CAREABLE
伏羲生物

公司简介
Company Profile

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

Welcome to CAREABLE

CAREABLE
伏羲生物

中国医药保健品进出口商会
非医用口罩白名单企业

取得国外标准认证或注册的非医用口罩生产企业清单

动态更新 日期：2020年6月12日 下载

序号	生产企业	统一社会信用代码	国外注册认证情况
151	伏羲生物科技（广东）有限公司 Careable Biotechnology Co.,Ltd.	91440700MA54BFN314	欧盟CE

双CE认证:
NB2163 B&C2
NB2797 B&C2

CAREABLE
伏羲生物

简介
About us

公司介绍：

伏羲生物料科技(广东)有限公司

CareAble Biotechnology Co., Ltd

是一家专业的民用防护口罩生产企业。我们拥有专业的技术人员， 先进的生产设备和监控测量设备。我们的产品:

CARE002 FFP2防护口罩取得欧盟NB2163, Module B+C2 CE 认证

CARE003 FFP2防护口罩取得欧盟NB2797, Module B+C2 CE 认证

CARE006 KN95防护口罩取得GB2626-2019 新国标认证.

我们目前拥有多条口罩生产线， 严格把控每批次的口罩的品质，坚持质量至上，为广大客户提供优质的产品和服务， 欢迎全球客商前来洽谈合作。

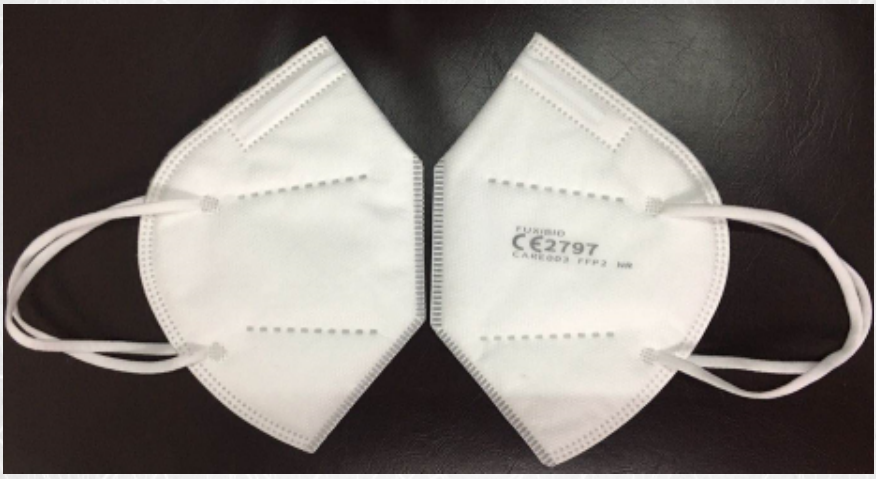
CAREABLE
伏羲生物

我们的产品
Our Product

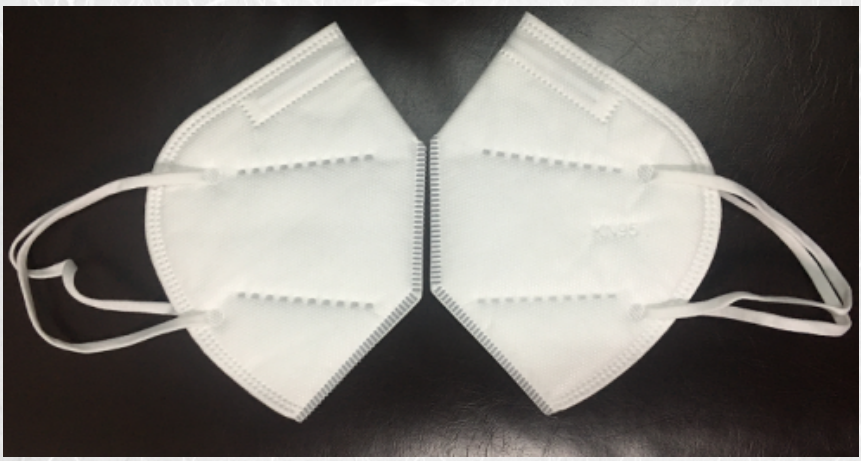
产品图片/Pictures

CARE002 FFP2

CARE003 FFP2



CARE006 KN95



CAREABLE
伏羲生物

营业执照
Business License

统一社会信用代码
91440700MA54BFN314

营业执照

(副 本) (副本号:1-1)

