



**伏羲生物科技(广东)有限公司**  
**CareAble Biotechnology Co., Ltd**



天空之吻™

Care Able™

伏羲生物

Make good mask with sincere heart

用心做好口罩





## 品牌故事

### STORY OF THE BRAND

---- People long to breathe freely!

---- People want to care and be cared for, and we care what people care!

#### The call of life--

Nothing is more precious than the desire that comes from everyone's heart. People pursue a healthy and natural quality of life, so that life is endowed with extraordinary significance. However, changes in the world environment often caught us by surprise.

CareAble, in order to better protect human life and health, we choose to actively explore, hard research, adhere to the quality, produce high-quality protective masks. Protect human health, keep people away from viruses, and create a healthy quality of life for humans.





# 经营理念

## Business Philosophy



**专业铸就品质，专注成就未来！  
用心做好口罩！**

**The specialty casts quality,  
the concentration achieve future  
success!  
Make Masks with Heart!**



# 创始人及发展历程

## The Founder and Company History

### James Jing

----the founder of CAREABLE,  
is a young entrepreneur born in the 1970s, has been committed to  
the development and production of human health products since 2005.  
He's always on the way to innovation.

2020

To fight against COVID-19, James promptly  
respond to the world's demand for masks, and  
develop CE standard protective masks in the  
shortest time, get CE certificate from Universal  
Certificate and BSI in May.

2014

In 2014, James started to work with his team on the  
development of a kind of window mesh to protect  
people against PM2.5.

2005

Since 2005, James has been working on the development  
of long-lasting insecticidal nets to stop the spread of  
malaria in Africa. His PandaNet2.0 has got WHO's (World  
Health Organization) recommendation in 2012.

# James Jing

---the founder

创造  
Create

拼搏  
Fighting

# 公司简介

## Company Profile

**Careable Biotechnology Co., Ltd**, a professional manufacturer specialized in developing, design, manufacturing and sales of particulate respirators, is located in Jiangmen city, Guangdong Province, covering an area of 20,000 square meters. With more than 600 workers, and more than 100 advanced production lines, its mask production capability reached 6 million pieces daily. Its PPE products have been exported to Europe, North and South America, Middle East, South Africa and Southeast Asia, gained good reputation from overseas clients. Careable pursues excellent quality, never stop renovation. "Make good masks with sincere heart" is Careable's slogan.



We are proud of our experienced and strong R&D team. our FFP2 particulate respirator CARE002 has got CE certificate from NB2163 (Universal Certificate); and CARE003 has got CE certificate from NB2797 (BSI); Our KN95 filtering respirator has passed China GB2626 -2019 testing. On the basis of continuous improvement of different standards, we will keep focusing on research and development of high filtration efficiency and low Breathing resistance products. We are together with People all over the world, fighting against COVID-19.





# 我们的团队

## OUR TEAM



**生产部**  
Production Dept  
Staff: 540

**研发部**  
R&D Dept  
Staff: 12

**品质部**  
QC Dept  
Staff: 20

**物控部**  
PMC  
Staff: 6

**人事行政**  
Administration Dept  
Staff: 5

**销售部**  
Sales Dept  
Staff: 10

**财务部**  
Financial Dept  
Staff: 4






## 主要生产设备及产能

## Main Production Equipment and Capacity

- **Production Area:**  
20,000 square meters
- **Workers: 600**
- **Production lines: 70**
- **Daily Capacity:**  
6,000,000pcs



Main Production Equipment	Pictures	Qty	Capacity Per Machine /pcs	Subtotal Capacity /pcs
High Speed Mask Machine		4	700,000	2,800,000
Fully-automatic Mask Machine		50	40,000	2,000,000
Half-automatic Mask Machine		16	75,000	1,200,000
Total Daily Capacity /pcs				6,000,000



# 生产车间展示 WORK SHOP

CAREABLE  
伏羲生物



# 产品展示

## OUR PRODUCT

CAREABLE  
伏羲生物

01

CARE002 ▶

FFP2 CE2163  
UNIVERSAL CERTIFICATE  
EN149:2001+A1:2009

02

CARE003 ▶

FFP2 CE2797  
BSI  
EN149:2001+A1:2009

03

CARE006 ▶

KN95  
GB2626-2019



## Individual Packaging

For better storage of the product, we use food-grade aluminum film coated bag for every mask.

Advantages:

1. Well protect the mask from bacteria, germs and insects;
2. Anti-corrosion, moisture-proof, water-proof
3. No deformation at high or low temperature
4. Good anti-static performance





# 产品包装 PACKAGING

CAREABLE  
伏羲生物

## CARE002 FFP2



## CARE003 FFP2




## CARE006 KN95



# 产品包装 PACKAGING

CAREABLE  
伏羲生物

No.	Ref. Pic	Packaging Style	Case Pack (pcs)	Carton Size (cm)			G.W./CTN (kg)	CBM/CTN
				L	W	H		
#1		5pcs per bag; 200bags per carton	1000	70	40	40	9.5	0.112
#2		1pc per bag; 20pcs per box; 50boxes per carton	1000	52	38	65	13	0.128

# 出货情况 SHIPMENT

CAREABLE  
伏羲生物



30million pcs  
To Italy

10million pcs  
To Germany

10million pcs  
To USA

5million pcs  
To South America





### Choose Qualified Material Supplier

1. Use qualified supplier only;
2. Audit the supplier factory before cooperation;
3. Test the material before use it;
4. Ensure stable supply of qualified material.



### Incoming Quality Control (IQC)

1. Test every roll of melt-blown fabric before get into warehouse, and every roll has a unique identification label;
2. Earloop cord must be stretched to three times its length.
3. Nose clip has to be folded up to 50 times and no broken.



### Production Process Quality Control

1. IPQC checking on each production line.
2. Randomly pick samples from each production line for testing of filtering efficiency, breathing resistance and pulling test for earloop.



### Final Quality Control

1. 100% Appearance inspection for all masks before packing.
2. Sample drawing for testing from each batch.

