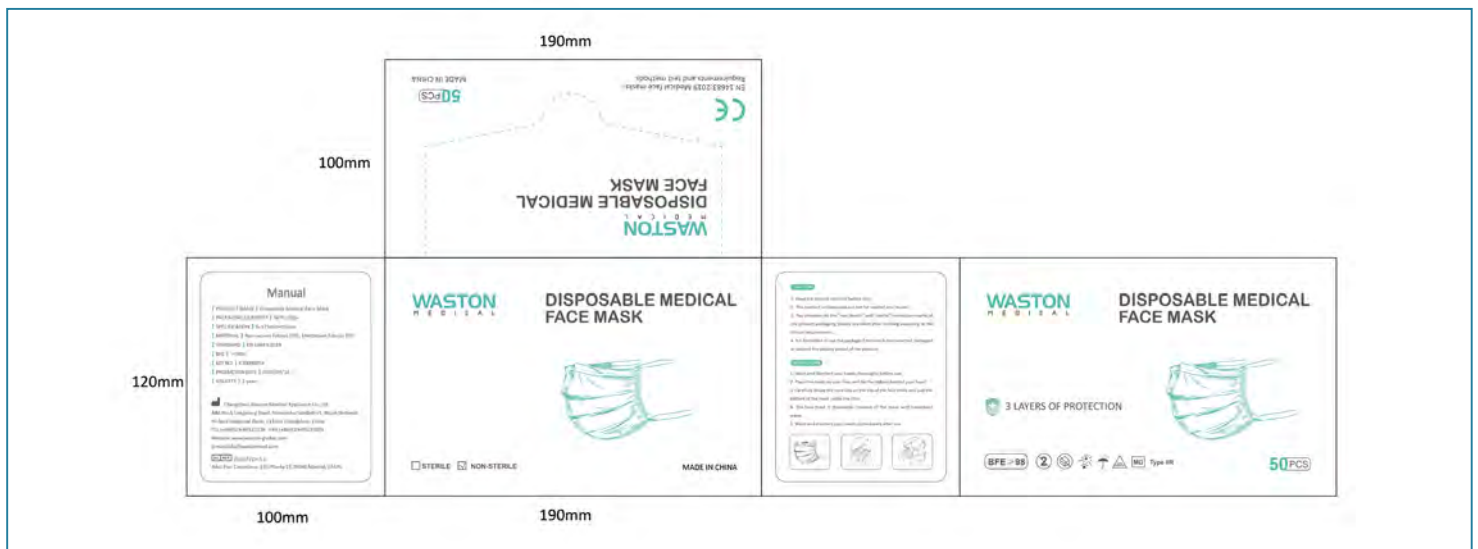


# PRODUCTS AND PACKAGING

Medical face mask(Ties)



Disposable Medical Face Mask(Ties)



# PRODUCTS AND PACKAGING

Protective face mask



Disposable Protective Face Mask  
(Non-medical)



# PRODUCTS AND PACKAGING

## KN95 Disposable Protective Face Mask



KN95 (Earloop Type)



KN95 (Head-strap Type)





# WHITE LIST FROM CCCMHPPIE

258	厦门市朗星节能照明股份有限公司 Xiamen Langxing Energy Saving Lighting Co., Ltd.	91350200671279823L	CE
259	秦皇岛市惠斯安普医学系统股份有限公司 Qinhuangdao Huisianpu Medical Systems Inc.	911303015728267567	CE
260	长沙比亚迪电子有限公司 Changsha BYD Electronics Co., Ltd.	91430112MA4QJE2J8D	CE
261	荆海兴绿十字医疗器材有限公司 Jingzhou Haixin Green Cross Medical Products Co., Ltd.	91421087747681457D	U.S. FDA 510(k) cleared
262	常州华森医疗器械有限公司 Changzhou Waston Medical Appliance Co., Ltd.	91320412735743809M	CE
263	江苏卓见医疗用品有限公司 Jiangsu Excellence Medical Supplies Co., Ltd.	9132040466381868XU	CE
264	无锡市宇寿医疗器械有限公司 Wuxi Yushou Medical Appliances Co., Ltd.	91320205250217624k	CE
265	江苏采纳医疗科技有限公司 Jiangsu Caina Medical Co., Ltd.	913202810710262756	CE
266	南京康友医疗科技有限公司 Canvon Medical Inc.	91320113134962555F	CE
267	常州国贸企业合作有限公司 Changzhou Intl. Trade & Enterprises Cooperative Co., Ltd.	913204047206643239	CE
268	常州市双马医疗器械有限公司 Changzhou Shuangma Medical Devices Co., Ltd.	913204027185820037	CE
269	江苏福瑞科技有限公司 Jiangsu FURUI Technology Co., Ltd.	9132010072057925X7	CE
270	江苏兴通生物科技集团有限公司 Jiangsu Xingtong Biotechnology Group Co., Ltd.	91321000798629851M	CE
271	江苏有爱科技有限责任公司 Jiangsu Yoai Technology Co., Ltd.	91320100MA1MELAJ10	CE
272	江阴华士医疗器械有限公司 Jiangyin Huashi Medical Equipment Co., Ltd.	91320281M1AMYQEX4K	CE
273	江阴市泛美医疗器械有限公司 Jiangyin Fanmei Medical Device Co., Ltd.	913202813309599517	CE

Link :

<http://en.cccmhpie.org.cn/Web/Content.aspx?queryStr=w7x08q7x15x15o3w8w1vS9z8w7x1X10x16x0X10x16o3w8w1u9v1u9v3v6v3>

# BUSINESS LICENSE

Registered capital: 177.33 million RMB

		编号 320483000202004140003	
统一社会信用代码 91320412735743809M (1/1)		<b>营业执照</b> (副本)	
			
		扫描二维码登录“国家企业信用信息公示系统”了解更多登记、备案、许可、监管信息。	
名称	常州华森医疗器械有限公司	注册资本	17733万元人民币
类型	有限责任公司(港澳台与境内合资)	成立日期	2002年04月17日
法定代表人	胡仁民	营业期限	2002年04月17日至2032年04月16日
经营范围	一类、二类、三类医疗器械的生产与销售。日用口罩（非医用）生产；日用口罩（非医用）销售；（涉及国家特别管理措施的除外，依法须经批准的项目，经相关部门批准后方可开展经营活动）；		
		住所	武进国家高新技术产业开发区南夏墅街道龙翔路5号
		登记机关	
		2020 年 04 月 14 日	