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　伏羲生物科技（广东）有限公司
类　　型　有限责任公司(自然人投资或控股)
法定代表人　谢英
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。）〓

注册资本　人民币伍佰万元
成立日期　2020年02月20日
营业期限　长期
住　　所　江门市宏兴路3号0幢（自编002）（信息申报制）

登记机关　江门市市场监督管理局

2020 年 3 月 25 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

CARE002 CE 2163 Module B

UNIVERSAL
CERTIFICATION
NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163 - PPE - 677

Respiratory protective devices, filtering half masks to protect against particles manufactured by

CAREABLE BIOTECHNOLOGY CO., LTD.

Building O, 3rd Hongxin Road, Jiangmen City, Guangdong, China

are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Model : CARE002
Filtering half mask
Total Inwards Leakage: Class – FFP2

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

This certificate is initially issued on **12 / 05 /2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE 2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - ISTANBUL - TURKEY T:+90 216 455 80 80
UNIVERSALCERT.COM

CARE002 CE 2163 Module C2

UNIVERSAL CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate No: 2163 - PPE – 677/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

CAREABLE BIOTECHNOLOGY CO., LTD.

Building O, 3rd Hongxin Road, Jiangmen City, Guangdong, China

Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial No.	Date	Issuing NB Nr.
CARE002	FFP2	2163-PPE-677	12.05.2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **12.05./2020** and will be valid for one year, until **11/05/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Umraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
UNIVERSALCERT.COM

CARE002 EN149测试报告
EN149：2001+A1:2009

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

CARE002 EN149测试报告
EN149：2001+A1:2009

Test Report

STFCE20200048 page 1 of 10

Product Name	CAREABLE Filtration Respirators	Specification Type	CARE002
		Trademark	——
Trust Unit	Careable Biotechnology Co., Ltd	Tel	——
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 陈敏 Examiner 杨森 Major tester 丁依

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

CARE002 EN149测试报告
EN149：2001+A1:2009

7.5 Material **Pass**[1]

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**[2]

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**[3]

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.

CARE002 EN149测试报告
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7.9.1 Total inward leakage **Pass**[4]

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***[5]

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%

Note6: Refer to Annex A for test data.

7.10 Compatibility with skin **Pass**[6]

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**[7]

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**[8]

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

Note9: Refer to Annex A for test data.

7.13 Head harness Pass[9]

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[10]

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[11]

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[12]

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.

CARE002 EN149测试报告
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7.17 Clogging N/A[13]

7.17.2 Breathing resistance N/A[13]

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[13]

Note14: Non-reusable respirator.

7.18 Demountable parts N/A[14]

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

Note15: No demountable parts.

CARE002 EN149测试报告
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Annex A: Summarization of Test Data

Clause		Result			Assessment
7.5	Material	Simulated wearing treatment	1#	No mechanical failure	Pass
			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	Pass
			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%	
		Temperature conditioned	14#	47 out of the 50 individual exercise results ≤11%	
			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%	
		Individual wearer arithmetic means			
		As received	9#	9 individual wearer arithmetic means≤ 8%	
			10#	9 individual wearer arithmetic means≤ 8%	
			11#	9 individual wearer arithmetic means≤ 8%	
			12#	9 individual wearer arithmetic means≤ 8%	
			13#	9 individual wearer arithmetic means≤ 8%	
		Temperature conditioned	14#	9 individual wearer arithmetic means≤ 8%	
			15#	9 individual wearer arithmetic means≤ 8%	
			16#	9 individual wearer arithmetic means≤ 8%	
			17#	9 individual wearer arithmetic means≤ 8%	
			18#	9 individual wearer arithmetic means≤ 8%	

