



用心做好口罩

Make good mask with sincere heart



2020

CAREABLE
BIOTECHNOLOGY Co., Ltd

伏羲生物



用心做好口罩



📍 Building O, Yeken Industrial Area, Jiangmen, Guangdong, China.

公司介绍：

伏羲生物，是一家专业的防护产品生产制造企业，工厂集研发，设计，生产，销售，我们的产品，完全按照USA FDA, 欧盟的CE, 中国的GB等国家，国际标准认证生产。在此基础上不断完善不同的标准，尤其是高等级产品的认证，并持续专注研发高效低电阻产品。我们拥有先进的生产工艺，严格的生产过程管理和完善的质量保证体系，我们秉承“以质量求生存，以创新求发展”的指导思想，始终把质量和创新放在首位，不断的提高客户满意度。

CAREABLE 的标准：

CHINA：GB 19083-2010；YY/T 0969-2013；YY 0469-2011；GB/T 32610-2016
欧洲：EN149：2001+A1-2009；FFP1≥80%，FFP2≥94%，FFP3≥97%。
澳洲：AS/NZS17162012
美国：NIOSH（National Institute of Occupational Safety and Health）：（Title 42 CFR Part 84）
韩国：KF（Korean filter）KF94：≥94%
日本：（MHLW）标准：JIST81512018

国家标准GB2626-2006

《呼吸防护用品-- 自吸过滤式防颗粒物呼吸器》



国标：GB2626-2006标准对防颗粒物口罩的分类和分级以及标示方法

滤料分类	过滤效率90%	过滤效率95%	过滤效率99.97%
KN类	√ KN90	√ KN95	KN100
KP类	√ KP90	√ KP95	KP100

KN: 适合防非油性颗粒物(固体和非油性液体颗粒物及微生物, 如煤尘、水泥尘、加工矿石、木材等)

KP: 适合防非油性和油性颗粒物(如油烟、柴油机尾气中的颗粒物等)

注：我司现在可生产、销售认证的KN90、KN95、KP90和KP95产品

对比：世康内控指标与国家标准，以KN95为例

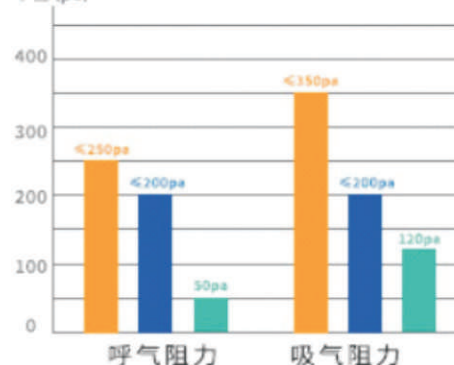
	呼气阻力	吸气阻力	过滤效率	头带拉力
国家标准	≤250pa	≤350pa	≥95%	10N, 持续10S
我司标准	≤200pa	≤200pa	≥97%	20N, 持续10S

■ 国家标准

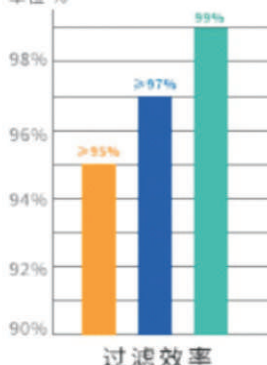
■ 我司内部检测标准

■ 实际检测数据

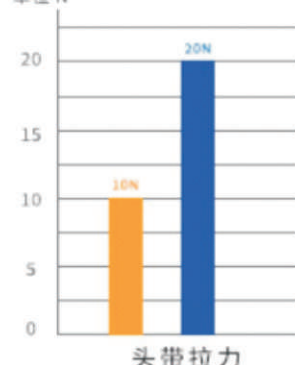
单位 (pa)