国家企业信用信息公示系统网址：  
<http://www.gsxt.gov.cn>

市场主体应当于每年1月1日至6月30日通过  
国家企业信用信息公示系统报送公示年度报告。

国家市场监督管理总局监制



# NMPA MANUFACTURE LICENSE

## 医疗器械生产许可证

许可证编号:苏食药监械生产许20020009号

企业名称:常州华森医疗器械有限公司

生产地址:江苏省武进高新技术产业开发区西湖路9号、江苏省武进区南夏墅街道龙翔路5号

法定代表人:胡仁民

生产范围:见医疗器械生产产品登记表

企业负责人:胡仁民

住 所:武进国家高新技术产业开发区南夏墅街道龙翔路5号

发证部门:江苏省药品监督管理局

有效期限:至 2021 年 08 月 29 日

发证日期: 2016 年 08 月 30 日

国家食品药品监督管理总局制

### 医疗器械生产产品登记表

企业名称	常州华森医疗器械有限公司			
许可证编号	苏食药监械生产许20020009号			
许可证有效期限	2016-08-30 至 2021-08-29			
生产范围	目类:6807-6-腹腔镜血管外科用其他器械,6808-6-一次性使用直线型切割缝合器,6808-6-一次性使用管型消化吻合器,6808-6-一次性使用直线缝合器,6808-腹部外科用其他器械,6809-6-一次性使用管型吻合器,6809-其他泌尿系统器械,6810-8-畸形(骨科)外科用其他器械,6815-注射穿刺器械,6822-其他医用光学器具、仪器及内窥镜设备,6865-4-表面缝合材料,6866-其他医用高分子材料及制品,02-13-手术器械-吻(缝)合器械及材料,04-17-脊柱外科辅助器械,14-06-与血管内导管配合用体外器械,14-13-手术室感染控制用品,14-14-医护人员防护用品,13-03-骨性植入物,6866-其他医用高分子材料及制品,13-01-骨接合植入物,13-03-骨性植入物			
生产产品列表				
序号	产品名称	注册号	登载日期	备注
1	单臂式骨科固定支架	苏械注准 20152100749	2016-08-30	
2	一次性使用腹腔镜切割吻合器及组件	苏械注准 20162220073	2016-08-30	
3	腹腔镜缝合器械包	苏械注准 20162100598	2016-08-30	
4	腹腔镜缝合器械包	苏械注准 20153461162	2016-08-30	
5	腹腔镜缝合器械包	苏械注准 20162100599	2016-08-30	
6	金属髓内钉系统	国械注准 20163460110	2016-08-30	
7	金属接骨空心螺钉	国械注准 20153461161	2016-08-30	
8	金属骨针	国械注准 20153462202	2016-08-30	
9	一次性使用加长管型吻合器	苏械注准 20162080862	2016-09-26	
10	腔内缝合器	国械注准 20163461489	2016-09-26	
11	一次性使用直线切割吻合器及钉仓组件	苏械注准 20162080861	2016-09-26	
12	一次性使用三排钉加长管型吻合器	苏械注准 20162080860	2016-09-26	

序号	产品名称	注册号	登记日期	备注
61	一次性使用医用口罩	苏械注准应总20202140052	2020-04-23	有效期至2021-04-22
62	医用外科口罩	苏械注准应总20202140063	2020-04-30	有效期至2021-04-25

发证部门(公章):江苏省药品监督管理局  
2020年04月30日

# CE CERTIFICATE



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
ZLG-BS-244.10.08  
www.zlg.de



Product Service

## EC Certificate

Full Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

No. G1 081989 0007 Rev. 02

### Manufacturer:

**Changzhou Waston  
Medical Appliance Co., Ltd.**  
No. 9 Xihu Road, Wujin Hi-Tech Industry Zone  
213164 Changzhou, Jiangsu  
PEOPLE'S REPUBLIC OF CHINA

### EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)  
Eiffestraße 80, 20537 Hamburg, GERMANY

### Product Category(ies):

General Spinal System, Metallic Bone Plates,  
Metallic Bone Screws, Metallic Intramedullary Nails,  
Circular Staplers, Linear Staplers, PPH Staplers,  
Linear Cutters, Curved Cutters, Orthopaedic  
External Fixation System, Endoscopic Cutters,  
Negative Pressure Wound Therapy System,  
Disposable Trocar, Sternal Fixation System,  
Intervertebral Fusion Cage, Kyphoplasty Balloon  
Catheter, Kyphoplasty Tool Kit

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

### Report No.:

SH1868707

### Valid from:

2019-04-02

### Valid until:

2023-03-07

Date, 2019-04-02

Stefan Preiß

Page 1 of 2

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
ZLG-BS-244.10.08  
www.zlg.de



Product Service

## EC Certificate

Full Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

No. G1 081989 0007 Rev. 02

### Facility(ies):

Changzhou Waston Medical Appliance Co., Ltd.  
No. 9 Xihu Road, Wujin Hi-Tech Industry Zone, 213164  
Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Changzhou Waston Medical Appliance Co., Ltd.  
Nanxiashu Street, Wujin Zone, No. 5 Longxiang Road, 213164  
Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Page 2 of 2

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



DAKKS  
Deutsche  
Akkreditierungsstelle  
D-2M-11321-01-00

TUV  
SUD  
Product Service

**Certificate**  
No. Q5 081989 0008 Rev. 02

**Holder of Certificate:** Changzhou Waston  
Medical Appliance Co., Ltd.  
No. 9 Xihu Road, Wujin Hi-Tech Industry Zone  
213164 Changzhou, Jiangsu  
PEOPLE'S REPUBLIC OF CHINA

**Certification Mark:**

**Scope of Certificate:** Design and Development, Production and Distribution of  
General Spinal System, Metallic Bone Plates, Metallic  
Bone Screws, Curved Cutters, Metallic Intramedullary  
Nails, Circular Staplers, Linear Staplers, PPH Staplers,  
Linear Cutters, Orthopaedic External Fixation System,  
Endoscopic Cutters, Negative Pressure Wound Therapy  
System, Disposable Trocar, EHMS Endoscopic Hernia  
Multifeed Stapler, Sternal Fixation System, Intervertebral  
Fusion Cage, Kyphoplasty Balloon Catheter, Kyphoplasty  
Tool Kit, Balloon Inflator, Disposable Medical Face Mask

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above  
has established and is maintaining a quality management system, which meets the requirements of the  
listed standard(s). See also notes overleaf.

**Report No.:** SH2068709

**Valid from:** 2020-06-03  
**Valid until:** 2022-03-07

**Date,** 2020-06-03  
Christoph Dicks  
Head of Certification/Notified Body

Page 1 of 2  
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAKKS  
Deutsche  
Akkreditierungsstelle  
D-2M-11321-01-00

TUV  
SUD  
Product Service

**Certificate**  
No. Q5 081989 0008 Rev. 02

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** Changzhou Waston Medical Appliance Co., Ltd.  
No. 9 Xihu Road, Wujin Hi-Tech Industry Zone, 213164 Changzhou,  
Jiangsu, PEOPLE'S REPUBLIC OF CHINA  
  
Changzhou Waston Medical Appliance Co., Ltd.  
Nanxiashu Street, Wujin Zone, No. 5 Longdang Road, 213164  
Changzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

Page 2 of 2  
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany



# MEDICAL MASK NMPA CERTIFICATE

Disposable Medical Face Mask

## 中华人民共和国医疗器械注册证

注册证编号：苏械注准应急 20202140052

注册人名称	常州华森医疗器械有限公司
注册人住所	武进国家高新技术产业开发区南夏墅街道龙翔路 5 号
生产地址	江苏省武进高新技术产业开发区西湖路 9 号、武进国家高新技术产业开发区南夏墅街道龙翔路 5 号
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	G-175mm × 95mm
结构及组成	由非织造布层、口罩带和鼻夹组成。口罩体分为三层：内、外层为聚丙烯无纺布、中间层为聚丙烯熔喷布。产品未灭菌，为一次性使用非无菌产品。
适用范围	适用于普通医疗环境中佩戴、阻隔口腔和鼻腔呼出或喷出污染物。
附 件	产品技术要求
其他内容	
备 注	非无菌产品有效期不超过 2 年。 熔喷布原材料供应商为：常州华森医疗器械有限公司