## Inspection Instructions

## Inspect instruction

ITEM No.	CARE002 CARE003	Product	Filtering Half Mask Particulate Respirator			File No.	FXQC-20005
Admit	Mike He	R&D Dept.	Xiao Tian	QA Dept.	Tian Ping	Date:	2020/5/6

## INSPECT ITEM &amp; STANDARD:

ITEM	Specification & introduction		Inspect method/facility	Inspect standard	
				AQL	LEVEL
Mask body	Appearance	1.Cleaning: Inspect at a distance of 50 cm within 3 seconds , not found any dirty spot, foreign particles, dust and hair.	Visual	0.65	N- II
		2.Flat, no worn, no fold, no unfilled corner, and feel soft	Visual	0.4	N- II
		3.Noseclip is totally integrated into the mask blank, and no any exposed, no sharp corner	Visual	0.4	N- II
		4. Ear loop is welded according the art work.	Visual	0 : OK 1:reject	5pieces/lot
	Printing	The printing is clear and correct, no ghosting ,no missing.	Visual	0.65	N- II
Ear Loop	Size	Overall size of mask : 155*105mm±5mm Nose bridge: 9±5mm	Ruler	0 : OK 1:reject	5pieces/lot
	Appearance	The place of welding should be symmetry, and the inaccuracy should be little than 1mm. No worn, nocolor differenceand no dust.	visual/ruler	0.4	N- II
	Length	Length: Left and right loop:(weld spot exclude) 19cm ± 5mm	Ruler	0 : OK 1:reject	5pieces/lot
	Welding tension	Single spot's tension:10N and keep 10s. Double spots' tension:20N and keep 10s.	Fixed value weight	0 : OK 1:reject	10pieces/lot
Product Function	Fabrics grams per square metre	Outer non-woven: 50gsm ±5% Melt-blown fabric: 25gsm ±5% Hot air filter cotton: 45gsm ±5% Inner non-woven : 25gsm ±5%	Electronic scale	0 : OK 1:reject	8pieces/lot
	Hydrophilism	Water repellent(Outside ply) Hydrophilism(Inner ply)	Drop water	0 : OK 1:reject	5pieces/lot
	Respiratory resistance	1. Flow rate: 30 L/min inhale:≤70Pa	DMS-GL37	0 : OK 1:reject	9pieces/lot
		1. Flow rate: 95 L/min inhale:≤240Pa			
		2. Flow rate: 160 L/min exhale:≤300Pa	DMS-GL37	0 : OK	12pieces/lot

## Inspect instruction

	Penetrate efficiency	≤6%	DMS-GL36	0 : OK 1:reject	9pieces/lot
	Filter efficiency	≥94%	DMS-GL36	0 : OK 1:reject	5pieces/lot
	Flame retardancy	Resistance time ≤5s	Flame spread tester	0 : OK 1:reject	4pieces/lot

Packing	1piece/bag,20bags/box,50boxes/carton Packing is complete, products/quantity is correct. Boxes and cartons are no damaged&dirty, and packing according to the order .	Visual	2.5	N- II
Packing material	Specification : blank disinfection bag Inner box :18.5*11*12.5cm±2mm carton : 5ply 57*39*64.5cm±1cm	Ruler	0 : OK 1:reject	5pieces/lot
	Printing&size should according to the artwork, the lot number should meet the request of order.	Visual	0.4	N- II
	1. Box is qualified(no dirty &worn&deformation&unstuck&mosquito) 2. No empty bag or box ,and all have stamped.	Visual	0.65	N- II

## Attention: The item not specified is the same with sample.

Change history

Date	Change information	Customer complaint	Mender

Explain: hand's feel and visual should be implement by veteran to guarantee product quality



# 检测设备

## Testing Equipment



主控制				
粒径	过滤效率%	当前压差 Pa	当前流量 L/min	
≥0.3um	99.95	141.33	95.99	
≥0.5um	99.521	设置时间 s	测量计时 s	
≥0.7um	99.703	60	0	
≥1.0um	99.849	气溶胶浓度 mg/m³		
≥2.0um	99.293	11.402		
≥5.0um	100.0			
<div>           气缸开           循环风开           测量启动           测量停止         </div>				

1. Filter efficiency detector
2. Aging Oven
3. Breathing resistance tester
4. Tension Meter







统一社会信用代码  
91440700MA54BFN314

营业执照



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。

(副 本) (副本号:1-1)

名 称	伏羲生物科技(广东)有限公司	注 册 资 本	人民币伍佰万元
类 型	有限责任公司(自然人投资或控股)	成 立 日 期	2020年02月20日
法 定 代 表 人	谢英	营 业 期 限	长期
经 营 范 围	生物技术研发及推广;研发、生产、销售:医护产品,防护用品,劳保用品,医疗器械,环保产品,消毒用品(不含危险化学品),知识产权服务,版权代理服务,货物或技术进出口(国家禁止或涉及行政审批的货物和技术进出口除外)。(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	江门市宏兴路3号0幢(自编002)(信息申报制)	

登 记 机 关



2020 年 3 月 25 日



中国医药保健品进出口商会认可非医用口罩白名单企业  
CCCMHPIE Published Non-Medical Use Face Masks Whist List Company



CHINA CHAMBER OF COMMERCE FOR  
IMPORT & EXPORT OF MEDICINES & HEALTH PRODUCTS

Chinese Version

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Major Policies

Analysis

Name List of Non-Medical Use Face Masks Companies with  
Certification/Authorization from other Countries

Friday, 12 June 2020 | Source : CHINA CHAMBER OF COMMERCEFOR IMPORT&EXPORT OF MEDICINES &HEALTH PRODUCTS | Author :

取得国外标准认证或注册的非医用口罩生产企业清单			
Name List of Non-Medical Use Face Masks Companies with Certification/Authorization from other Countries			
Updated : 12 June, 2020			
Download			
序号 No.	生产企业 Company	统一社会信用代码 Uniform Social Credit Code	国外注册认证情况 Status of Certification / Authorization in Other Countires
151	伏羲生物科技（广东）有限公司 Careable Biotechnology Co.,Ltd.	91440700MA54BFN314	CE



**对外贸易经营者备案登记表**

备案登记表编号: 03618875      统一社会信用代码: 91440700MA54BFN314  
进出口企业代码: \_\_\_\_\_

经营者中文名称	伏羲生物科技(广东)有限公司		
经营者英文名称	Careable Biotechnology 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	江门市宏兴路3号0 幢(自编002)		
经营场所(中文)	江门市宏兴路3号0 幢(自编002)		
经营场所(英文)	Building O 3rd Hongxin Road Jiangmen City Guangdong China		
联系电话	0750-3089979	联系传真	_____
邮政编码	529000	电子邮箱	1196399272@qq.com
工商登记注册日期	2020-2-20	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	谢英	有效证件号	513024196103153984
注册资金	伍佰万元	(折美元)	

依法办理工商登记的外国(地区)企业或个体工商户(独资经营者)还须填写以下内容

企业法定代表人/ 个体工商户负责人姓名	_____	有效证件号	_____
企业资产/个人财产	_____	(折美元)	

备注

\_\_\_\_\_

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。

**海关进出口货物收发货人备案回执**

企业名称	伏羲生物科技(广东)有限公司
统一社会信用代码	91440700MA54BFN314
海关备案日期	2020-03-26
海关编码	44079619Q6
检验检疫备案号	5952100040
有效期	长期



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。



July 21, 2020

Careable Biotechnology Co., Ltd  
Building O, No. 3 Hongxin Road  
Jiangmen City Guangdong, CN 529000

EUA201341/A001

Re: FFRs Made in China

Dear Flora Fan:

This letter is in response to your request that the Food and Drug Administration (FDA) add your respirator models CARE002 and CARE003 as authorized respirators to the Emergency Use Authorization (EUA) for non-NIOSH-approved filtering facepiece respirators manufactured in China<sup>1</sup>, which was revised and reissued under Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) on June 6, 2020. We have reviewed your request to be added to Appendix A of this EUA and determined that models included meet the eligibility criteria in the June 6, 2020 EUA for non-NIOSH approved respirators made in China. As such, your respirator(s) is hereby added to Appendix A as an authorized respirator.

