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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

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 丁欣

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.

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.

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.

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%	

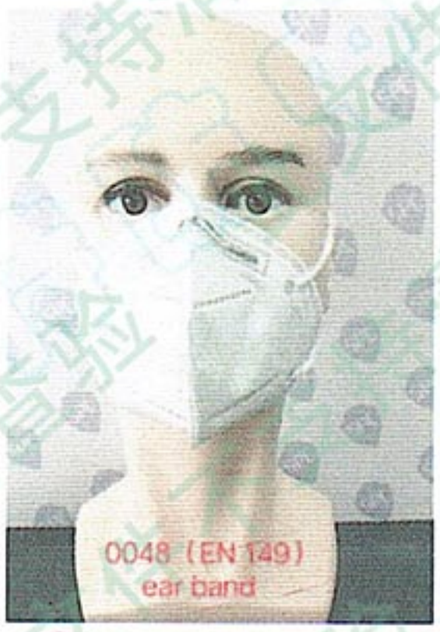
Clause		Result			Assessment
7.9.2	Penetration of filter material/%	Sodium chloride test(95L/min)			Pass
		As received	19#	0.81	
			20#	0.72	
			21#	0.76	
		Simulated wearing treatment	22#	0.89	
			23#	0.94	
			24#	0.97	
		M.S.+T.C.	25#	1.23	
			26#	1.31	
			27#	1.26	
		Paraffin oil test(95L/min)			
		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	

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		

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	

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



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