审批部门：江苏省药品监督管理局

批准日期：2021 年 04 月 21 日

有效期至：2024 年 04 月 21 日

# NMPA TEST REPORT

Disposable Medical Face Mask

## 检 验 报 告

### Test Report

( 2020 ) ZC 类第 0447 号

样 品 名 称  
Product Name

一次性使用医用口罩

规 格 型 号  
Specifications

G-175mm×95mm

检 验 类 别  
Test Category

注册检验

委 托 单 位  
Entrusting Unit

常州华森医疗器械有限公司

江 苏 省 医 疗 器 械 检 验 所

Jiangsu Testing and Inspection Institute for Medical Devices

## 江苏省医疗器械检验所

### 检验报告首页

报告编号: 2020ZC0447

首页1页 W2页 S1页 Z1页 共5页

样品名称	一次性使用医用口罩	样品编号	SLZC2003108
送样 (√)	抽样 ( )		
商标	/	规格型号	G-175mm×95mm
委托方	常州华森医疗器械有限公司	检验类别	注册检验
委托方通讯地址	江苏省武进高新技术产业开发区 西湖路9号, 江苏省武进区南夏墅 街道龙翔路5号	产品编号/批号	S20030001
标示生产单位	常州华森医疗器械有限公司	抽样单编号	/
受检单位	常州华森医疗器械有限公司	生产日期	2020.03.04
抽样单位	/	样品数量	212只
抽样地点	/	抽样基数	/
抽样日期	/	检验地点	本检验所试验室
收样日期	2020年3月16日	检验日期	2020年3月19日-2020年4月17日
检验项目	全项目		
检验依据	常州华森医疗器械有限公司产品技术要求《一次性使用医用口罩》		
检验结论	被检样品符合常州华森医疗器械有限公司产品技术要求《一次性使用医用口罩》规定的要求 (检验报告专用章或检验师公章) 签发日期 2020年3月19日		
备注	1) 报告中的“—”表示此项不适用, 报告中“/”表示此项空白。 2) 报告页眉中的“W”表示物理, “S”表示生物, “Z”表示照片。		

批准: 王培良

职务: 检验师



# NMPA TEST REPORT-ENGLISH

Disposable Medical Face Mask

## Test Report

No. 2020-ZC-0447

Product Name Disposable Medical Face Mask  
Specification G-175mm×95mm  
Test Category Registration Inspection  
Entrusting Unit Changzhou Waston Medical Appliance Co., Ltd.

Jiangsu Testing and Inspection Institute for Medical Devices

Jiangsu Testing and Inspection Institute for Medical Devices

Inspection Report Front Page

No. 2020ZC0447

Front page 1 page, W2 pages, S1 page, Z1 page, all 5 pages

Product name	Disposable Medical Face Mask		Sample No.	SLZC2003108
	Submission (√)	Sampling ( )		
Trademark	/		Model and specification	G-175mm×95mm
Entrusting party name	Changzhou Waston Medical Appliance Co., Ltd.		Inspection type	Registration Inspection
Entrusting party address	No.9 Xihu Road, Wujin Hi-tech Industry Zone, Jiangsu Province/ No.5 Longxiang Road, Nanxiashu Subdistrict, Wujin District, Jiangsu Province		Product No.	S20030001
Manufacturer	Changzhou Waston Medical Appliance Co., Ltd.		Sampling List No.	/
Inspected Unit	Changzhou Waston Medical Appliance Co., Ltd.		Manufacturing date	2020.03.04
Sampling Unit	/		Sample Quantity	212
Sampling place	/		Basic number of sampling	/
Sampling Date	/		Inspection location	Testing Laboratories
Sample received Date	16 <sup>th</sup> March 2020		Inspection Date	19 <sup>th</sup> March 2020~ 17 <sup>th</sup> April 2020
Inspection Item	All items			
Inspection basis	Changzhou Waston Medical Appliance Co., Ltd. 《Disposable Medical Face Mask》 Technical Requirements.			
Inspection conclusion	The products inspected comply with Changzhou Waston Medical Appliance Co., Ltd. 《Disposable Medical Face Mask》 Technical Requirements. (Inspection Report Stamp or Inspection Institute Stamp) Issued date: 19 <sup>th</sup> April 2020			
Remarks	1. "-" means inapplicable, "/" means blank 2. W is for Physical, S is for Biological and Z is for Photo in the headers			

Approved by: Fang Jingxian  
Title: Authorized Signatory

# SURGICAL MASK NMPA CERTIFICATE

Surgical Face Mask

## 中华人民共和国医疗器械注册证

注册证编号：苏械注准应急 20202140063

注册人名称	常州华森医疗器械有限公司
注册人住所	武进国家高新技术产业开发区南夏墅街道龙翔路 5 号
生产地址	江苏省武进高新技术产业开发区西湖路 9 号、武进国家高新技术产业开发区南夏墅街道龙翔路 5 号
代理人名称	不适用
代理人住所	不适用
产品名称	医用外科口罩
型号、规格	W-17.5cm × 9.5cm
结构及组成	由内外两层无纺布、过滤层、口罩带和鼻夹组成。口罩体分为三层：内、外层为聚丙烯无纺布、中间层为聚丙烯熔喷布。产品未灭菌，为一次性使用非无菌产品。
适用范围	适用于临床医务人员在有创操作等过程中佩戴。
附 件	产品技术要求
其他内容	
备 注	非无菌产品有效期不超过二年。 熔喷布原材料供应商为：江苏康泰医疗器材有限公司。



审批部门：江苏省药品监督管理局

批准日期：2020 年 04 月 26 日

有效期至：2021 年 04 月 25 日

# NMPA TEST REPORT

Surgical Face Mask

## 检 验 报 告

### Test Report

( 2020 ) ZC 类第 0449 号

样 品 名 称  
Product Name

医用外科口罩

规 格 型 号  
Specifications

W-17.5cm×9.5cm

检 验 类 别  
Test Category

注册检验

委 托 单 位  
Entrusting Unit

常州华森医疗器械有限公司

江苏省医疗器械检验所

Jiangsu Testing and Inspection Institute for Medical Devices

## 江苏省医疗器械检验所 检验报告首页

报告编号: 2020ZC0449

首页1页 W2页 S1页 Z1页 共5页

样品名称	医用外科口罩		样品编号	SLZC2003107
	送样 (√)	抽样 ( )		
商标	/		规格型号	W-17.5cm×9.5cm
委托方	常州华森医疗器械有限公司		检验类别	注册检验
委托方通讯地址	江苏省武进高新技术产业开发区 西湖路9号, 江苏省武进区南夏墅 街道龙翔路5号		产品编号/批号	S20030002
标示生产单位	常州华森医疗器械有限公司		抽样单编号	/
受检单位	常州华森医疗器械有限公司		生产日期	2020.03.04
抽样单位	/		样品数量	212只
抽样地点	/		抽样基数	/
抽样日期	/		检验地点	本检验所试验室
收样日期	2020年3月16日		检验日期	2020年3月19日-2020年4月17日
检验项目	全项目			
检验依据	常州华森医疗器械有限公司产品技术要求《医用外科口罩》			
检验结论	被检样品符合常州华森医疗器械有限公司产品技术要求《医用外科口罩》规定的要求。 (检验报告专用章或检验单位公章) 签发日期 2020年4月9日			
备注	1) 报告中的“—”表示此项不适用, 报告中“/”表示此项空白。 2) 报告页眉中的“W”表示物理, “S”表示生物, “Z”表示照片。			

批准: 李培俊

职务: 技术负责人

# KN95 (GB 2626-2006) TEST REPORT

KN95 Disposable Protective Face Mask



171021110579



中国认可  
国际互认  
检测  
TESTING  
CNAS L7901

## 检验检测报告

TEST REPORT



STFWT202010449

产品名称  
Product Name  
KN95 防护口罩  
(自吸过滤式防颗粒物呼吸器)

委托单位  
Trust Unit  
常州华森医疗器械有限公司

生产单位  
Manufacturer  
常州华森医疗器械有限公司

检验检测类别  
Test Category  
委托送样检验



## 检验检测报告

Test Report

STFWT202010449

共 4 页 第 1 页  
Page 1 of 4

产品名称 Product Name	KN95 防护口罩(自吸过滤式防颗粒物呼吸器)	规格型号 Specification Type	—
委托单位 Trust Unit	常州华森医疗器械有限公司	商 标 Trademark	—
生产单位 Manufacturer	常州华森医疗器械有限公司	电 话 Tel	13813695879
样品数量 Sample Quantity	40 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	2020-04-21
样品状态 Samples Conditions	符合检测要求	批号/货号 Serial Number	KKDW0001
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。		
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:  
Approver