Having concluded that the eligibility criteria are met, I am adding your respirators to Appendix A, as described in the Scope of Authorization (Section II). As such, these respirator models are authorized for use by healthcare personnel in healthcare settings in accordance with CDC recommendations and subject to the Conditions of Authorization (Section IV) of the attached letter. We remind you that, among other things, you are required to meet the following labeling requirements:

Appendix A: Authorized Imported, Non-NIOSH Approved Respirators  
Manufactured in China (Updated: July 21, 2020)

The table below includes a list of non-NIOSH respirators authorized by [this Umbrella EUA](#) for emergency use during the COVID-19 public health emergency.

As stated in the EUA, authorized respirators should be used in accordance with CDC's recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: [Strategies for Optimizing the Supply of N95 Respirators](#).

Search:  Show  entries

Manufacturer	Respirator Model(s)	Instructions for Use
Careable Biotechnology Co., Ltd.	CARE002, CARE003	

Showing 1 to 1 of 1 entries (filtered from 83 total entries) Previous 1 Next

2020/6/9

Confirmation Page

Help (/help/index.html)

DRLM Home (mainMenu.htm) > Change Registration Information for a Facility

Facility

Products Listing

### Update Registration Successful

Facility: CAREABLE BIOTECHNOLOGY CO.,LTD , Jiangmen , Guangdong, CHINA

Registration/FEI Number: 3016678425/3016678425

The Owner/Operator Number for this Registration is: 10062832.

#### Facility Information

Registration Number:  
3016678425

Initial Importer:  
N

Facility Name:  
CAREABLE BIOTECHNOLOGY CO.,LTD

Address:  
Building O,3rd Hongxin Road,  
Jiangmen, Guangdong, 529000, CHINA

DUNS Number:

Foreign Trade Zone:  
N

Facility URL:

Other Business Trade Name(s):

#### Owner/Operator Information

Owner/Operator Number:  
10062832

Contact Name:  
JAMES JING

Company:  
CAREABLE BIOTECHNOLOGY CO.,LTD

Address:  
Building O,3rd Hongxin Road  
Jiangmen, GUANGDONG, 529000, CHINA

Telephone:  
86 - 750 - 3082005

Fax:

-

E-mail:

careable@lifeideastech.com

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SEARCH

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### Establishment Registration & Device Listing

FDA Home Medical Devices Databases

1 result found for Establishment Registration or FEI Number : 3016678425

New Search

Establishment Name	Registration Number	Current Registration Yr
CAREABLE BIOTECHNOLOGY CO.,LTD CHINA	3016678425	2020
<ul style="list-style-type: none"> <li>Accessory, Surgical Aquarel - Face Mask</li> <li>Strip, Temperature Forehead, Liquid Crystal - Infrared Temperature Detector, Infrared Temperature Instrument</li> <li>Disinfectant, Medical Devices - Disinfect Hand Sanitizer, Disinfectant, Medical Alcohol, Sterilization Paper</li> <li>Non-Surgical Isolation Gown - Disposable Latex Gloves, Disposable Medical Cap, Face Mask, Medical Boot Cover, Medical Protective Clothing, Protective Glasses</li> <li>Shield, Eye, Ophthalmic (Including Sunlamp, Protective Eyewear And Post-Mydriatic Eyewear) - Protective Glasses</li> <li>Respirator, Surgical - KN95 Mask, N 95 Mask</li> <li>Cap, Surgical - Disposable Medical Cap</li> <li>Shoe And Shoe Cover, Conductive - Medical Boot Cover</li> </ul>		Manufacturer

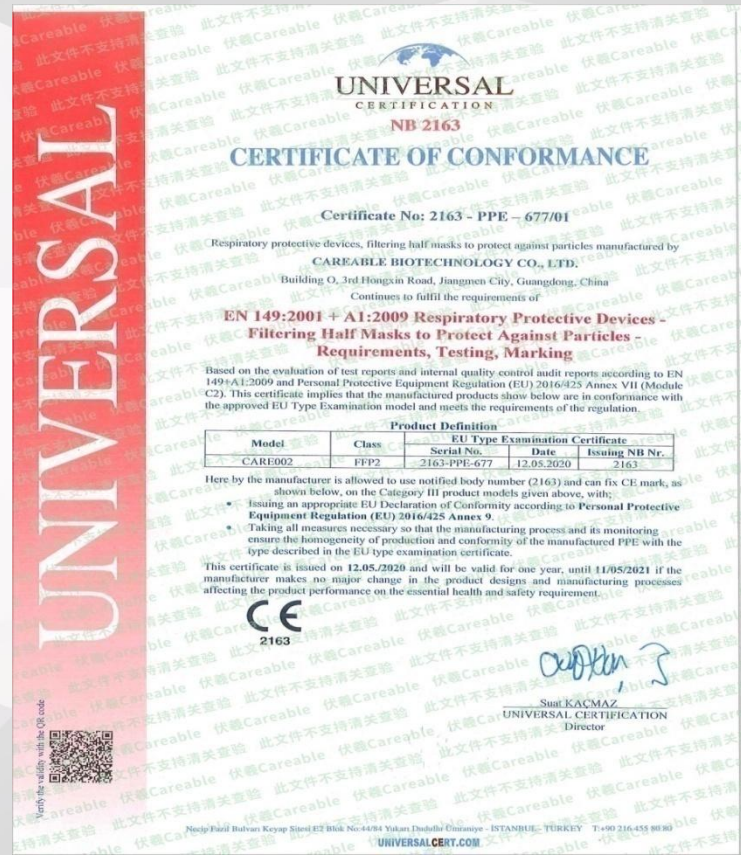
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企业注册号码/Registration number: 3016678425  
所有人号码/Owner/Operator Number: 10062832