单位 %

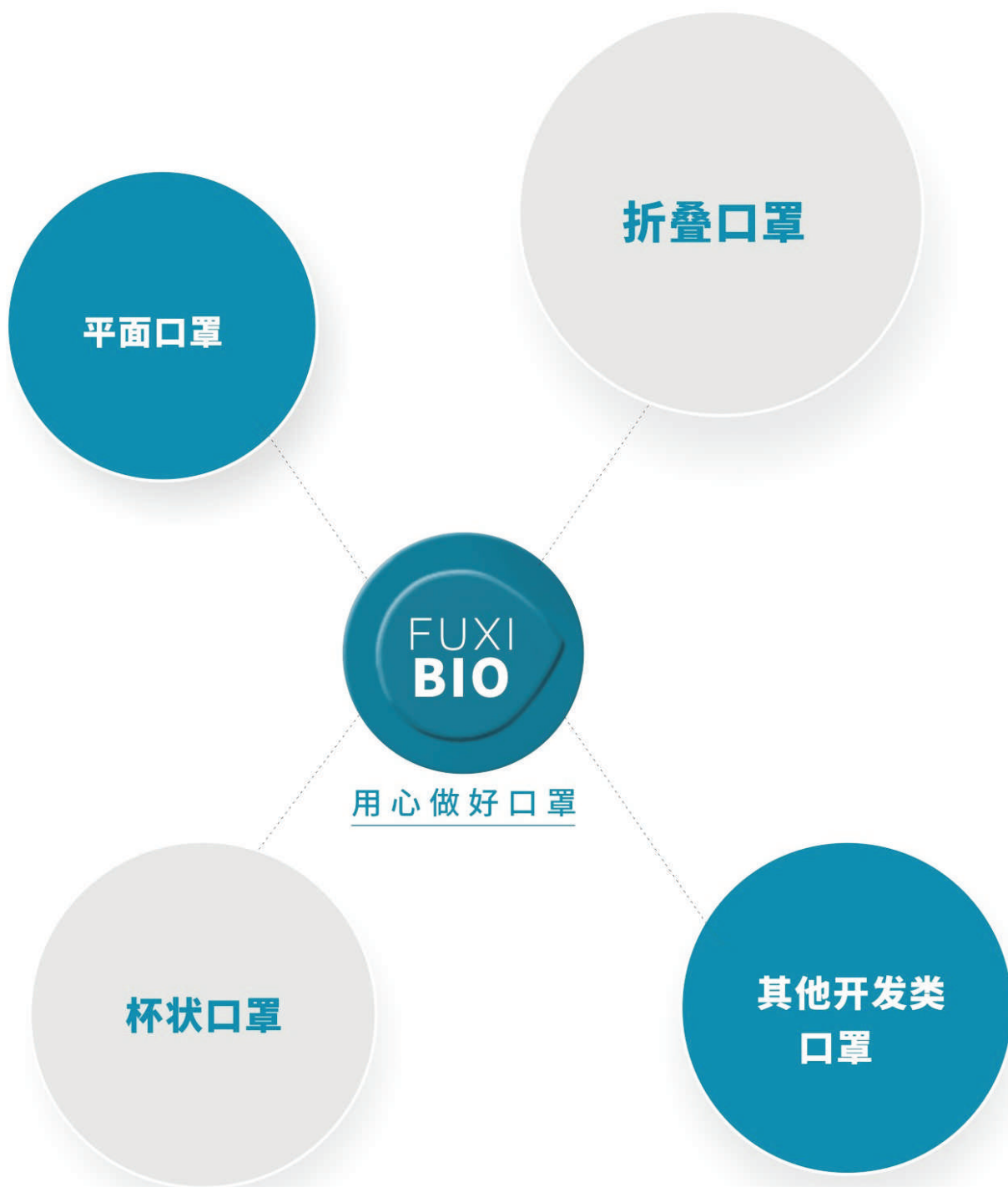


单位 N



持续10S

CONTENTS 目录





天空之吻TM

Care Able

伏羲生物

Make good mask with sincere heart

用心做好口罩



Care Able

CAREABLE
BIOTECHNOLOGY Co., Ltd



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.



CareAble Biotechnology Co., Ltd

COMPANY 企业文化 CULTURE



一个成功的企业必须拥有着科学的管理理念，良好的运作模式，有竞争意识和合作精神的管理团队，优秀而独特的企业文化。还有最重要的企业素质----锐意进取的决心和勇气！

而这些都是我们伏羲生物所拥有的！

A successful enterprise must have a concept of scientific management, a good operation mode, a team with the sense of competition and cooperation, and excellent and unique corporate culture. And the most important enterprise quality is ---- Determination and courage to forge ahead!

And these are what we CAREABLE have!

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!**

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.