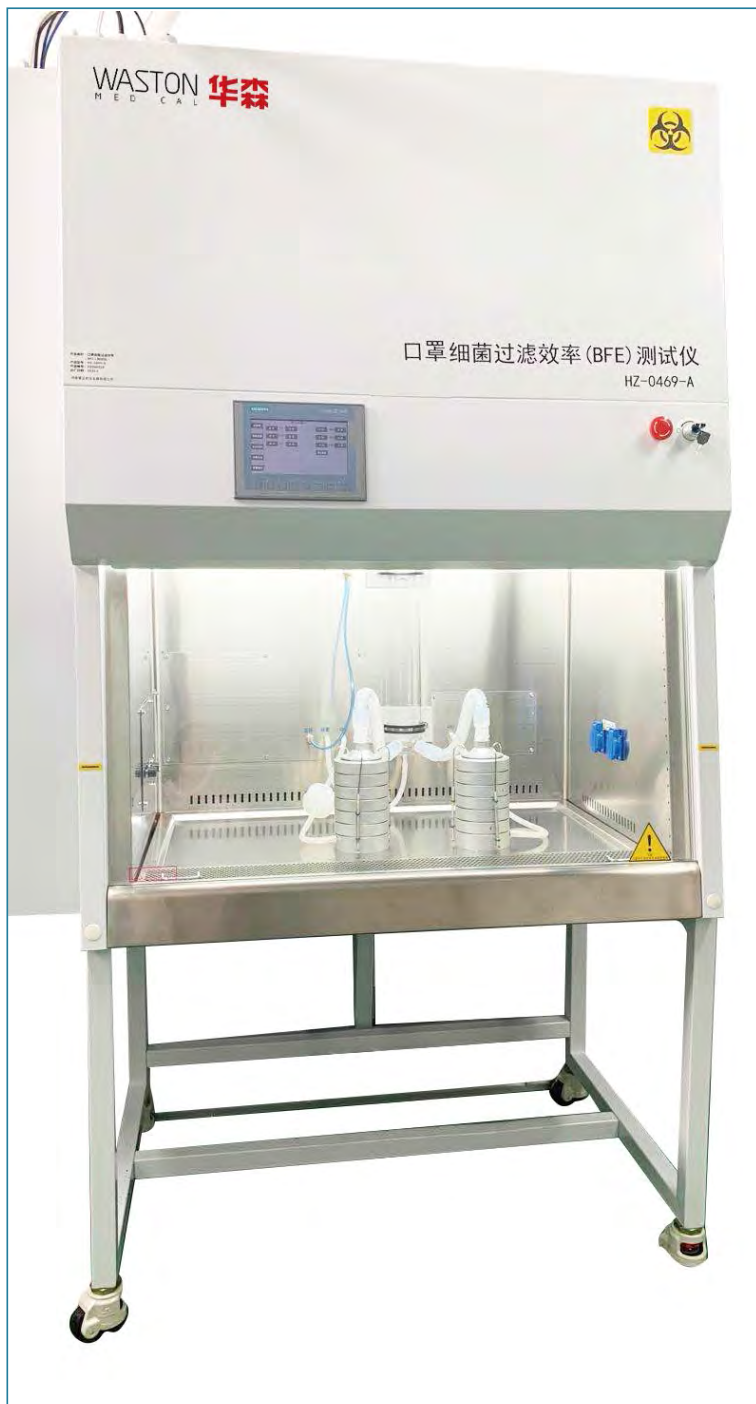
审核:  
Examiner

主 检:  
Major tester

签发日期: 2020-05-09  
Signatum Date



# BFE/PFE TESTING EQUIPMENT



BFE



PFE



# FDA ESTABLISHMENT REGISTRATION & DEVICE LISTING

https://www.accessdata.fda.gov/scripts/cdrh/cdoci/crl/nl.cfm

U.S. Department of Health & Human Services

**FDA U.S. FOOD & DRUG ADMINISTRATION**

Follow FDA | En Español

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

### Establishment Registration & Device Listing

FDA Home Medical Devices Databases

1 result found for Owner Operator Name :  
waston

New Search

Establishment Name	Registration Number	Current Registration Yr
CHANGZHOU WASTON MEDICAL APPLIANCE CO., LTD CHINA	No number listed	2020
* Face Mask (Except N95 Respirator) For General Public/healthcare Personnel Per IIE Guidance - Face Mask		Manufacturer
* Respirator, Surgical - Disposable Protective Face Mask		Manufacturer

Can't find what you're looking for? Try a new search

Page Last Updated: 06/15/2020  
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.  
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | العربية | English

https://www.accessdata.fda.gov/scripts/cdrh/cdoci/crl/nl.cfm?id=684667&pcd=MSH

U.S. Department of Health & Human Services

**FDA U.S. FOOD & DRUG ADMINISTRATION**

Follow FDA | En Español

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

### Establishment Registration & Device Listing

FDA Home Medical Devices Databases

New Search Back To Search Results

Proprietary Name:	Disposable Protective Face Mask
Classification Name:	RESPIRATOR, SURGICAL
Product Code:	MSH
Device Class:	2
Regulation Number:	878.4040
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	CHANGZHOU WASTON MEDICAL APPLIANCE CO., LTD
Owner/Operator:	Changzhou Waston Medical Appliance Co., Ltd
Owner/Operator Number:	10068550
Establishment Operations:	Manufacturer

Page Last Updated: 06/15/2020  
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.  
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | العربية | English

https://www.accessdata.fda.gov/scripts/cdrh/cdoci/crl/nl.cfm?id=665325&pcd=CQR

U.S. Department of Health & Human Services

**FDA U.S. FOOD & DRUG ADMINISTRATION**

Follow FDA | En Español

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

### Establishment Registration & Device Listing

FDA Home Medical Devices Databases

New Search Back To Search Results

Proprietary Name:	Face Mask
Classification Name:	FACE MASK (EXCEPT N95 RESPIRATOR) FOR GENERAL PUBLIC/HEALTHCARE PERSONNEL PER IIE GUIDANCE
Product Code:	QKR
Device Class:	Not Classified
Registered Establishment Name:	CHANGZHOU WASTON MEDICAL APPLIANCE CO., LTD
Owner/Operator:	Changzhou Waston Medical Appliance Co., Ltd
Owner/Operator Number:	10068550
Establishment Operations:	Manufacturer

Page Last Updated: 06/15/2020  
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.  
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | العربية | English

# ASTM F2100 TEST REPORT

intertek

Total Quality Account

Test Report

Number: GZHT02296769

Report Ref:	GZHT02296769
Date Received:	May 28, 2020
Date Issued:	Jun 05, 2020

Company Name:	CHANGZHOU WASTON MEDICAL APPLIANCE CO., LTD.
Address:	NO.5 LONGXIANG ROAD, NANXIASHU SUBDISTRICT, WUJIN NATIONAL HI-TECH INDUSTRIAL ZONE, CHANGZHOU PEOPLE'S REPUBLIC OF CHINA
Contact Name:	

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:	
End Uses	Medical Face Mask
Ratings	Level 1
Sample Name	Disposable Medical Face Mask
Size	-
Colour	Blue&White
Manufacturer	ASTM F2100-19 <sup>11</sup>
Date received/ Test Started	May 28, 2020

Test was conducted on specific items, at our client's request.