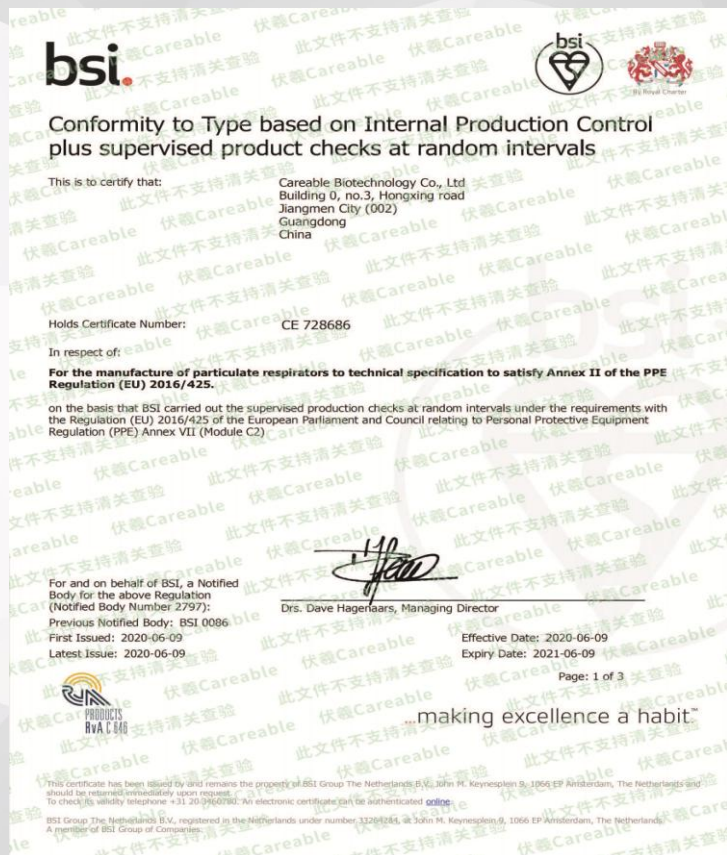
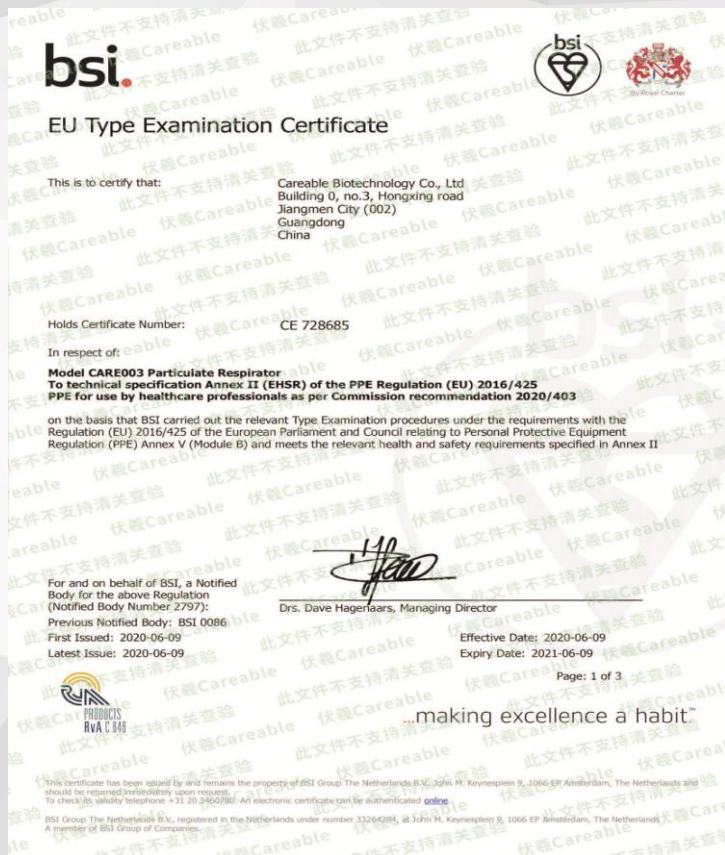
FDA 官网查询, 查询路径 :  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>





CE证书-Module B/CE Certificate-Module B

CE证书-Module C2/CE Certificate-Module C2







中国认可  
国际互认  
检测  
TESTING  
CNAS L7901

# 检验检测报告

## TEST REPORT



STFCE20200048

Product Name	CAREABLE Filtration Respirators
Trust Unit	Careable Biotechnology Co., Ltd
Manufacturer	
Test Category	Entrusted Inspection



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



Test Report

STFCE20200048

page 1 of 10

Product Name	CAREABLE Filtration Respirators	Specification Type	CARE002
Trust Unit	Careable Biotechnology Co., Ltd	Trademark	—
Manufacturer	—	Sample Grade	FFP2
Sample Quantity	70	Sample Receiving Date	2020-04-14
Test Category	Entrusted inspection	Serial Number	—
Samples Conditions	Meet the testing requirements		
Document and Decide Accordance	EN 149: 2001+A1: 2009 《Respiratory protective devices -Filtering half masks to protect against particles-Requirements, testing, marking》		
Test Conclusion	The samples were tested, the items tested meet the requirements of EN 149:2001+A1:2009 standard for FFP2 level. Signature Date: 2020-04-30		
Remarks	The head harness of the mask provided by the applicant is ear hanging. Compatibility with skin is not recognized by the center. The test data are only for reference. The sample is not marked for reuse and does not require testing for blocking performance. The test conclusion of this report is only for the items inspected and does not mean that the uninspected items or functions meet the requirements. The results apply to the sample as received.		

Approver

Examiner

Major tester



JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS.

STFCE20200048

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7.5 Material

Pass<sup>1</sup>

Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Note2: Refer to Annex A for test data.

7.6 Cleaning and disinfecting

N/A<sup>3</sup>

If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.

Note3: Non-reusable respirator.

7.7 Practical performance

Pass<sup>3</sup>

The particle filtering half mask shall undergo practical performance tests under realistic conditions.

Note4: Refer to Annex A for test data.

7.8 Finish of parts

Pass

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.



JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS.

STFCE20200048

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7.9.1 Total inward leakage

Pass<sup>4</sup>

For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than:

and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than  
22% for FFP1, 8% for FFP2, 2% for FFP3

Note5: Refer to Annex A for test data.

7.9.2 Penetration of filter material

Pass<sup>5</sup>

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

This report may not be published except in full unless permission for the publication of an approved extract has been obtained in writing.

Note6: Refer to Annex A for test data.

7.10 Compatibility with skin

Pass<sup>6</sup>

Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.

Note7: Refer to Annex A for test data.

7.11 Flammability

Pass<sup>7</sup>

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

Note8: Refer to Annex A for test data.

7.12 Carbon dioxide content of the inhalation air

Pass<sup>8</sup>

The carbon dioxide content of the inhalation air (dead space) shall not exceed an

Note9: Refer to Annex A for test data.



JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS.