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Clause		Result			Assessment
7.9.2	Penetration of filter material/%	Sodium chloride test(95L/min)			Pass
		As received	19#	0.81	
			20#	0.72	
			21#	0.76	
		Simulated wearing treatment	22#	0.89	
			23#	0.94	
			24#	0.97	
		M.S.+T.C.	25#	1.23	
			26#	1.31	
			27#	1.26	
		Paraffin oil test(95L/min)			
		As received	28#	1.68	
			29#	1.74	
			30#	1.79	
		Simulated wearing treatment	31#	1.88	
			32#	1.96	
			33#	1.92	
		M.S.+T.C.	34#	2.04	
			35#	2.18	
			36#	2.11	
7.10	Compatibility with skin	As received	9#	No irritation or any other adverse effect to health	Pass
			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	
		Temperature conditioned	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	
			17#	No irritation or any other adverse effect to health	
			18#	No irritation or any other adverse effect to health	
7.11	Flammability	As received	37#	Didn't burn	Pass
			38#	Didn't burn	
		Temperature conditioned	39#	Didn't burn	
			40#	Didn't burn	

CARE002 EN149测试报告
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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.			
		17#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		18#	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	As received	7#	Passed the practical performance tests		Pass
			8#	Passed the practical performance tests		

CARE002 EN149测试报告
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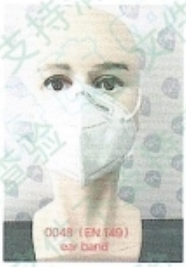
Clause		Result					Assessment
				Inhalation		Exhalation	
				30 l/min	95 l/min	160 l/min	
		As received					
7.16	Breathing resistance (mbar)	41#	A	0.3	0.9	1.4	Pass
			B	0.3	0.9	1.4	
			C	0.3	0.9	1.4	
			D	0.3	0.9	1.4	
			E	0.4	1.0	1.5	
		42#	A	0.3	0.9	1.4	
			B	0.3	0.9	1.4	
			C	0.4	0.9	1.5	
			D	0.3	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	

CARE002 EN149测试报告
EN149：2001+A1:2009

Clause		Result					Assessment
				Inhalation		Exhalation	
				30 l/min	95 l/min	160 l/min	
		Temperature conditioned					
7.16	Breathing resistance	47#	A	0.3	0.9	1.4	Pass
			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.

CARE003 CE2797-Module B

bsi.

bsi

EU Type Examination Certificate

This is to certify that:

Careable Biotechnology Co., Ltd
Building 0, no.3, Hongxing road
Jiangmen City (002)
Guangdong
China

Holds Certificate Number: CE 728685

In respect of:

Model CARE003 Particulate Respirator
To technical specification Annex II (EHSR) of the PPE Regulation (EU) 2016/425
PPE for use by healthcare professionals as per Commission recommendation 2020/403

on the basis that BSI carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

Previous Notified Body: BSI 0086

First Issued: 2020-06-09

Effective Date: 2020-06-09

Latest Issue: 2020-06-09

Expiry Date: 2021-06-09

PRODUCTS
RvA C 841

...making excellence a habit.™

CARE003 CE2797-Module B

EU Type Examination Certificate

No. CE 728685

Product Specification

Product Name:	Particulate Respirator.
Product Type:	Particulate filtering half masks for use by Healthcare professionals.
Model:	**CARE003.**
Classification:	FFP2 NR un-valved.
Technical Specification:	Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425.
Product Description:	The respirator is non-reusable, secured to the face of the user by a pair of elasticated ear straps, and has no exhalation valve. The respirator is FFP2 class, vertical fold flat type. The respirator listed on this certificate is for use by healthcare workers, first responders and other personnel involved in the efforts to contain the COVID-19 virus and avoid its further spread. The product covered by this certificate is not approved for industrial applications and the certificate is only valid as long as EU Commission recommendation sheet 2020/403 remains applicable.
Product Assessments:	BSI's PPE for Healthcare Professionals 2020/403 – RPE Technical Specification.