Prepared And Checked By:  
For Intertek Testing Services Shenzhen Ltd, Guangzhou Branch

  
Lin Lin  
General Manager

QIN / abbyqzeng

 Page 1 Of 8

Intertek Testing Services, Shenzhen Ltd, Guangzhou Branch  
深圳天祥质量检测有限公司广州分公司

Room 02, 13/F & Room 01, E101ME20ME30ME40ME50ME60ME70ME80ME90ME100ME110ME120ME130ME140ME150ME160ME170ME180ME190ME200ME210ME220ME230ME240ME250ME260ME270ME280ME290ME300ME310ME320ME330ME340ME350ME360ME370ME380ME390ME400ME410ME420ME430ME440ME450ME460ME470ME480ME490ME500ME510ME520ME530ME540ME550ME560ME570ME580ME590ME600ME610ME620ME630ME640ME650ME660ME670ME680ME690ME700ME710ME720ME730ME740ME750ME760ME770ME780ME790ME800ME810ME820ME830ME840ME850ME860ME870ME880ME890ME900ME910ME920ME930ME940ME950ME960ME970ME980ME990ME1000ME1010ME1020ME1030ME1040ME1050ME1060ME1070ME1080ME1090ME1100ME1110ME1120ME1130ME1140ME1150ME1160ME1170ME1180ME1190ME1200ME1210ME1220ME1230ME1240ME1250ME1260ME1270ME1280ME1290ME1300ME1310ME1320ME1330ME1340ME1350ME1360ME1370ME1380ME1390ME1400ME1410ME1420ME1430ME1440ME1450ME1460ME1470ME1480ME1490ME1500ME1510ME1520ME1530ME1540ME1550ME1560ME1570ME1580ME1590ME1600ME1610ME1620ME1630ME1640ME1650ME1660ME1670ME1680ME1690ME1700ME1710ME1720ME1730ME1740ME1750ME1760ME1770ME1780ME1790ME1800ME1810ME1820ME1830ME1840ME1850ME1860ME1870ME1880ME1890ME1900ME1910ME1920ME1930ME1940ME1950ME1960ME1970ME1980ME1990ME2000ME2010ME2020ME2030ME2040ME2050ME2060ME2070ME2080ME2090ME2100ME2110ME2120ME2130ME2140ME2150ME2160ME2170ME2180ME2190ME2200ME2210ME2220ME2230ME2240ME2250ME2260ME2270ME2280ME2290ME2300ME2310ME2320ME2330ME2340ME2350ME2360ME2370ME2380ME2390ME2400ME2410ME2420ME2430ME2440ME2450ME2460ME2470ME2480ME2490ME2500ME2510ME2520ME2530ME2540ME2550ME2560ME2570ME2580ME2590ME2600ME2610ME2620ME2630ME2640ME2650ME2660ME2670ME2680ME2690ME2700ME2710ME2720ME2730ME2740ME2750ME2760ME2770ME2780ME2790ME2800ME2810ME2820ME2830ME2840ME2850ME2860ME2870ME2880ME2890ME2900ME2910ME2920ME2930ME2940ME2950ME2960ME2970ME2980ME2990ME3000ME3010ME3020ME3030ME3040ME3050ME3060ME3070ME3080ME3090ME3100ME3110ME3120ME3130ME3140ME3150ME3160ME3170ME3180ME3190ME3200ME3210ME3220ME3230ME3240ME3250ME3260ME3270ME3280ME3290ME3300ME3310ME3320ME3330ME3340ME3350ME3360ME3370ME3380ME3390ME3400ME3410ME3420ME3430ME3440ME3450ME3460ME3470ME3480ME3490ME3500ME3510ME3520ME3530ME3540ME3550ME3560ME3570ME3580ME3590ME3600ME3610ME3620ME3630ME3640ME3650ME3660ME3670ME3680ME3690ME3700ME3710ME3720ME3730ME3740ME3750ME3760ME3770ME3780ME3790ME3800ME3810ME3820ME3830ME3840ME3850ME3860ME3870ME3880ME3890ME3900ME3910ME3920ME3930ME3940ME3950ME3960ME3970ME3980ME3990ME4000ME4010ME4020ME4030ME4040ME4050ME4060ME4070ME4080ME4090ME4100ME4110ME4120ME4130ME4140ME4150ME4160ME4170ME4180ME4190ME4200ME4210ME4220ME4230ME4240ME4250ME4260ME4270ME4280ME4290ME4300ME4310ME4320ME4330ME4340ME4350ME4360ME4370ME4380ME4390ME4400ME4410ME4420ME4430ME4440ME4450ME4460ME4470ME4480ME4490ME4500ME4510ME4520ME4530ME4540ME4550ME4560ME4570ME4580ME4590ME4600ME4610ME4620ME4630ME4640ME4650ME4660ME4670ME4680ME4690ME4700ME4710ME4720ME4730ME4740ME4750ME4760ME4770ME4780ME4790ME4800ME4810ME4820ME4830ME4840ME4850ME4860ME4870ME4880ME4890ME4900ME4910ME4920ME4930ME4940ME4950ME4960ME4970ME4980ME4990ME5000ME5010ME5020ME5030ME5040ME5050ME5060ME5070ME5080ME5090ME5100ME5110ME5120ME5130ME5140ME5150ME5160ME5170ME5180ME5190ME5200ME5210ME5220ME5230ME5240ME5250ME5260ME5270ME5280ME5290ME5300ME5310ME5320ME5330ME5340ME5350ME5360ME5370ME5380ME5390ME5400ME5410ME5420ME5430ME5440ME5450ME5460ME5470ME5480ME5490ME5500ME5510ME5520ME5530ME5540ME5550ME5560ME5570ME5580ME5590ME5600ME5610ME5620ME5630ME5640ME5650ME5660ME5670ME5680ME5690ME5700ME5710ME5720ME5730ME5740ME5750ME5760ME5770ME5780ME5790ME5800ME5810ME5820ME5830ME5840ME5850ME5860ME5870ME5880ME5890ME5900ME5910ME5920ME5930ME5940ME5950ME5960ME5970ME5980ME5990ME6000ME6010ME6020ME6030ME6040ME6050ME6060ME6070ME6080ME6090ME6100ME6110ME6120ME6130ME6140ME6150ME6160ME6170ME6180ME6190ME6200ME6210ME6220ME6230ME6240ME6250ME6260ME6270ME6280ME6290ME6300ME6310ME6320ME6330ME6340ME6350ME6360ME6370ME6380ME6390ME6400ME6410ME6420ME6430ME6440ME6450ME6460ME6470ME6480ME6490ME6500ME6510ME6520ME6530ME6540ME6550ME6560ME6570ME6580ME6590ME6600ME6610ME6620ME6630ME6640ME6650ME6660ME6670ME6680ME6690ME6700ME6710ME6720ME6730ME6740ME6750ME6760ME6770ME6780ME6790ME6800ME6810ME6820ME6830ME6840ME6850ME6860ME6870ME6880ME6890ME6900ME6910ME6920ME6930ME6940ME6950ME6960ME6970ME6980ME6990ME7000ME7010ME7020ME7030ME7040ME7050ME7060ME7070ME7080ME7090ME7100ME7110ME7120ME7130ME7140ME7150ME7160ME7170ME7180ME7190ME7200ME7210ME7220ME7230ME7240ME7250ME7260ME7270ME7280ME7290ME7300ME7310ME7320ME7330ME7340ME7350ME7360ME7370ME7380ME7390ME7400ME7410ME7420ME7430ME7440ME7450ME7460ME7470ME7480ME7490ME7500ME7510ME7520ME7530ME7540ME7550ME7560ME7570ME7580ME7590ME7600ME7610ME7620ME7630ME7640ME7650ME7660ME7670ME7680ME7690ME7700ME7710ME7720ME7730ME7740ME7750ME7760ME7770ME7780ME7790ME7800ME7810ME7820ME7830ME7840ME7850ME7860ME7870ME7880ME7890ME7900ME7910ME7920ME7930ME7940ME7950ME7960ME7970ME7980ME7990ME8000ME8010ME8020ME8030ME8040ME8050ME8060ME8070ME8080ME8090ME8100ME8110ME8120ME8130ME8140ME8150ME8160ME8170ME8180ME8190ME8200ME8210ME8220ME8230ME8240ME8250ME8260ME8270ME8280ME8290ME8300ME8310ME8320ME8330ME8340ME8350ME8360ME8370ME8380ME8390ME8400ME8410ME8420ME8430ME8440ME8450ME8460ME8470ME8480ME8490ME8500ME8510ME8520ME8530ME8540ME8550ME8560ME8570ME8580ME8590ME8600ME8610ME8620ME8630ME8640ME8650ME8660ME8670ME8680ME8690ME8700ME8710ME8720ME8730ME8740ME8750ME8760ME8770ME8780ME8790ME8800ME8810ME8820ME8830ME8840ME8850ME8860ME8870ME8880ME8890ME8900ME8910ME8920ME8930ME8940ME8950ME8960ME8970ME8980ME8990ME9000ME9010ME9020ME9030ME9040ME9050ME9060ME9070ME9080ME9090ME9100ME9110ME9120ME9130ME9140ME9150ME9160ME9170ME9180ME9190ME9200ME9210ME9220ME9230ME9240ME9250ME9260ME9270ME9280ME9290ME9300ME9310ME9320ME9330ME9340ME9350ME9360ME9370ME9380ME9390ME9400ME9410ME9420ME9430ME9440ME9450ME9460ME9470ME9480ME9490ME9500ME9510ME9520ME9530ME9540ME9550ME9560ME9570ME9580ME9590ME9600ME9610ME9620ME9630ME9640ME9650ME9660ME9670ME9680ME9690ME9700ME9710ME9720ME9730ME9740ME9750ME9760ME9770ME9780ME9790ME9800ME9810ME9820ME9830ME9840ME9850ME9860ME9870ME9880ME9890ME9900ME9910ME9920ME9930ME9940ME9950ME9960ME9970ME9980ME9990ME10000ME10010ME10020ME10030ME10040ME10050ME10060ME10070ME10080ME10090ME10100ME10110ME10120ME10130ME10140ME10150ME10160ME10170ME10180ME10190ME10200ME10210ME10220ME10230ME10240ME10250ME10260ME10270ME10280ME10290ME10300ME10310ME10320ME10330ME10340ME10350ME10360ME10370ME10380ME10390ME10400ME10410ME10420ME10430ME10440ME10450ME10460ME10470ME10480ME10490ME10500ME10510ME10520ME10530ME10540ME10550ME10560ME10570ME10580ME10590ME10600ME10610