

# TEST REPORT



**Report No.: JKF20034101**

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

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

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Report No. : JKF20034101

Report date: 2020-12-08

The information are provided by client(applicant):				
Sample Information	Sample Name:	Filtering half mask		
	Style No.:	Care0961K		
	Brand:	Fuxi Care		
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:	2020-12-02	Testing period:	2020-12-02 to 2020-12-08
	Quantity:	70 Pieces		
	Sample description:	White mask		
	Basis of judgment:	EN 149:2001+A1:2009 FFP2 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 FFP2 NR			
Test Result	Please refer to next pages.			
Remark	/			

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## Test Results:

### Clause 7.5 Material

( EN 149:2001+A1:2009 Clause 8.2 & 8.3.1 & 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 & 8.5 & 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

**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	46 out of the 50 individual exercise $\leq$ 11% 8 out of the 10 individual wearer arithmetic means $\leq$ 8%	Pass

Table 7.9.1-A Inward leakage test data

Subject	Sample No.	Condition	Walk (%)	Head side/side (%)	Head up/down (%)	Talk (%)	Walk (%)	Mean (%)
CQQ	1	As received	6.915	7.814	7.415	10.251	7.314	7.942
WLJ	2		5.617	6.810	6.091	10.991	6.591	7.220
WG	3		9.415	10.615	10.364	15.361	11.947	11.540
ZJH	4		6.954	7.941	6.519	8.915	6.487	7.363
TLB	5		5.619	6.415	7.006	10.935	7.641	7.523
ZMY	6	Temperature conditioned	8.614	6.817	7.015	9.718	6.691	7.771
LJF	7		10.574	9.609	11.569	18.841	10.694	12.257
HML	8		6.481	6.552	7.138	9.891	6.947	7.402
RK	9		5.369	6.814	7.136	10.364	8.314	7.599
ZD	10		4.369	5.147	5.618	9.617	6.108	6.172

Table 7.9.1-B Facial dimensions

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
CQQ	136	167	125	65
WLJ	132	159	110	60
WG	120	152	109	57
ZJH	122	150	104	50
TLB	125	152	111	57
ZMY	137	150	120	60
LJF	125	135	90	55
HML	124	130	115	55
RK	112	161	146	50
ZD	116	160	115	55

**Clause 7.9.2 Penetration of filter material**

( EN 149:2001+A1:2009 Clause 8.11 & 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	0.250
		12	0.078
		13	0.077
	Simulated wearing treatment	14	0.112
		15	0.065
		16	0.038
	Mechanical strength+ Temperature conditioned	17	0.750
		18	0.415
		19	0.492
Paraffin oil test	As received	20	1.768
		21	3.810
		22	3.353
	Simulated wearing treatment	23	1.817
		24	3.995
		25	2.617
	Mechanical strength+ Temperature conditioned	26	5.827
		27	5.526
		28	5.931

Flow conditioning: single filter: 95.0 L/min

**Clause 7.10 Compatibility with skin**

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

**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	0.26
	34	0.29
	35	0.28
		Mean value: 0.28

**Clause 7.13 Head harness**

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

**Clause 7.15 Exhalation valve**

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

Requirement	Results	Rating
<p>A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.</p> <p>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.</p> <p>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.</p> <p>When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.</p>	Not applicable (No exhalation valve)	N/A

**Clause 7.16 Breathing resistance**

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

Requirement	Results	Rating																						
<p>The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.</p> <table border="1" data-bbox="263 1064 1021 1317"> <thead> <tr> <th rowspan="3">Classification</th> <th colspan="3">Maximum permitted resistance (mbar)</th> </tr> <tr> <th colspan="2">Inhalation</th> <th>Exhalation</th> </tr> <tr> <th>30L/min</th> <th>95L/min</th> <th>160L/min</th> </tr> </thead> <tbody> <tr> <td>FFP1</td> <td>0.6</td> <td>2.1</td> <td>3.0</td> </tr> <tr> <td>FFP2</td> <td>0.7</td> <td>2.4</td> <td>3.0</td> </tr> <tr> <td>FFP3</td> <td>1.0</td> <td>3.0</td> <td>3.0</td> </tr> </tbody> </table>	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	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	0.48	0.47	0.49	0.48	0.48
		37	0.49	0.48	0.47	0.48	0.48
		38	0.49	0.50	0.49	0.49	0.49
	Simulated wearing treatment	39	0.47	0.48	0.47	0.47	0.48
		40	0.48	0.47	0.48	0.48	0.48
		41	0.49	0.48	0.49	0.47	0.49
	Temperature conditioned	42	0.45	0.45	0.45	0.45	0.44
		43	0.45	0.44	0.45	0.44	0.44
		44	0.44	0.44	0.43	0.43	0.43

Test item	Condition	Sample No.	A	B	C	D	E
Inhalation (95 L/min)	As received	36	1.73	1.74	1.75	1.73	1.74
		37	1.75	1.75	1.76	1.77	1.75
		38	1.75	1.77	1.76	1.75	1.76
	Simulated wearing treatment	39	1.72	1.73	1.72	1.71	1.72
		40	1.74	1.75	1.74	1.74	1.73
		41	1.74	1.74	1.75	1.76	1.75
	Temperature conditioned	42	1.68	1.67	1.67	1.66	1.67
		43	1.67	1.66	1.67	1.66	1.65
		44	1.64	1.63	1.63	1.65	1.66
Exhalation (160 L/min)	As received	36	2.28	2.29	2.28	2.30	2.30
		37	2.29	2.30	2.31	2.30	2.30
		38	2.30	2.29	2.32	2.32	2.31
	Simulated wearing treatment	39	2.26	2.29	2.27	2.26	2.25
		40	2.25	2.23	2.24	2.26	2.25
		41	2.29	2.27	2.30	2.28	2.27
	Temperature conditioned	42	2.14	2.13	2.13	2.14	2.15
		43	2.13	2.14	2.15	2.16	2.15
		44	2.11	2.10	2.11	2.12	2.12

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 & 8.10)

Requirement	Results	Rating
<p><b>7.17.2 Breathing resistance:</b></p> <p><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.</p> <p><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.</p> <p><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.</p>	Optional for single shift device only	Not required

**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



### Sample photo



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

## STATEMENT

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