STFCE20200048

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7.13 Head harness

Pass<sup>9</sup>

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining

Note10: Refer to Annex A for test data.

7.14 Field of vision

Pass<sup>10</sup>

The field of vision is acceptable if determined so in practical performance tests.

Note11: Refer to Annex A for test data.

7.15 Exhalation valve

N/A<sup>11</sup>

A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.

If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.

Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.

When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.

Note12: Valve-less respirator.

7.16 Breathing resistance

Pass<sup>12</sup>

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Note13: Refer to Annex A for test data.



JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS.



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7.17 Clogging

N/A<sup>13</sup>

7.17.2 Breathing resistance

N/A<sup>13</sup>

Valved particle filtering half masks:

After clogging the inhalation resistances shall not exceed:

FFP1: 4 mbar, FFP2: 5 mbar, FFP3: 7 mbar at 95L/min continuous flow

The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow

Valveless particle filtering half masks

After clogging the inhalation and exhalation resistances shall not exceed:

FFP1: 3 mbar, FFP2: 4 mbar, FFP3: 5 mbar at 95L/min continuous flow

7.17.3 Penetration of filter material

	Sodium chloride test 95	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

N/A<sup>13</sup>

Note14: Non-reusable respirator.

7.18 Demountable parts

N/A<sup>14</sup>

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand

Note15: No demountable parts.



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Annex A: Summarization of Test Data

Clause		Result		Assessment
7.5	Material	Simulated wearing treatment	1#	No mechanical failure
			2#	No mechanical failure
			3#	No mechanical failure
		Temperature conditioned	4#	No mechanical failure
			5#	No mechanical failure
			6#	No mechanical failure
7.9	Practical performance	As received	7#	No mechanical failure
			8#	No mechanical failure
7.9.1	Total inward leakage	Individual exercise result		Pass
		As received	9#	47 out of the 50 individual exercise results ≤ 11%
			10#	47 out of the 50 individual exercise results ≤ 11%
			11#	47 out of the 50 individual exercise results ≤ 11%
			12#	47 out of the 50 individual exercise results ≤ 11%
			13#	47 out of the 50 individual exercise results ≤ 11%
			14#	47 out of the 50 individual exercise results ≤ 11%
		Temperature conditioned	15#	47 out of the 50 individual exercise results ≤ 11%
			16#	47 out of the 50 individual exercise results ≤ 11%
			17#	47 out of the 50 individual exercise results ≤ 11%
			18#	47 out of the 50 individual exercise results ≤ 11%
			19#	47 out of the 50 individual exercise results ≤ 11%
			20#	47 out of the 50 individual exercise results ≤ 11%
		As received	21#	9 individual wearer arithmetic means ≤ 8%
			22#	9 individual wearer arithmetic means ≤ 8%
			23#	9 individual wearer arithmetic means ≤ 8%
			24#	9 individual wearer arithmetic means ≤ 8%
			25#	9 individual wearer arithmetic means ≤ 8%
			26#	9 individual wearer arithmetic means ≤ 8%
		Temperature conditioned	27#	9 individual wearer arithmetic means ≤ 8%
			28#	9 individual wearer arithmetic means ≤ 8%
			29#	9 individual wearer arithmetic means ≤ 8%
			30#	9 individual wearer arithmetic means ≤ 8%
			31#	9 individual wearer arithmetic means ≤ 8%
			32#	9 individual wearer arithmetic means ≤ 8%



JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS.



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Clause	Result		Assessment
7.9.2	Penetration of filter material/%	Sodium chloride test(95L/min)	
		19#	0.81
		20#	0.72
		21#	0.76
		22#	0.89
		23#	0.94
		24#	0.97
		25#	1.23
		26#	1.31
		27#	1.26
		Paraffin oil test(95L/min)	
		28#	1.68
		29#	1.74
		30#	1.79
		31#	1.88
		32#	1.96
		33#	1.92
		34#	2.04
7.10	Compatibility with skin	35#	2.18
		36#	2.11
		9#	No irritation or any other adverse effect to health
		10#	No irritation or any other adverse effect to health
		11#	No irritation or any other adverse effect to health
		12#	No irritation or any other adverse effect to health
		13#	No irritation or any other adverse effect to health
		14#	No irritation or any other adverse effect to health
		15#	No irritation or any other adverse effect to health
		16#	No irritation or any other adverse effect to health
7.11	Flammability	17#	No irritation or any other adverse effect to health
		18#	No irritation or any other adverse effect to health
		37#	Didn't burn
		38#	Didn't burn
		39#	Didn't burn
		40#	Didn't burn

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Clause		Result				Assessment
7.12	Carbon dioxide content of the inhalation air/%	As received				Pass
		41#	42#	43#	Mean value	
		0.52	0.53	0.51	0.52	
7.13	Head hardness	As received				Pass
		9#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		10#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		11#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		12#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		13#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		Temperature conditioned				
		14#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		15#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		16#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
7.14	Field of vision	17#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			Pass
		18#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		As received	7#	Passed the practical performance tests		
		8#	Passed the practical performance tests			

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Clause		Result				Assessment
		Inhalation		Exhalation		
		30 l/min	95 l/min	160 l/min		
		As received				
7.16	Breathing resistance (mbar)	41#	A	0.3	0.9	1.4
			B	0.3	0.9	1.4
			C	0.3	0.9	1.4
			D	0.3	0.9	1.4
			E	0.4	1.0	1.5
		42#	A	0.3	0.9	1.4
			B	0.3	0.9	1.4
			C	0.4	0.9	1.5
			D	0.3	1.0	1.4
			E	0.3	0.9	1.4
		43#	A	0.3	0.9	1.4
			B	0.4	0.9	1.5
			C	0.3	1.0	1.4
			D	0.3	0.9	1.4
			E	0.3	0.9	1.4
		Simulated wearing treatment				
		44#	A	0.3	0.9	1.4
			B	0.3	0.9	1.4
			C	0.4	1.0	1.4
			D	0.3	0.9	1.5
			E	0.3	0.9	1.4
		45#	A	0.4	1.0	1.5
			B	0.3	0.9	1.4
			C	0.3	0.9	1.4
D	0.3		0.9	1.4		
E	0.3		0.9	1.4		
46#	A	0.3	0.9	1.4		
	B	0.3	0.9	1.4		
	C	0.3	0.9	1.4		
	D	0.4	1.0	1.5		
	E	0.3	0.9	1.4		
Pass						



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Clause		Result				Assessment	
7.16	Breathing resistance	Inhalation		Exhalation		Pass	
		30 l/min		160 l/min			
		Temperature conditioned					
		47#	A	0.3	0.9		1.4
			B	0.3	0.9		1.4
			C	0.4	1.0		1.5
			D	0.4	0.9		1.5
			E	0.3	1.0		1.4
		48#	A	0.3	0.9		1.4
			B	0.3	0.9		1.4
			C	0.4	1.0		1.4
			D	0.3	0.9		1.5
			E	0.4	1.0		1.5
		49#	A	0.3	0.9		1.4
			B	0.4	1.0		1.5
			C	0.3	0.9		1.4
			D	0.3	0.9		1.4
E	0.3		0.9	1.4			
7.16	Breathing resistance	A: facing directly ahead B: facing vertically upwards C: facing vertically downwards D: lying on the left side E: lying on the right side					
		Remarks : M.S.: Mechanical strength; T.C.: Temperature conditioning					

Original Sample



=====  
End of Report



JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS.