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



WORK SHOP



Quality Control

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 & STANDARAD:

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 worm, 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
	Size	Overall size of mask : 155*105mm±5mm Nose bridge: 9±5mm	Ruler	0 : OK 1:reject	5pieces/lot
Ear Loop	Appearance	The place of welding should be symmetry, and the inaccuracy should be little than 1mm. No worm, 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	Outter 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) Hydrophilia(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

				1:reject	
	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

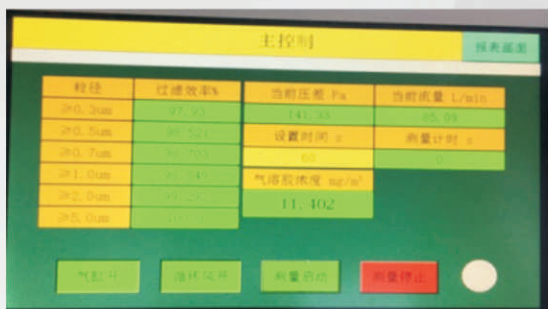
Attation: The item not specified is the same with sample.

Change history

Date	Change information	Cuatomer complaint	Mender

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

Testing Equipment







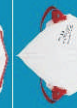







- 1、Filter efficiency detector
- 2、Aging Oven
- 3、Breathing resistance tester
- 4、Tension Meter

ISO9001 Certificate



CareAble Mask Spec Listing

Item	Product Name	Pictures	Valve	Category	CE NO.	CE NO.	Note
care002	FFP2 folded mask			FFP2	CE 2163		EUA Approved
care003	FFP2 folded mask			FFP2	CE 2797		EUA Approved
care0910	FFP2 cup mask		Valve	FFP2	CE 2797		EUA Approved
care2006	FFP2 cup mask			FFP2		CE 0099	EUA Approved
care2006V	FFP2 cup mask		Valve	FFP2		CE 0099	EUA Approved
care1980V	FFP2 folded mask		Valve	FFP2		CE 0099	EUA Approved
care1986	FFP3 folded mask			FFP3	CE 1463	CE 0099	EUA Approved
care1986V	FFP3 folded mask		Valve	FFP3	CE 1463	CE 0099	EUA Approved
care1981V	FFP3 cup mask		Valve	FFP3	CE 1463	CE 0099	EUA Approved
care2001	FFP3 cup mask			FFP3		CE 0099	EUA Approved
care001	disposable			GB/T32610		China	
care0961	disposable			Gb38880		China	

EUA 授权

FDA U.S. FOOD & DRUG
ADMINISTRATION

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 China¹, 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:

商务部白名单

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

Chinese Version

[Home](#) [About Us](#) [Events](#) [News](#) [Public Relations](#) [Analysis](#) [Members](#) [Suppliers](#) [Contact Us](#)Name List of Non-Medical Use Face Masks Companies with
Certification/Authorization from other Countries

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

[Events](#)[Video](#)[Industry News](#)[Major Policies](#)[Analysis](#)

取得国外标准认证或注册的非医口罩生产企业清单

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 Countries
151	伏羲生物科技(广东)有限公司 Careable Biotechnology Co., Ltd	91440700MA54BFN314	CE
666	伏羲生物科技(广东)有限公司 Careable Biotechnology Co., Ltd	91440700MA54BFN314	美国EUA



Care Able

CAREABLE
BIOTECHNOLOGY Co., Ltd



用心做好口罩

欧洲EN149 认证系列口罩

Careable
Protective Mask
FFP2

CARE0910



型 号	描 述	包 装	认 证 号
CARE0910	FFP2 FFP2 NR EN 149:2001 +A1:2009 Cup mask With value With soft pad	10PCS/BOX 20BOXES/CARTON	CE2797 B+C2



Care Able

CAREABLE
BIOTECHNOLOGY Co., Ltd



用心做好口罩

欧洲EN149 认证系列口罩

Careable
Protective Mask
FFP3

CARE1981V



型 号	描 述	包 装	认 证 号
CARE1981V	FFP3 FFP3 NR EN 149:2001+A1:2009 Cup mask With value With soft pad	10PCS/BOX 20BOXES/CARTON	CE 1463 B+C2



用心做好口罩

欧洲EN149 认证系列口罩

Careable
Protective Mask
FFP2

CARE2006



型 号	描 述	包 装	认 证 号
CARE2006	FFP2 FFP2 NR EN 149:2001 +A1:2009 Cup mask With soft pad	10PCS/BOX 20BOXES/CARTON	CE 0099



用心做好口罩

欧洲EN149 认证系列口罩

Careable
Protective Mask
FFP2

CARE2006V



型 号	描 述	包 装	认 证 号
CARE2006V	FFP2 FFP2 NR EN 149:2001 +A1:2009 Cup mask With soft pad	10PCS/BOX 20BOXES/CARTON	CE 0099