ME10620ME10630ME10640ME10650ME10660ME10670ME10680ME10690ME10700ME10710ME10720ME10730ME10740ME10750ME10760ME10770ME10780ME10790ME10800ME10810ME10820ME10830ME10840ME10850ME10860ME10870ME10880ME10890ME10900ME10910ME10920ME10930ME10940ME10950ME10960ME10970ME10980ME10990ME11000ME11010ME11020ME11030ME11040ME11050ME11060ME11070ME11080ME11090ME11100ME11110ME11120ME11130ME11140ME11150ME11160ME11170ME11180ME11190ME11200ME11210ME11220ME11230ME11240ME11250ME11260ME11270ME11280ME11290ME11300ME11310ME11320ME11330ME11340ME11350ME11360ME11370ME11380ME11390ME11400ME11410ME11420ME11430ME11440ME11450ME11460ME11470ME11480ME11490ME11500ME11510ME11520ME11530ME11540ME11550ME11560ME11570ME11580ME11590ME11600ME11610ME11620ME11630ME11640ME11650ME11660ME11670ME11680ME11690ME11700ME11710ME11720ME11730ME11740ME11750ME11760ME11770ME11780ME11790ME11800ME11810ME11820ME11830ME11840ME11850ME11860ME11870ME11880ME11890ME11900ME11910ME11920ME11930ME11940ME11950ME11960ME11970ME11980ME11990ME12000ME12010ME12020ME12030ME12040ME12050ME12060ME12070ME12080ME12090ME12100ME12110ME12120ME12130ME12140ME12150ME12160ME12170ME12180ME12190ME12200ME12210ME12220ME12230ME12240ME12250ME12260ME12270ME12280ME12290ME12300ME12310ME12320ME12330ME12340ME12350ME12360ME12370ME12380ME12390ME12400ME12410ME12420ME12430ME12440ME12450ME12460ME12470ME12480ME12490ME12500ME12510ME12520ME12530ME12540ME12550ME12560ME12570ME12580ME12590ME12600ME12610ME12620ME12630ME12640ME12650ME12660ME12670ME12680ME12690ME12700ME12710ME12720ME12730ME12740ME12750ME12760ME12770ME12780ME12790ME12800ME12810ME12820ME12830ME12840ME12850ME12860ME12870ME12880ME12890ME12900ME12910ME12920ME12930ME12940ME12950ME12960ME12970ME12980ME12990ME13000ME13010ME13020ME13030ME13040ME13050ME13060ME13070ME13080ME13090ME13100ME13110ME13120ME13130ME13140ME13150ME13160ME13170ME13180ME13190ME13200ME13210ME13220ME13230ME13240ME13250ME13260ME13270ME13280ME13290ME13300ME13310ME13320ME13330ME13340ME13350ME13360ME13370ME13380ME13390ME13400ME13410ME13420ME13430ME13440ME13450ME13460ME13470ME13480ME13490ME13500ME13510ME13520ME13530ME13540ME13550ME13560ME13570ME13580ME13590ME13600ME13610ME13620ME13630ME13640ME13650ME13660ME13670ME13680ME13690ME13700ME13710ME13720ME13730ME13740ME13750ME13760ME13770ME13780ME13790ME13800ME13810ME13820ME13830ME13840ME13850ME13860ME13870ME13880ME13890ME13900ME13910ME13920ME13930ME13940ME13950ME13960ME13970ME13980ME13990ME14000ME14010ME14020ME14030ME14040ME14050ME14060ME14070ME14080ME14090ME14100ME14110ME14120ME14130ME14140ME14150ME14160ME14170ME14180ME14190ME14200ME14210ME14220ME14230ME14240ME14250ME14260ME14270ME14280ME14290ME14300ME14310ME14320ME14330ME14340ME14350ME14360ME14370ME14380ME14390ME14400ME14410ME14420ME14430ME14440ME14450ME14460ME14470ME14480ME14490ME14500ME14510ME14520ME14530ME14540ME14550ME14560ME14570ME14580ME14590ME14600ME14610ME14620ME14630ME14640ME14650ME14660ME14670ME14680ME14690ME14700ME14710ME14720ME14730ME14740ME14750ME14760ME14770ME14780ME14790ME14800ME14810ME14820ME14830ME14840ME14850ME14860ME14870ME14880ME14890ME14900ME14910ME14920ME14930ME14940ME14950ME14960ME14970ME14980ME14990ME15000ME15010ME15020ME15030ME15040ME15050ME15060ME15070ME15080ME15090ME15100ME15110ME15120ME15130ME15140ME15150ME15160ME15170ME15180ME15190ME15200ME15210ME15220ME15230ME15240ME15250ME15260ME15270ME15280ME15290ME15300ME15310ME15320ME15330ME15340ME15350ME15360ME15370ME15380ME15390ME15400ME15410ME15420ME15430ME15440ME15450ME15460ME15470ME15480ME15490ME15500ME15510ME15520ME15530ME15540ME15550ME15560ME15570ME15580ME15590ME15600ME15610ME15620ME15630ME15640ME15650ME15660ME15670ME15680ME15690ME15700ME15710ME15720ME15730ME15740ME15750ME15760ME15770ME15780ME15790ME15800ME15810ME15820ME15830ME15840ME15850ME15860ME15870ME15880ME15890ME15900ME15910ME15920ME15930ME15940ME15950ME15960ME15970ME15980ME15990ME16000ME16010ME16020ME16030ME16040ME16050ME16060ME16070ME16080ME16090ME16100ME16110ME16120ME16130ME16140ME16150ME16160ME16170ME16180ME16190ME16200ME16210ME16220ME16230ME16240ME16250ME16260ME16270ME16280ME16290ME16300ME16310ME16320ME16330ME16340ME16350ME16360ME16370ME16380ME16390ME16400ME16410ME16420ME16430ME16440ME16450ME16460ME16470ME16480ME16490ME16500ME16510ME16520ME16530ME16540ME16550ME16560ME16570ME16580ME16590ME16600ME16610ME16620ME16630ME16640ME16650ME16660ME16670ME16680ME16690ME16700ME16710ME16720ME16730ME16740ME16750ME16760ME16770ME16780ME16790ME16800ME16810ME16820ME16830ME16840ME16850ME16860ME16870ME16880ME16890ME16900ME16910ME16920ME16930ME16940ME16950ME16960ME16970ME16980ME16990ME17000ME17010ME17020ME17030ME17040ME17050ME17060ME17070ME17080ME17090ME17100ME17110ME17120ME17130ME17140ME17150ME17160ME17170ME17180ME17190ME17200ME17210ME17220ME17230ME17240ME17250ME17260ME17270ME17280ME17290ME17300ME17310ME17320ME17330ME17340ME17350ME17360ME17370ME17380ME17390ME17400ME17410ME17420ME17430ME17440ME17450ME17460ME17470ME17480ME17490ME17500ME17510ME17520ME17530ME17540ME17550ME17560ME17570ME17580ME17590ME17600ME17610ME17620ME17630ME17640ME17650ME17660ME17670ME17680ME17690ME17700ME17710ME17720ME17730ME17740ME17750ME17760ME17770ME17780ME17790ME17800ME17810ME17820ME17830ME17840ME17850ME17860ME17870ME17880ME17890ME17900ME17910ME17920ME17930ME17940ME17950ME17960ME17970ME17980ME17990ME18000ME18010ME18020ME18030ME18040ME18050ME18060ME18070ME18080ME18090ME18100ME18110ME18120ME18130ME18140ME18150ME18160ME18170ME18180ME18190ME18200ME18210ME18220ME18230ME18240ME18250ME18260ME18270ME18280ME18290ME18300ME18310ME18320ME18330ME18340ME18350ME18360ME18370ME18380ME18390ME18400ME18410ME18420ME18430ME18440ME18450ME18460ME18470ME18480ME18490ME18500ME18510ME18520ME18530ME18540ME18550ME18560ME18570ME18580ME18590ME18600ME18610ME18620ME18630ME18640ME18650ME18660ME18670ME18680ME18690ME18700ME18710ME18720ME18730ME18740ME18750ME18760ME18770ME18780ME18790ME18800ME18810ME18820ME18830ME18840ME18850ME18860ME18870ME18880ME18890ME18900ME18910ME18920ME18930ME18940ME18950ME18960ME18970ME18980ME18990ME19000ME19010ME19020ME19030ME19040ME19050ME19060ME19070ME19080ME19090ME19100ME19110ME19120ME19130ME19140ME19150ME19160ME19170ME19180ME19190ME19200ME19210ME19220ME19230ME19240ME19250ME19260ME19270ME19280ME19290ME19300ME19310ME19320ME19330ME19340ME19350ME19360ME19370ME19380ME19390ME19400ME19410ME19420ME19430ME19440ME19450ME19460ME19470ME19480ME19490ME19500ME19510ME19520ME19530ME19540ME19550ME19560ME19570ME19580ME19590ME19600ME19610ME19620ME19630ME19640ME19650ME19660ME19670ME19680ME19690ME19700ME19710ME19720ME19730ME19740ME19750ME19760ME19770ME19780ME19790ME19800ME19810ME19820ME19830ME19840ME19850ME19860ME19870ME19880ME19890ME19900ME19910ME19920ME19930ME19940ME19950ME19960ME19970ME19980ME19990ME20000