3204582 - Test Report.

## Introduction.

This report has been prepared by Paul Waller and relates to the activity detailed below:

Job/Registration Details	Client Details
<b>Job number:</b> 3204582 <b>Job type:</b> Testing Samples Submitted <b>Start Date:</b> 14/05/2020 <b>Test type:</b> Type <b>Sample ID:</b> 10189621 / 10190018 <b>Registration:</b> CE 728685 <b>Scheme:</b> Negative pressure RPE <b>Protocol:</b> PP123 <b>Scheme Manager:</b> Kinga Demetriou	Careable Biotechnology Co., Ltd. Building 0, No. 3 Hongxing road Jiangmen City Guangdong China

The report has been approved for issue by T Wicksey - Senior Test Engineer

Approved For Issue
 Issue Date: 22 May 2020

## Objectives.

This is an independent test evaluation to only certain clauses or sub-clauses of the agreed specification in accordance with the following test programme:  
BSI COVID-19 filtering face piece technical specification, for COVID-19 masks for use by healthcare workers

## Product Scope.

COVID-19 masks for use by healthcare workers

## Report Summary.

The samples were received on 11 May 2020 and the testing was started on 14 May 2020.

The samples submitted complied with the requirements of the test work conducted.



3204582 - Test Report.

## Test Samples.

Sample ID	ER Number	Description
1 to 19	10189621 / 10190018	Model: CARE 003 FFP2 UN

## Description of Test Samples.

Sample Description
COVID-19 masks for use by healthcare workers: Model: CARE 003 FFP2 UN

## 3204582 - Test Report

**Testing in accordance with BSI COVID-19 filtering face piece technical specification**  
Technical testing specification for COVID-19 masks for use by healthcare workers

Appendix A - Test Panel Data
Product Photographs

## 3204582 - Test Report

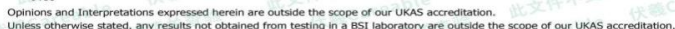
Pass: Complies. Tested by BSI engineers at BSI laboratories

Pass 1: Compiles. Witnessed by BSI engineers in manufacturers laboratory.  
 Pass 2: Compiles. Tests carried out by third party lab; results accepted by BSI.  
 Pass 3: Report resulted in uncertainty and states that Compliance is more probable than non-compliance  
 Fair: Non-compliance. Product does not meet the requirements of this clause.  
 Fair: Report resulted in uncertainty and states that Non-compliance is more probable than compliance.  
 N/T: Not Tested  
 N/A: Not Applicable  
 AR: As Received  
 TC: Temperature Conditioned  
 WS: Simulated Wear  
 FT: Flow Tested  
 MS: Mechanical strength  
 MMDf: Manufactures Minimum Design Flow  
 MMDc: Manufactures Minimum Design Condition

This Test Report is issued subject to the conditions stated in current issue of 'BSI Terms of Service'. The results contained herein apply only to the particular sample(s) tested and to the specific tests carried out, as detailed in this Test Report. The issuing of this Test Report does not indicate any measure of Approval, Certification, Supervision, Control or Surveillance by BSI of any product. No extract, abridgement or abstraction from a Test Report may be published or used to advertise a product without the written consent of BSI, who reserve the absolute right to agree or reject all or any of the details of any items or publicity for which consent may be sought.

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BSI  
Kitemark House  
Maylands Avenue  
Hemel Hempstead  
Hertfordshire  
HP2 4SQ







3204582 - Test Report.

### Test Results.

Testing in accordance with **BSI COVID-19 filtering face piece technical specification**

BS EN 149:2001 +A1:2009 Technical testing specification for COVID-19 masks for use by healthcare workers

CLAUSE	REQUIREMENTS	ASSESSMENT
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#### 7.7

##### Practical performance

The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections.

Pass

Testing in accordance with **BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers**

During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded:  
a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.

Table A: Practical performance

Test candidate	Sample	Head harness comfort	Security of fastenings	Field of vision	Comments	Any other comments	Assessment
JA1	1 AR	OK	OK	Good		None	Pass
JS3	2 AR	OK	OK	OK		None	Pass

#### 7.9

##### Leakage

#### 7.9.1

##### Total inward leakage

The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration.

Test in accordance with clause 8.5 of the standard.

Pass

Testing in accordance with **BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers**

5 test subjects, masks tested 'As received'. All individual exercise results tests shall be not greater than 1.1 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2).

Table B: Clause 7.9.1 - Total inward leakage

Test candidate	Sample	Pre test condition	Inward Leakage (%)					Average	Assessment
			A	B	C	D	E		
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking		
GR1	3	AR	0.13	0.11	0.17	0.05	0.23	0.14	Pass
LM2	4	AR	0.31	0.21	0.26	1.24	0.24	0.45	Pass
JS2	5	AR	2.74	2.98	2.48	0.70	1.89	2.16	Pass
JA1	6	AR	3.63	5.01	5.12	1.23	2.81	3.56	Pass
JB1	7	AR	1.87	2.54	2.11	3.21	3.24	2.60	Pass



3204582 - Test Report.

### Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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#### 7.9.2

##### Penetration of filter material

Testing in accordance with **BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers**

3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3 min test. Testing shall be done in accordance with  $\pm 1.1, 0\%$  limit for both PO and NaCl.

Pass

Table C: Clause 8.11 - Sodium Chloride penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
8	AR	95	< 6	0.124
9	AR			0.096
10	AR			0.087

Table D: Clause 8.11 - Paraffin oil penetration test

Sample number	Pre-test condition	Flow through filter (l/min)	Penetration (%)	
			Limit	Actual
11	AR	95	< 6	0.391
12	AR			0.602
13	AR			0.636

#### 7.12

##### Carbon dioxide content of inhalation air

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0% (by volume).

Pass

Test in accordance with clause 8.7 of the standard.

Table E: Clause 8.7 - Carbon Dioxide content of the inhalation air

Sample	Pre-test condition	Dead space CO <sub>2</sub> (%)	
		Limit	Measured
14	AR	< 1.0	0.43
15	AR		0.48
16	AR		0.41



bsi.