Care Able

CAREABLE
BIOTECHNOLOGY Co., Ltd



用心做好口罩

欧洲EN149 认证系列口罩

Careable
Protective Mask
FFP3

CARE2001



型 号	描 述	包 装	认 证 号
CARE2001	FFP3 FFP3 NR EN 149:2001 +A1:2009 Cup mask With soft pad	10PCS/BOX 20BOXES/CARTON	CE 0099



用心做好口罩

欧洲EN149 认证系列口罩

Careable
Protective Mask
FFP2

CARE1980V



型 号	描 述	包 装	认 证 号
CARE1980V	FFP2 FFP2 NR EN 149:2001 +A1:2009 With value	10PCS/BOX 20BOXES/CARTON	CE 0099



Care Able

CAREABLE
BIOTECHNOLOGY Co., Ltd



用心做好口罩

欧洲EN149 认证系列口罩

Careable
Protective Mask
FFP3

CARE1986V



型 号	描 述	包 装	认 证 号
CARE1986V	FFP3 FFP3 NR EN 149:2001 +A1:2009 With value	10PCS/BOX 20BOXES/CARTON	CE 1463



用心做好口罩

欧洲EN149 认证系列口罩

Careable
Protective Mask
FFP3

CARE1986



型 号	描 述	包 装	认 证 号
CARE1986	FFP3 FFP3 NR EN 149:2001 +A1:2009	10PCS/BOX 20BOXES/CARTON	CE1463



Care Able

CAREABLE
BIOTECHNOLOGY Co., Ltd



用心做好口罩

欧洲EN149 认证系列口罩

Careable
Protective Mask
FFP2

CARE002



型 号	描 述	包 装	认 证 号
CARE002	普通防护口罩 FFP2NR EN 149:2001+A1:2009 With value	10PCS/BOX 20BOXES/CARTON	CE2163



用心做好口罩

欧洲EN149 认证系列口罩

Careable
Protective Mask
FFP2

CARE003



型 号	描 述	包 装	认 证 号
CARE003	FFP2 FFP2 NR EN 149:2001 +A1:2009	10PCS/BOX 20BOXES/CARTON	CE2797



用心做好口罩

儿童防护口罩

Careable
Protective Mask

CARE0961



型 号	描 述	包 装	认 证 号
CARE0961	一次性儿童防护口罩	10 PCS /BOX 20 BOXES/CARTON	Gb38880
CARE0961	一次性儿童防护口罩	10 PCS /BOX 20 BOXES/CARTON	Gb38880



用心做好口罩

GB一次性防护口罩

Careable
Protective Mask

CARE001



型 号	描 述	包 装	认 证 号
CARE001	普通防护口罩 FFP2NR EN 149:2001+A1:2009	10PCS/BOX 20BOXES/CARTON	GB2626-2019

