



中国认可  
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检测  
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CNASL0354

# TEST REPORT



**Report No.: JKF20022835R2**

**Applicant : CareAble Biotechnology Co.,Ltd**

**Zhejiang Academy of Science and Technology for Inspection and Quarantine**

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Report date: 2020-11-17

The information are provided by client(applicant):				
Sample Information	Sample Name:	Filtering half mask		
	Style No.:	CARE1988		
	Size:	CARE1988		
	Brand:	FUXIBIO		
Customer Information	Applicant:	CareAble Biotechnology Co.,Ltd		
	Address:	Building O, no.3, hongxing road, jiangmen city (002)		
	Manufacturer:	CareAble Biotechnology Co.,Ltd		
	Manufacturer address:	Building O, no.3, hongxing road, jiangmen city (002)		
The information are confirmed by testing organization:				
Test Information	Date of sample received:	2020-10-19	Testing period:	2020-10-19 to 2020-10-23
	Quantity:	110 Pieces		
	Sample description:	White mask		
	Basis of judgment:	EN 149:2001+A1:2009 FFP3 NR Respiratory protective devices—Filtering half masks to protect against particles —Requirements, testing, marking		
Test Conclusion	The items tested meet the requirements of EN 149:2001+A1:2009 FFP3 NR			
Test Result	Please refer to next pages.			
Remark	This report (which has modified Brand 、Address and Manufacturer address) is to replace the original report (report number JKF20022835R1 issued on 2020-10-26), the original report also void.			

Edit:

Ye yiwen

Sign:

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**Test Results:****Clause 7.5 Material**

(EN 149:2001+A1:2009 Clause 8.2 &amp; 8.3.1 &amp; 8.3.2)

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

**Clause 7.6 Cleaning and disinfecting**

(EN 149:2001+A1:2009 Clause 8.4 &amp; 8.5 &amp; 8.11)

Requirement	Results	Rating
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. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	Not applicable (Not designed to be re-usable)	N/A

**Clause 7.7 Practical performance**

(EN 149:2001+A1:2009 Clause 8.4)

Requirement	Results	Rating
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.	No imperfections	Pass

**Clause 7.8 Finish of parts**

(EN 149:2001+A1:2009 Clause 8.2)

Requirement	Results	Rating
Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs	Pass



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**Clause 7.9.1 Total inward leakage**

(EN 149:2001+A1:2009 Clause 8.5)

Requirement	Results	Rating
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: 25% for FFP1, 11% for FFP2, 5% for FFP3 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	47 out of the 50 individual exercise $\leq 5\%$ 8 out of the 10 individual wearer arithmetic means $\leq 2\%$	Pass

Table 7.9.1-A Inward leakage test data

Subject	Sample No.	Condition	Walk (%)	Head side/side (%)	Head up/down (%)	Talk (%)	Walk (%)	Mean (%)
TLB	1	As received	1.288	1.074	1.126	1.224	1.766	1.296
TY	2		1.284	1.065	1.154	5.362	0.764	1.926
HML	3		0.954	0.988	1.147	1.346	0.687	1.024
LJF	4		0.708	1.124	1.176	2.154	0.587	1.150
CQQ	5		1.524	1.145	1.654	1.789	1.654	1.553
WLJ	6	Temperature conditioned	0.698	0.875	1.547	5.987	2.456	2.312
ZJH	7		0.897	0.756	0.642	1.175	0.689	0.832
RK	8		1.623	1.347	1.176	5.988	1.548	2.336
ZD	9		0.687	0.578	0.645	1.023	0.668	0.720
WG	10		1.623	1.325	1.524	1.347	1.587	1.481

Table 7.9.1-B Facial dimensions

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
TLB	125	152	111	57
TY	126	124	95	54
HML	124	130	115	55
LJF	125	135	90	55
CQQ	136	167	125	65
WLJ	132	159	110	60
ZJH	122	150	104	50
RK	112	161	146	50
ZD	116	160	115	55
WG	120	152	109	57





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**Clause 7.9.2 Penetration of filter material**

(EN 149:2001+A1:2009 Clause 8.11 &amp; EN 13274-7:2019)

Requirement			Results	Rating
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.			Detail refer to Table 7.9.2	Pass
Classification	Sodium chloride test 95 L/min	Paraffin oil test 95 L/min		
FFP1	≤20%	≤20%		
FFP2	≤6%	≤6%		
FFP3	≤1%	≤1%		

Table 7.9.2 Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
Sodium chloride test	As received	11	0.001
		12	0.001
		13	0.001
	Simulated wearing treatment	14	0.001
		15	0.002
		16	0.002
	Mechanical strength+ Temperature conditioned	17	0.007
		18	0.010
		19	0.013
Paraffin oil test	As received	20	0.001
		21	0.001
		22	0.001
	Simulated wearing treatment	23	0.002
		24	0.002
		25	0.002
	Mechanical strength+ Temperature conditioned	26	0.017
		27	0.025
		28	0.027
Flow conditioning: single filter: 95.0 L/min			

**Clause 7.10 Compatibility with skin**

(EN 149:2001+A1:2009 Clause 8.4 &amp; 8.5)