intertek

Total Quality Account

Test Report

Number: GZHT02296794

Report Ref:	GZHT02296794
Date Received:	May 28, 2020
Date Issued:	Jun 05, 2020

Company Name:	CHANGZHOU WASTON MEDICAL APPLIANCE CO., LTD
Address:	NO.5 LONGXIANG ROAD, NANXIASHU SUBDISTRICT, WUJIN NATIONAL HI-TECH INDUSTRIAL ZONE, CHANGZHOU PEOPLE'S REPUBLIC OF CHINA
Contact Name:	

The Following Sample Was Submitted And Identified By/On
---

# CE DECLARATION OF CONFORMITY

## Declaration of Conformity

Manufacturer:	<b>Changzhou Waston Medical Appliance Co., Ltd</b> No.5 Longxiang Road, Nanxiashu Subdistrict, Wujin National Hi-Tech Industrial Zone, 213164 Changzhou, PEOPLE'S REPUBLIC OF CHINA
European Representative:	<b>ZOUSTECH S.L.</b> Pso. Castellana,141-Planta 19, 28046-Madrid, SPAIN
Product Name	Disposable Medical Face Mask
Model Number:	G-175mm×95mm, G-145mm×95mm, W-17.5cm×9.5cm, W-14.5cm×9.5cm
UMDNS-Code:	12447

Classification (MDD, Annex IX): Class I Rule 1

Conformity Assessment Route: **Annex VII**

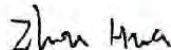
We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

Manufacturer takes full responsibility of the content of Declaration of Conformity.

### DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC modified with the Directive 2007/47

Signature: 

Name: Zhou Hua

Place& Date: Changzhou, 2020-05-04

Position: Management Representative



# CE PRODUCT NOTIFICATIONS

# ZOUSTECH

[www.zoustech.eu](http://www.zoustech.eu)

Zoustech, your trusted partner

Representing you in EU!

## CONFIRMATION OF PRODUCT NOTIFICATION

This is to confirm that Zoustech S.L., has registered under the AEMPS (Spanish Agency for Medicines and Medical Devices), the following medical devices:

Number in the contract	Product name in English	Product name in Spanish
1	Disposable Medical Face Mask	Mascarilla facial de protección médica

**Manufacturer:** CHANGZHOU WASTON MEDICAL APPLIANCE CO., LTD

**Address:** No.5 Longxiang Road, Nanxiashu Subdistrict, Wujin National HiTech Industrial Zone, 213164 Changzhou, P.R. China

**Registered under number:** RPS/825/2020 (See attached the electronic notification)

The Manufacturer has declared that these devices comply with the regulation including all the general safety and performance requirements.

Zoustech has complied with its commitment of registering the above mentioned devices under the AEMPS and will not have any other further obligation, compromise or responsibility.

14 May, 2020

  
Zoustech S.L.  
Pto. Castellana, 141 - Pl. 19  
28049 Madrid - Spain  
CIF: B87637591

Mr. Rubén Valle Ibaseta  
On behalf of  
ZOUSTECH SL

ZOUSTECH S.L.  
Pto. Castellana, 141 - Planta 19  
28049 Madrid - Spain  
CIF: B87637591

INSCRITA EN EL REGISTRO MERCANTIL DE MADRID, TOMO 35086, FOLIO 147, HOJA M-630984, INSCRIPCIÓN 1



# AEMPS REGISTRATION

Envíos Telemáticos

Page 1 of 1



Registro de  
Responsables de  
Productos Sanitarios



Usuario: RUBÉN VALLE IBASETA

Desconectar

Registro de Responsables de Productos Sanitarios - RPS/825/2020

Datos de la notificación

## Datos de registro

Nº Registro: RPS/825/2020 Fecha Registro: 14/05/2020

## Datos del Responsable

Tipo de Responsable (\*): Rep. Autorizado Tipo de entidad: Empresa  
CIF (\*): B87637591 Nombre (\*): ZOUSTECH S.L.  
Dirección (\*): Paseo de la castellana 141 Planta 19  
Localidad (\*): Madrid  
Provincia (\*): Madrid CP (\*): 28046  
Teléfono (\*): 694 426 446 Fax:  
e-mail (\*): legal@zoustech.eu Web:

## Datos del Fabricante

Nombre o Razón Social (\*): Changzhou Waston Medical Appliances Co., Ltd.  
Dirección (\*): No.5 Longxiang Road, Nanxiashu Subdistrict, Wujin National Hi-Tech Industrial Z.  
Localidad (\*): Changzhou  
País (\*): República Popular China CP: 213164  
Teléfono (\*): Fax:  
e-mail (\*): Web:

## Datos de Productos Comunicados

Estatus (\*): Primera Comunicación

## Relación de Productos

### Listado de Productos Sanitarios

Se encontro una fila.