First Issued: 2020-06-09
Latest Issue: 2020-06-09

Effective Date: 2020-06-09
Expiry Date: 2021-06-09

CARE003 CE2797-
Module C2

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By Royal Charter

Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

This is to certify that:

Careable Biotechnology Co., Ltd
Building 0, no.3, Hongxing road
Jiangmen City (002)
Guangdong
China

Holds Certificate Number: CE 728686

In respect of:

For the manufacture of particulate respirators to technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425.

on the basis that BSI carried out the supervised production checks at random intervals under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex VII (Module C2)

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Drs. Dave Hagenaars, Managing Director

Previous Notified Body: BSI 0086
First Issued: 2020-06-09
Latest Issue: 2020-06-09

Effective Date: 2020-06-09
Expiry Date: 2021-06-09

RvA C 646 PRODUCTS

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CARE003 CE2797-Module C2

Conformity to Type based on Internal Production Control plus supervised product checks at random intervals

No. CE 728686

Product manufactured by:

Careable Biotechnology Co., Ltd.
Building 0, No. 3 Hongxing road
Jiangmen City
Guangdong
China

Product details

The respiratory protective device covered by the scope of this Module C2 Certificate and the Technical Specification to which the product is manufactured are as follows:

Product type:	Particulate filtering half masks for use by Healthcare professionals.
Model and classifications:	CARE003 FFP2 NR
Technical Specification:	Technical specification to satisfy Annex II of the PPE Regulation (EU) 2016/425. BSI's PPE for Healthcare Professionals 2020/103 – RPE Technical Specification.

First Issued: 2020-06-09
Latest Issue: 2020-06-09

Effective Date: 2020-06-09
Expiry Date: 2021-06-09

CARE003 BSI Testing Report EN149:2001+A1:2009

Test Report 3204582.

Careable Biotechnology Co., Ltd.

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CARE003 BSI Testing Report EN149:2001+A1:2009

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3204582 - Test Report.

Introduction.

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

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

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.

CARE003 BSI Testing Report EN149:2001+A1:2009

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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

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CARE003 BSI Testing Report EN149:2001+A1:2009

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3204582 - Test Report.

Test Requirements.

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

EN 149:2001+A1:2009 Performance requirement	EN 149:2001+A1:2009 Test method clause	Requirement	Assessment
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. *2 test subjects, masks tested 'As received'*	Testing shall be done in accordance with 8.4.	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.	Pass
7.9 Leakage **7.9.1 Total inward leakage** *5 test subjects, masks tested 'As received'*	Testing shall be done in accordance with 8.5.	All samples must achieve All individual exercise results tests shall be not greater than 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2)	Pass
7.9 Leakage **7.9.2 Penetration of filter material** *3 test samples masks tested 'As received', for NaCl (Sodium Chloride) and PO (Paraffin oil), 3min test*	Testing shall be done in accordance with 8.11	6% for both PO and NaCl	Pass
7.12 Carbon dioxide content of the inhalation air *3 test samples, masks tested 'As received'*	Testing shall be done in accordance with 8.7.	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).	Pass
7.16 Breathing resistance *3 test samples, masks tested 'As received'*	Testing shall be done in accordance with 8.9	The breathing resistances shall meet the requirements of; 30l/min – 0.7mbar (inhale) 95l/min – 2.4mbar (inhale) 160l/min – 3.0mbar (exhale)	Pass
Appendix A - Test Panel Data			
Product Photographs			

CARE003 BSI Testing Report EN149:2001+A1:2009

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3204582 - Test Report.

Glossary of Terms.

Pass: Complies. Tested by BSI engineers at BSI laboratories
Pass 1: Complies. Witnessed by BSI engineers in manufacturers laboratory.
Pass 2: Complies. Tests carried out by third party lab; results accepted by BSI.
Pass*: Report resulted in uncertainty and states that Compliance is more probable than non-compliance.
Fail: Non-compliance. Product does not meet the requirements of this clause.
Fail*: 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
SW: Simulated Wear
FT: Flow Tested
MS: Mechanical strength
MMDF: Manufactures Minimum Design Flow
MMDC: Manufactures Minimum Design Condition

Conditions of Issue.

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.

Should you wish to speak with BSI in relation to this report, please contact Customer Services on +44 (0)8450 80 9000.