3204582 - Test Report.

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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**7.16**  
**Breathing resistance**  
**Testing in accordance with BSI COVID-19 filtering face piece technical specification, for masks for use by healthcare workers**  
**3 test samples masks tested 'As received'. Test in accordance with clause 8.9 of the standard.**  
**The breathing resistances shall meet the requirements of FFP2: 30l/min – 0.7mbar (inhalation), 95l/min – 2.4mbar (inhalation), 160l/min – 3.0mbar (exhalation)**

Pass

Table F: Clause 8.9 – Breathing resistance. Inhalation resistance at a continuous flow

Sample	Pre-test condition	Continuous flow (l/min)	Inhalation resistance (mbar)	
			Limit	Measured
17	AR	30	< 0.7	0.45
18	AR			0.47
19	AR			0.45
17	AR	95	< 2.4	1.45
18	AR			1.60
19	AR			1.50

Table G: Clause 8.9 – Breathing resistance. Exhalation resistance at a continuous flow, measured in five orientations with the worst case reported

Sample	Pre-test condition	Continuous flow (l/min)	Exhalation resistance (mbar)	
			Limit	Measured
17	AR	160	< 3.0	2.30
18	AR			2.55
19	AR			2.37

bsi.

3204582 - Test Report.

Appendix A. – Test Panel Data

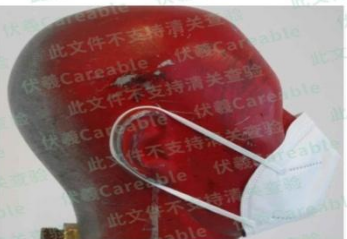
Test Candidate	Length of face	Width of face	Facial Dimensions (mm)			Sex
			Face depth	Width of mouth	Head Circumference	
JA1	117	134	129	49	565	Male
JS3	126	134	124	49	600	Male
GR1	124	145	126	49	590	Male
LM2	110	148	125	44	589	Male
JS2	126	142	125	57	575	Male
JB1	114	144	108	59	574	Male

Note: All candidates were clean shaven

Product photographs.



Front view



Side View



Inside View

\*\*\*End of Report\*\*\*

天纺标检测认证股份有限公司  
国家针织产品质量监督检验中心

检验报告



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客户提供的信息 Information Provided by Client	委托单位/地址 Applicant	伏羲生物科技(广东)有限公司 Careable Biotechnology Co., Ltd 江门市兴路3号0楼(自编002) Building 0,3rd, hongxing road, jiangmen city guangdong China				送样人: Contact	---
	生产单位/地址 Manufacturer	伏羲生物科技(广东)有限公司 Careable Biotechnology Co., Ltd 江门市兴路3号0楼(自编002) Building 0,3rd, hongxing road, jiangmen city guangdong China				电话: Tel. ---	---
	样品信息 Information of Submitted Sample	样品名称: Sample Name	一次性KN95防护口罩 KN95 FILTRATION RESPIRATORS		商标: Trademark	FUXIBIO	
		样品总数: Sample Count	90个 90Pieces		颜色: Colour	-----	
		型号规格: Size	CARE006		安全类别: Safety	---	
	质量等级: Quality Grade	-----		安全类别: Category	---		
	产品款号或货号: Style No. or Order No.	-----					
样品描述 Test Part Description	1# 白色口罩 White Mask						
检验性质 Test Type	委托检验 Commission Test	样品受理日期 Date of Submission	2020-06-03	报告签发日期 Date of Checking	2020-06-11		
执行标准 Test Standards	GB 2626-2019 GB 2890-2009						
检验结论 Conclusion	检验结果及符合性见附页。 Test results and compliance refer to next page(s).						
非标准检验方法说明 Non-standard Check Methods	检验单位盖章Stamp of Inspection Center						
检验结果的不确定度 Uncertainty of Result	贴样 Sample Attached						
备注 Remarks	客户要求所检项目按GB 2626-2019标准判定。 As per client's request, the test items are judged according to the standard GB 2626-2019.						

批准: 李学雷 审核: 何振 编制: 于静茹  
Approver: 李学雷 Checker: 何振 Editor: 于静茹

天纺标检测认证股份有限公司  
国家针织产品质量监督检验中心

检验报告



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检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	方法标准/备注 Test Method/Remarks
1# 白色口罩 White Mask						
呼吸阻力 Respiratory Resistance	呼气阻力 Expiratory Resistance	Pa	≤210	未预处理样品 Samples Without Pretreatment 1: 112 2: 115 预处理样品 Samples With Pretreatment 1: 106 2: 103	符合 Pass	GB 2626-2019
	吸气阻力 Inspiratory Resistance	Pa	≤210	未预处理样品 Samples Without Pretreatment 1: 121 2: 127 预处理样品 Samples With Pretreatment 1: 113 2: 120	符合 Pass	GB 2626-2019
可燃性 Flammability	续燃时间 Afterflame Time	s	≤5	0	符合 Pass	GB 2626-2019
外观检查 Appearance Inspection	样品表面 Surface of The Sample	---	按标准要求 As per standard requirement	+	符合 Pass	GB 2626-2019
	部件材料和结构 Material and Construction	---	按标准要求 As per standard requirement	+		
	部件经过温度湿度预处理后 The components after the temperature and humidity pretreatment	---	按标准要求 As per standard requirement	+		
死腔 Dead Space	---	%	≤1	0.6	符合 Pass	GB 2626-2019
视野 View	下方视野 View Below	°	≥35	61	符合 Pass	GB 2890-2009
	双目视野 Binocular View	%	≥65	≥65		

天纺标检测认证股份有限公司  
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检验报告

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检测项目 Test Items	项目描述 Description	单位 Unit	标准值 Standard Requirement	实测值 Results	评价 Conclusions	方法标准/备注 Test Method/Remarks
头带 Head Harness	---	---	不应出现滑脱、断裂。 Have no slippage or breaking.	10N负荷持续10秒，头带未出现滑脱、断裂。 The head harness have no slippage or breaking for 10s under 10N loading.	符合 Pass	GB 2626-2019

表中“+”表示符合标准要求，“X”表示不符合标准要求。  
+ Meet the standard requirements, X Not Meet the standard requirements.  
以下空白  
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国家针织产品质量监督检验中心



检验报告

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样 品 Sample







## Page 1 of 20

CAREABLE BIOTECHNOLOGY CO., LTD  
BUILDING 0, 3RD, HONGXING ROAD, JIANGMEN CITY GUANGDONG CHINA

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

SGS Job No. :	SHHL2006522849MD - SH
OTS Subcontract Id :	20016914
OTS Report Number :	SHHL2006522849MD
Style No. :	CARE003
Brand :	FUXIBIO
Date of Sample Received :	15 Jun 2020
Testing Period :	15 Jun 2020 - 19 Jun 2020
Test Requested :	As requested by client. SVL

As requested by client, SVHC screening is performed according to:

- (i) Two hundred and five (205) substances in the Candidate List of Substances of Very High Concern (SVHC) for authorization published by European Chemicals Agency (ECHA) on and before Jan 16, 2020 regarding Regulation (EC) No 1907/2006 concerning the REACH.
- (ii) Five (5) substances in the Public Consultation List of potential Substances of Very High Concern (SVHC) published by European Chemicals Agency (ECHA) on Mar 3, 2020 regarding Regulation (EC) No 1907/2006 concerning the REACH.