Listado de Productos Sanitarios			
Nombre Comercial	Tipo de Producto	Estado del producto	Acción
MASCARILLA FACIAL DE PROTECCIÓN MÉDICA	Clase I	Primera Comunicación	

Comentarios

Enviar Solicitud



Agencia Española de Medicamentos y Productos Sanitarios

Parque Empresarial "Las Mercedes", Edif. 8, C/ Campezo 1 - 28022 MADRID | e-Mail: [incidencias\\_aplicaciones@aemps.es](mailto:incidencias_aplicaciones@aemps.es)



# EN 14683 TEST REPORT

SGS



中国认可  
国际互认  
检测  
TESTING  
CNAS L0599

**Test Report**

**SL52025258782301TX**

**Date: June 17, 2020**

**Page 1 of 3**

CHANGZHOU WASTON MEDICAL APPLIANCE CO., LTD.  
NO.5 LONGXIANG ROAD, NANXIASHU SUBDISTRICT, WUJIN NATIONAL HI-TECH INDUSTRIAL  
ZONE, 213164 CHANGZHOU, PEOPLE'S REPUBLIC OF CHINA

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	: (A) Disposable Medical Face Mask
Style No.	: G-175mm X 95mm
Composition	: (A) Non-woven fabric, Meltblown fabric
Sample Color	: (A) Blue
Manufacturer	: CHANGZHOU WASTON MEDICAL APPLIANCE CO., LTD.
Supplier	: CHANGZHOU WASTON MEDICAL APPLIANCE CO., LTD.
Sample Receiving Date	: May 27, 2020
Testing Period	: May 27, 2020 - Jun 17, 2020
Test Result(s)	: Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).
Test Performed	: Selected test(s) as requested by applicant

Signed for and on behalf of  
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

*Sara Guo*

*Dongjing Liu* *Hailian Xuan*

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)



Unless otherwise agreed in writing, this document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com/en/terms-and-conditions.aspx> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com/en/terms-and-conditions/terms-e-document.aspx>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of Client's instructions, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested and such sample(s) are retained for 30 days only.

Attention: To check the authenticity of testing/inspection report & Certificate, please contact us at telephone: (86-755) 8307 1443, or email: [CN.Decoded@sgs.com](mailto:CN.Decoded@sgs.com)  
3<sup>rd</sup> Building No.889, Yishan Road, Xuhui District Shanghai, China 200233 1 (86-21) 61402666 1 (86-21) 64958763 [www.sgsgroup.com.cn](http://www.sgsgroup.com.cn)  
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 1 (86-21) 61402666 1 (86-21) 64958763 [sgs.china@sgs.com](mailto:sgs.china@sgs.com)

Member of the SGS Group (SGS SA)

# THERAPEUTIC GOODS ADMINISTRATION (AUSTRALIA TGA) CERTIFICATE



Australian Government  
Department of Health  
Therapeutic Goods Administration

## Australian Register of Therapeutic Goods Certificate

Issued to

**Beyond Bio Pty Ltd**

for approval to supply

**Beyond Bio Pty Ltd - Mask, surgical, single use**

<b>ARTG Identifier</b>	335920
<b>ARTG Start Date</b>	6/05/2020
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	35177
<b>GMDN Term</b>	Mask, surgical, single use
<b>Intended Purpose</b>	A disposable device made from fabric or other material placed over the nose and mouth by medical personnel to prevent the transmission of airborne organisms while surgery is being performed.

Manufacturer Details	Address	Certificate number(s)
Changzhou Waston Medical Appliance Co Ltd	No 5 Longxiang Road Nanxiashu Subdistrict Wujin National Hi-Tech Industrial Zone , Changzhou , 2 13164 China	

### ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### Products Covered by This Entry

#### 1. Mask, surgical, single use

### Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration  
PO Box 100, Woden ACT 2606 Australia  
Phone: 1800 020 653  
Email: [info@tga.gov.au](mailto:info@tga.gov.au)

ARTG Identifier: 335920  
ARTG Start Date: 6/05/2020

# THERAPEUTIC GOODS ADMINISTRATION (AUSTRALIA TGA) CERTIFICATE

注册证书链接 [http://tga-search.clients.funnelback.com/s/search.html?collection=tga-artg&profile=record&meta\\_i=335920](http://tga-search.clients.funnelback.com/s/search.html?collection=tga-artg&profile=record&meta_i=335920)

The screenshot shows the Australian Government Department of Health Therapeutic Goods Administration website. The header includes the Australian Government logo and a search bar labeled 'Search TGA'. The navigation menu includes 'Home', 'Safety information', 'Consumers', 'Health professionals', 'Industry', 'About the TGA', and 'News room'. The main content area is titled 'ARTG search' and provides information about the Australian Register of Therapeutic Goods (ARTG). It states that search results include Consumer Medicines Information (CMI), Product Information (PI), and Public Summary documents. A search bar labeled 'Search the ARTG' is present, along with links for 'Advanced search +' and 'Help'. Below the search bar, the results for ARTG ID 335920 are displayed in a table.

Product name	Mask, surgical, single use
Active ingredients	
Sponsor name	Beyond Bio Pty Ltd
ARTG entry for	Medical Device Included Class 1
Public ARTG summary	<a href="#">ARTG ID 335920 - public ARTG summary (pdf)</a>

# THERAPEUTIC GOODS ADMINISTRATION (AUSTRALIA TGA) CERTIFICATE



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 335920 Beyond Bio Pty Ltd - Mask, surgical, single use

**ARTG entry for** Medical Device Included Class 1

**Sponsor** Beyond Bio Pty Ltd

**Postal Address** 18 Fairlight Avenue, East Killara, NSW, 2071  
Australia

**ARTG Start Date** 6/05/2020

**Product Category** Medical Device Class 1

**Status** Active

**Approval Area** Medical Devices

### Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.  
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

### Manufacturers

Name	Address
Changzhou Waston Medical Appliance Co Ltd	No 5 Longxiang Road Nanxiashu Subdistrict Wujin National Hi-Tech Industrial Zone, Changzhou, 213164 China

### Products

#### 1. Mask, surgical, single use

Product Type	Single Device Product	Effective Date	6/05/2020
--------------	-----------------------	----------------	-----------

**GMDN** 35177 Mask, surgical, single use

**Intended Purpose** A disposable device made from fabric or other material placed over the nose and mouth by medical personnel to prevent the transmission of airborne organisms while surgery is being performed.

### Specific Conditions

No Specific Conditions included on Record

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary



# PRODUCTION ENVIRONMENT





# More Professional More Effective

Your Reliable Waston

**WASTON**  
M E D I C A L

Changzhou Waston Medical Appliance Co.,Ltd  
No.5 Longxiang Road, Nanxiashu Subdistrict, Wujin National Hi-Tech  
Industrial Zone, 213164 Changzhou, PEOPLE'S REPUBLIC OF CHINA  
TEL:(+86)13861235399 / (+86)18106119688 / (+86)15051967169  
Email:info@wastonmed.com  
www.waston-global.com