BSI
Kitemark House
Maylands Avenue
Hemel Hempstead
Hertfordshire
HP2 4SQ

UKAS TESTING
0135

Opinions and Interpretations expressed herein are outside the scope of our UKAS accreditation.
Unless otherwise stated, any results not obtained from testing in a BSI laboratory are outside the scope of our UKAS accreditation.

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BSI Testing Report
EN149:2001+A1:2009

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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
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. Test in accordance with clause 8.4 of the standard. ***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.*	Pass

Table A: Practical performance

Test candidate	Sample	Comments				Assessment
		Head harness comfort	Security of fastenings	Field of vision	Any other comments	
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. ***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 11 % (for FFP2) and, in addition, all arithmetic means for the total inward leakage shall be not greater than 8 % (for FFP2).*	Pass

Table B: Clause 7.9.1 - Total inward leakage

Test candidate	Sample	Pre test condition	Inward Leakage (%)						Assessment
			A	B	C	D	E		
			Walking	Walking with head side to side	Walking with head up & down	Walking and talking	Walking	Average	
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

CARE003 BSI Testing Report
EN149:2001+A1:2009

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Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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 8.11. 6% 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_2 (%)	
		Limit	Measured
14	AR	< 1.0	0.43
15	AR		0.48
16	AR		0.41

CARE003 BSI Testing Report
EN149:2001+A1:2009

Test Results. (Continued)

CLAUSE	REQUIREMENTS	ASSESSMENT
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 (inhale), 95l/min – 2.4mbar (inhale), 160l/min – 3.0mbar (exhale)*	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

CARE003 BSI Testing Report
EN149:2001+A1:2009

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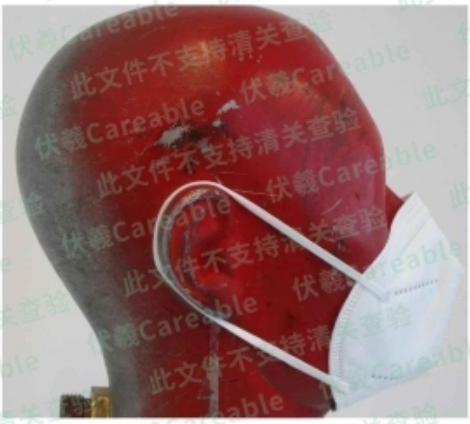
Appendix A. – Test Panel Data

Test Candidate	Facial Dimensions (mm)					Sex
	Length of face	Width of face	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

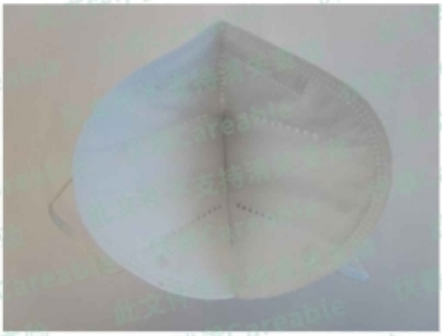
Note: All candidates were clean shaven

Product photographs.

Front view



Side View



Inside View

End of Report

CARE006 国标报告
GB2626-2006

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

170011263663 170011260277 (2017)国认监认字(100)号

中国认可 国际互认 检测 TESTING CNAS L0608

检验报告

CKTC-WT20035629

客户提供信息 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 江门市宏兴路3号0幢（自编002） Building 0,3rd, hongxing road, jiangmen city guangdong China 送样人: --- Contact 电话: Tel. ---
	生产单位/地址 Manufacturer	伏羲生物科技（广东）有限公司 Careable Biotechnology Co., Ltd 江门市宏兴路3号0幢（自编002） Building 0,3rd, hongxing road, jiangmen city guangdong China
	样品信息 Information of Submitted Sample	样品名称: 一次性KN95防护口罩 Sample Name KN95 FILTRATION RESPIRATORS 商标: FUXIBIO Trademark 样品总数: 90个 Sample Count 90Pieces 号型规格: CARE006 Size 颜色: ---------- Colour 质量等级: ---------- Quality Grade 安全类别: --- Safety 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). 检验单位盖章Stamp of Inspection Unit
非标准检验方法说明 Non-standard Check Methods		----------
检验结果的不确定度 Uncertainty of Result		----------
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.