Test Results : Please refer to next page(s)

### Summary :

According to the ruling of the Court of Justice of the European Union on the definition of an article under REACH, and the specified scope and evaluation screening, the test results of SVHC are  $\leq 0.1\%$  (w/w) in the articles of the submitted sample.

PASS



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Test Result: (Substances in the Candidate List of SVHC)

Batch	Substance Name	CAS No.	001 Concentration (%)	RL (%)
-	All tested SVHC in candidate list	-	ND	-

Test Result: (Substances in the Consultation List of potential SVHC)

Batch	Substance Name	CAS No.	001 Concentration (%)	RL (%)
-	All listed SVHC in consultation list	-	ND	-

Test Result: (Substances in the Candidate List of SVHC)

Batch	Substance Name	CAS No.	003 Concentration (%)	RL (%)
-	All tested SVHC in candidate list	-	ND	-

Test Result: (Substances in the Consultation List of potential SVHC)

Batch	Substance Name	CAS No.	003 Concentration (%)	PL (%)
-	All tested SVHC in consultation list	-	ND	-

[illegible]

7. <http://www.irs.gov/efile> 200203  
 中国、上海、南京、北京、深圳、杭州、香港、香港 200203  
 156 86-21-646000 156 86-21-646079  
 156 86-21-646094 156 86-21-646080

Shortage of the B35 Group (925-54)



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Appendix

Full list of tested SVHC:

Batch	No.	Substance Name	CAS No.	RL (%)
I	1	4,4'-Diaminodiphenylmethane(MDA)	101-77-9	0.100
I	2	5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)	81-15-2	0.100
I	3	Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)	85535-84-8	0.100
I	4	Anthracene	120-12-7	0.100
I	5	Benzyl butyl phthalate (BBP)	85-68-7	0.100
I	6	Bis (2-ethylhexyl)phthalate (DEHP)	117-81-7	0.100
I	7	Bis(tributyltin)oxide (TBTO)	56-35-9	0.100
I	8	Cobalt dichloride*	7646-79-9	0.010
I	9	Diarsenic pentaoxide*	1303-28-2	0.010
I	10	Diarsenic trioxide*	1327-53-3	0.010
I	11	Dibutyl phthalate (DBP)	84-74-2	0.100
I	12	Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified ( $\alpha$ -HBCDD, $\beta$ -HBCDD, $\gamma$ -HBCDD) <sup>16</sup>	25637-99-4, 3194-55-6	0.100
I	13	Lead hydrogen arsenate*	7784-40-9	0.010
I	14	Sodium dichromate*	7789-12-0, 10588-01-9	0.010
I	15	Triethyl arsenate*	15606-95-8	0.010
II	16	2,4-Dinitrotoluene	121-14-2	0.100
II	17	Acrylamide	79-06-1	0.100
II	18	Anthracene oil**	90640-80-5	0.100
II	19	Anthracene oil, anthracene paste**	90640-81-6	0.100
II	20	Anthracene oil, anthracene paste, anthracene fraction**	91995-15-2	0.100

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中国·上海·徐汇区宜山路889号5号楼 邮编: 200220	TEL (86-21) 61432534	FAX (86-21) 61152880	e: spg_china@spg.com

Member of the SGS Group (SGS SA)

SGS Supplier Creditability & Capacity Audit Report



Report No.: SCCA2020070301

Supplier Creditability & Capacity Audit Report

Report:			
Supplier Name	Careable Biotechnology Co., Ltd. 伏羲生物科技（广东）有限公司		
Supplier Address	Building O, No.3, Hongxing Road, Pengjiang District, Jiangmen City, Guangdong Province, China		
Client Information	/		
Name of Assessor	Lynn Hu	Reviewed by	Roger Wang
Audited Date	03 Jul., 2020	Expiry Date	02 Jul., 2021

Assessment Scope:
Section 1: Company Profile
Section 2: Personnel
Section 3: Main Market
Section 4: Manufacturing Ability
Section 5: Certificate
Section 6: Quality Control Management
Section 7: Development Plan
Section 8: Production Flow Chart
Section 9: Attachment

Comments
Careable Biotechnology Co., Ltd. is established in 2020, located in Building O, No.3, Hongxing Road, Pengjiang District, Jiangmen City, Guangdong Province, China, is a manufacturer with 356 staffs, specializing in the research, development, production and sale of Non-medical KN95 face mask, There were 93 production machines in the factory, all machines were in good condition on audit day. Procedure of equipment maintenance has been established and implemented. The company has passed CE product certificates for Non-medical KN95 face mask, and obtained ISO9001:2015 quality management system certificate.



Report No.: SCCA2020070301

Section 1: Company Profile

1.1 Basic Information			
Name of Supplier	Careable Biotechnology Co., Ltd. 伏羲生物科技（广东）有限公司		
Address in License	Building O, No.3, Hongxing Road, Pengjiang District, Jiangmen City, Guangdong Province, China		
Audited Address	Building O, No.3, Hongxing Road, Pengjiang District, Jiangmen City, Guangdong Province, China		
Main Product	Disposable KN95 filtering respirator FFP2 particulate respirator FFP3 particulate respirator		
Industry experience	The audited company has 5 months industry experience and technology manager has 5 years industry experience.		
License Number	91440700MA54BFN314	Corporate Representative	Ms. Ying Xie
Registration Date	20 Feb., 2020	Expiry Date	Long term
Registered Capital	RMB 5,000,000	Paid-in Capital	/
Area of Office	300 square meters	Area of Workshop	2,500 square meters
1.2 Contact Way			
Company Representative	Ms. Ying Xie / General Manager		
Tel. number	0086-750-2633130		
E-mail	james.jing@lifeideastech.com	URL	www.careablemask.com

# The End

CAREABLE

伏羲生物



## CareAble Biotechnology Co., Ltd

Address : Building O, 3rd Hongxin Road, Jiangmen, Guangdong, China

Web: [www.careablemask.com](http://www.careablemask.com)

Email: [careable@lifeideastech.com](mailto:careable@lifeideastech.com)

Tel: 0086-750-3082101; 13923086090