Requirement	Results	Rating
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.	No irritation or any other adverse effect to health	Pass



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**Clause 7.11 Flammability**

(EN 149:2001+A1:2009 Clause 8.6)

Requirement	Results	Rating
When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5s after removal from the flame.	Detail refer to Table 7.11	Pass

Table 7.11 Flammability

Condition	Sample No.	Result
As received	29	Not burn
	30	Not burn
Temperature conditioned	31	Not burn
	32	Not burn

**Clause 7.12 Carbon dioxide content of the inhalation air**

(EN 149:2001+A1:2009 Clause 8.7)

Requirement	Results	Rating
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume).	Detail refer to Table 7.12	Pass

Table 7.12 Carbon dioxide content of the inhalation air

Condition	Sample No.	Result (%)
As received	33	0.94
	34	0.90
	35	0.92
		Mean value: 0.9

**Clause 7.13 Head harness**

(EN 149:2001+A1:2009 Clause 8.4 &amp; 8.5)

Requirement	Results	Rating
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 total inward leakage requirements for the device.	Comply	Pass

**Clause 7.14 Field of vision**

(EN 149:2001+A1:2009 Clause 8.4)

Requirement	Results	Rating
The field of vision is acceptable if determined so in practical performance tests.	Comply	Pass





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**Clause 7.15 Exhalation valve**

(EN 149:2001+A1:2009 Clause 8.2 &amp; 8.9.1 &amp; 8.3.4 &amp; 8.8)

Requirement	Results	Rating
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.	Not applicable (No exhalation valve)	N/A

**Clause 7.16 Breathing resistance**

(EN 149:2001+A1:2009 Clause 8.9)

Requirement				Results	Rating				
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.				Detail refer to Table 7.16	Pass				
						Classification	Maximum permitted resistance (mbar)		
							Inhalation		Exhalation
							30L/min	95L/min	160L/min
						FFP1	0.6	2.1	3.0
						FFP2	0.7	2.4	3.0
						FFP3	1.0	3.0	3.0

Table 7.16 Breathing resistance (mbar)

Test item	Condition	Sample No.	A	B	C	D	E
Inhalation (30 L/min)	As received	36	0.69	0.69	0.69	0.68	0.69
		37	0.68	0.68	0.69	0.68	0.68
		38	0.68	0.68	0.68	0.67	0.68
	Simulated wearing treatment	39	0.68	0.67	0.67	0.68	0.68
		40	0.68	0.69	0.69	0.68	0.69
		41	0.70	0.70	0.69	0.70	0.69
	Temperature conditioned	42	0.63	0.63	0.63	0.63	0.63
		43	0.62	0.62	0.62	0.62	0.62
		44	0.62	0.63	0.63	0.63	0.63



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Test item	Condition	Sample No.	A	B	C	D	E
Inhalation (95 L/min)	As received	36	2.53	2.52	2.53	2.53	2.54
		37	2.53	2.52	2.53	2.54	2.52
		38	2.54	2.52	2.53	2.53	2.52
	Simulated wearing treatment	39	2.49	2.51	2.50	2.51	2.50
		40	2.51	2.52	2.49	2.50	2.52
		41	2.63	2.62	2.62	2.63	2.63
	Temperature conditioned	42	2.16	2.17	2.17	2.17	2.16
		43	2.17	2.15	2.17	2.16	2.14
		44	2.16	2.17	2.16	2.17	2.17
Exhalation (160 L/min)	As received	36	2.97	2.94	2.96	2.97	2.95
		37	2.93	2.90	2.92	2.89	2.90
		38	2.90	2.90	2.87	2.92	2.91
	Simulated wearing treatment	39	2.90	2.88	2.84	2.87	2.88
		40	2.83	2.85	2.89	2.90	2.85
		41	2.87	2.89	2.91	2.90	2.88
	Temperature conditioned	42	2.79	2.77	2.74	2.79	2.80
		43	2.82	2.81	2.79	2.80	2.79
		44	2.77	2.79	2.80	2.82	2.81

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

#### Clause 7.17 Clogging

(EN 149:2001+A1:2009 Clause 8.9 &amp; 8.10)

Requirement	Results	Rating
<b>7.17.2 Breathing resistance:</b> <b>7.17.2.1 Valved particle filtering half masks</b> After clogging the inhalation resistances shall not exceed FFP1:4mbar, FFP2:5mbar, FFP3:7mbar at 95 L/min continuous flow; The exhalation resistance shall not exceed 3mbar at 160 L/min continuous flow. <b>7.17.2.2 Valveless particle filtering half masks</b> After clogging the inhalation and exhalation resistances shall not exceed FFP1:3mbar, FFP2:4mbar, FFP3:5mbar at 95 L/min continuous flow. <b>7.17.3 Penetration of filter material:</b> All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements given in 7.9.2, for the Penetration test according to EN 13274-7, after the clogging treatment.	Not applicable (Single shift use only)	N/A

#### Clause 7.18 Demountable parts

(EN 149:2001+A1:2009 Clause 8.2)

Requirement	Results	Rating
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	Comply	Pass





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Sample photo



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

## STATEMENT

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