贴 样 Sample Attached

Face side up

批准: Approver 审核: Checker 编制: Editor

CARE006 国标报告
GB2626-2006

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

170011263663 170011260277 (2017)国认监认字(100)号

中国认可 国际互认 检测 TESTING CNAS L0608

CKTC-WT20035629

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		
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 Component 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 Blow	°	≥35	61	符合 Pass	GB 2890-2009
	双目视野 Binocular View	%	≥65	≥65		

CARE006 国标报告
GB2626-2006

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

CKTC-WT20035629

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
Blank Part Below

CARE006 国标报告
GB2626-2006

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

170011263663 170011260277 (2017)国认监认字(100)号

中国认可 国际互认 检测 TESTING CNAS L0608

CKTC-WT20035629

样 品 Sample

CAREABLE
伏羲生物

对外贸易经营者备案登记表
Foreign Trade Registration

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负责人签字、盖章。

备案登记机关
签　章
2020 年 03 月 25 日

企业海关备案编码
Customs Register code

海关进出口货物收发货人备案回执

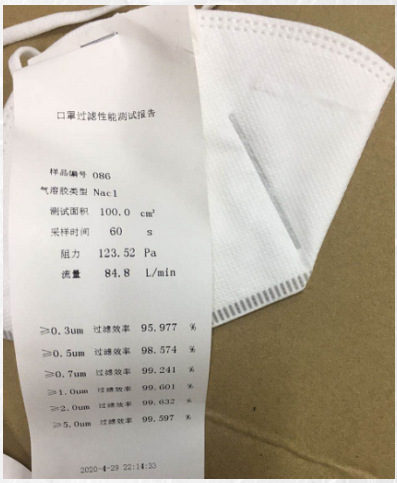
企业名称	伏羲生物科技（广东）有限公司
统一社会信用代码	91440700MA54BFN314
海关备案日期	2020-03-26
海关编码	4407961906
检验检疫备案号	5952100040
有效期	长期

中华人民共和国海关
高沙海关
进出口货物收发货人备案专用章
2020年3月26日

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

品质控制
Quality Control

Filter efficiency Tester



Inspection Instructions

Inspect instruction

ITEM No.	CARE002	Product	CAREABLE Filtration Respirators	File No.	FXQC-20005
Admit		R&D Dept.	QA Dept.	TAB	Date

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 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
	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 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	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) Hydropphilia(Inner ply)	Drop water	0：OK 1:reject	5pieces/lot
	Respiratory resistance	Water flow:95 L/min	DMS-GL37	0：OK 1:reject	9pieces/lot
		1. inhale≤400Pa exhale≤400Pa			
		2. inhale≤500Pa	DMS-GL37	0：OK	12pieces/lot

Inspect instruction

				1:reject	
	Penetrate efficiency	≤5%	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	Customer complaint	Mender

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

包装图
Packaging

CARE002 #1 Packaging:

package	pcs/ctn	CTN dimension (cm)			G.W/ctn (kg)	CBM per ctn
		L	W	H		
1pc per bag; 20 bags per box (18x10xH12.5cm) ; 50 boxes per carton	1000	57	38	64.5	13.00	0.140

包装图
Packaging

CARE002 #2 Packaging:

package	pcs/ctn	CTN dimension (cm)			G.W/ctn (kg)	CBM per ctn
		L	W	H		
5pcs per bag; 200bags per carton	1000	70	40	40	9.5	0.112

包装图
Packaging

CARE003 #1 Packaging:

package	pcs/ctn	CTN dimension (cm)			G.W/ctn (kg)	CBM per ctn
		L	W	H		
1pc per bag; 20 bags per box (18x10xH12.5cm) ; 50 boxes per carton	1000	57	38	64.5	13.00	0.140

包装图
Packaging

CARE003 #2 Packaging:

package	pcs/ctn	CTN dimension (cm)			G.W/ctn (kg)	CBM per ctn
		L	W	H		
5pcs per bag; 200bags per carton	1000	70	40	40	9.5	0.112

谢谢观看

THANK YOU