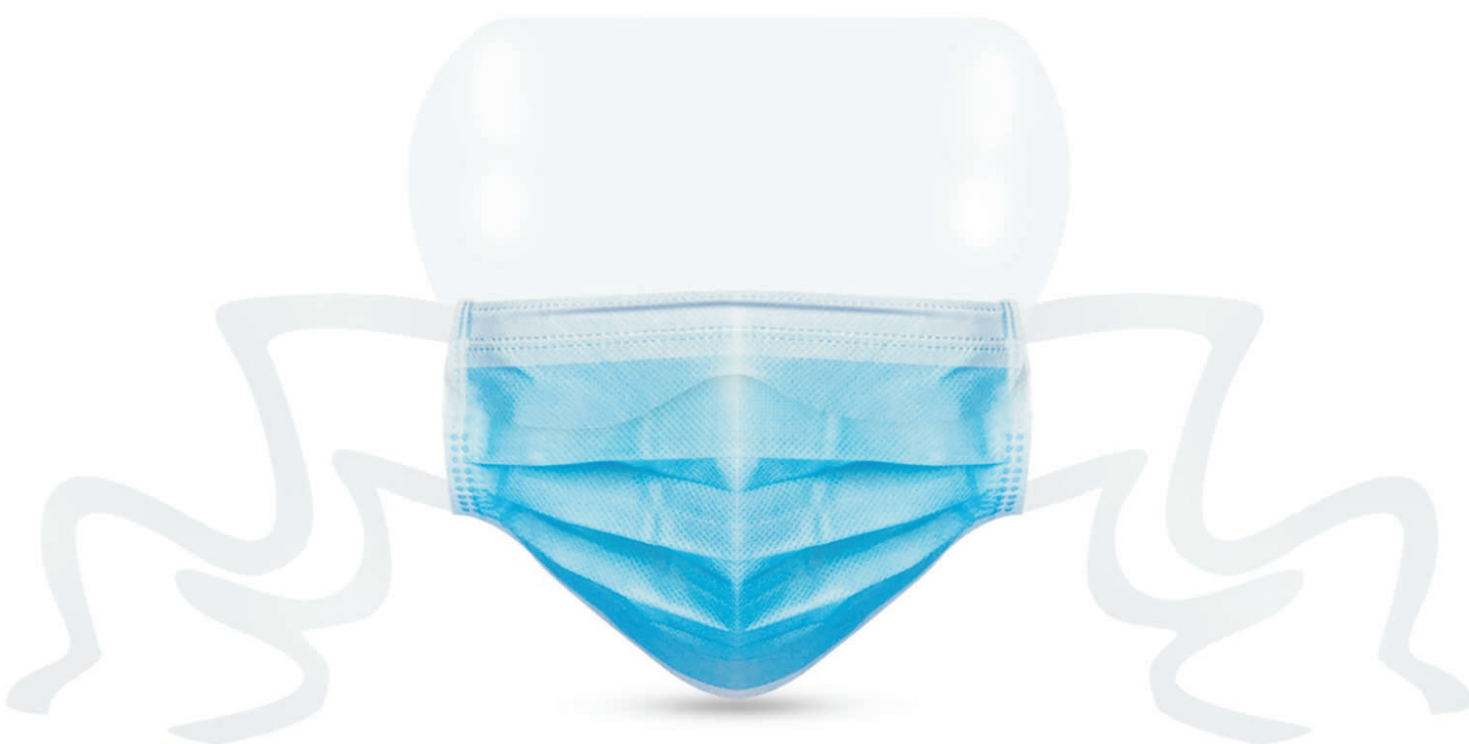


用心做好口罩

GB一次性防护绑带式口罩

Careable
Protective Mask

CARE009P



型 号	描 述	包 装	认 证 号
CARE009P	一次性护眼绑带口罩 GB2626-2019	10PCS/BOX 20BOXES/CARTON	GB4361-2019



用心做好口罩

GB一次性防护绑带式口罩

Careable
Protective Mask

CARE009



型 号	描 述	包 装	认 证 号
CARE009	一次性护口罩 GB2626-2019 绑带式	10PCS/BOX 20BOXES/CARTON	GB4361-2019



用心做好口罩

GB一次性防护口罩

Careable
Protective Mask

CARE008



型 号	描 述	包 装	认 证 号
CARE008	加强防护口罩 GB 2626-2019 外置鼻梁条 调节耳带 活性炭层	10PCS/BOX 20BOXES/CARTON	GB2626-2019



Care Able

CAREABLE
BIOTECHNOLOGY Co., Ltd



用心做好口罩

棉布防护口罩

Careable
Protective Mask

CARE606



型 号	描 述	包 装	认 证 号
CARE606	棉布防护口罩	10PCS/BOX 20BOXES/CARTON	NA



用心做好口罩

清凉防护口罩

Careable
Protective Mask

CARE0917



型 号	描 述	包 装	认 证 号
CARE0917	凉感防护防护面罩	10PCS/BOX 20BOXES/CARTON	NA



用心做好口罩

透明防护面罩

Careable
Protective Mask

CARE1993



型 号	描 述	包 装	认 证 号
CARE1986	透明防护面罩	10PCS/BOX 20BOXES/CARTON	NA

CAREABLE CERTIFICATE 公司证书

GB/T 19001-2016/ISO9001:2015

SGS FACTORY AUDI

SGS REACH TEST

EN149:2001+A1:2009

NB 2797

NB 2163

NB 0909

GB2626-2016

GB2626-2019

EN149:2001+A1:2009

GB38880-2020

GB32610 TYPE I,II,III,


























Care Able

CAREABLE
BIOTECHNOLOGY Co., Ltd



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

部分产品清单

认证标准	产品目录					
EN 149:2001+A1:2009 FFP2		CARE2006		CARE2006V		CARE1980V
		CARE002		CARE003		
EN 149:2001+A1:2009 FFP3		CARE2001		CARE1981V		CARE1986
		CARE1986V				
GB 2626-2016 GB 2626-2019		CARE006		CARE0913		
						
GB 32610-2006 TYPE I,II,III		CARE009P		CARE009		CARE001
		CARE008				
NIOSH		CARE1186		CARE1186V		CARE1518V
		CARE1518				
GB38880		CARE0961				



伏羲生物科技（广东）有限公司

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