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TEST REPORT

Particulate respirator-half facepiece

EN 149: 2001 +A1: 2009 Respiratory protective devices — Filtering half masks to protect against particles —
Requirements, testing, marking

Product:

Respiratory Protective Mask

Report No:

2020 (D) - 0768T

Client:

Guangdong GangRong Medical Technology Co., Ltd.

Model (s):

GR200

Date(s) of tests:

2020.05.16-2020.05.30

DESCRIPTION OF SAMPLES

General Information

Classification

Main Components White cup mask

Manufacturer

FFP2 NR

Manufacturer Address

Guangdong GangRong Medical Technology Co., Ltd.

Floor 2, Block 13, Building 2, No. 68, Zhenxing Road, Dabu Village, Sanxiang Town,

Zhongshan City

Signed:

陈倬为 Chen Zhuowei

Authorized Signatory, Lab Director

Issued: 2020.5.30

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Conditions:

The test results presented in this report relate to the samples tested only.

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The authenticity of this test report and its contents can be verified by contacting the laboratory.

Note. This test report is the replacement and cancellation for test report No. 2020 (D) - 0768.

Test Results

7.3 Visual inspection Not tested¹

The visual inspection shall include the marking and information supplied by the manufacturer.

Notel: As requested by the client, marking and information supplied by the manufacturer was not inspected.

7.4 Package Pass²

Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.

Note2: In accordance with the requirement.

7.5 Material Pass

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.

Note3: No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2.

7.6 Cleaning and disinfecting

N/A4

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.

Note4: Single shift use only.

7.7 Practical performance

Page5

The particle filtering half mask shall undergo practical performance tests under realistic conditions. Note5: No imperfections.

7.8 Finish of parts

Pass6

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

Note6: No sharp edges or burrs.

7.9.1 Total inward leakage

Pass7

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

Note7: FFP2 respirator. Test results are shown in Annex A Table 7.9.1-A&B.

7.9.2 Penetration of filter material

Pass8

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

Sodium chloride test 95 l/min

Paraffin oil test 95 l/min

FFP1

≤20%

≤20%

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FFP2

≤6%

≤6%

FFP3

≤1%

≤1%

Note8: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.

7.10 Compatibility with skin

Pass'

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.

Note9: No irritation or any other adverse effect to health.

7.11 Flammability

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.

Note10: Test results are shown in Annex A Table 7.11.

7.12 Carbon dioxide content of the inhalation air

Pass11

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume) Note11: Test results are shown in Annex A Table 7.12.

7.13 Head harness

Pass12

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. Note12: Head harness can be donned and removed easily, adjustable or self-adjusting and have sufficiently robust to hold the particle filtering half mask firmly.

7.14 Field of vision

The field of vision is acceptable if determined so in practical performance tests.

Note13: Pass the practical performance tests.

7.15 Exhalation valve

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.

Note14: No exhalation valve.

7.16 Breathing resistance

Pass15

Classification 30 l/min	Ma Ma	aximum permitted resistance (mba	ar)		
	Inhalati	on	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		

Note15: FFP2 respirator. Test results are shown in Annex A Table 7.16.

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7.17 Clogging

N/A16

7.17.2 Breathing resistance

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

Soc	dium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	€20%	≤20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%
Note16: Single	shift use only.	

7.18 Demountable parts

Pass¹⁷

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand Note17: In accordance with the requirement.

9 Marking

Not tested

9.1 Packaging

The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.

- 9.1.1 The name, trademark or other means of identification of the manufacturer or supplier.
- 9.1.2 Type-identifying marking.
- 9.1.3 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

- 9.1.4 The number and year of publication of this European Standard.
- 9.1.5 At least the year of end of shelf life. The end of shelf life may be informed by a pictogram as shown in Figure 12a, where yyyy/mm indicates the year and month.
- 9.1.6 The sentence 'see information supplied by the manufacturer', at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.
- 9.1.7 The manufacturer's recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.
- **9.1.8** The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D". This letter shall follow the classification marking preceded by a single space.

9.2 Particle filtering half mask

Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:

9.2.1 The name, trademark or other means of identification of the manufacturer or supplier.

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9.2.2 Type-identifying marking.

- 9.2.3 The number and year of publication of this European Standard.
- 9.2.4 Classification

The appropriate class (FFP1, FFP2 or FFP3) followed by a single space and then: "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D.

- 9.2.5 If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the classification marking preceded by a single space
- 9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

End of Test Results

Annex A: Summarization of Test Data

Table 7.9.1-A Inward leakage test data

Test specification: EN 149-2001 Clause 8.5

Sample No.	- I ODGILLOD WGHKI VAI		Head up/down(%)	Talk(%)	Walk(%)	Mean(%)		
1	A.R.	8.25	8.77	8.70	8.37	8.42	8.5 6.6	
2	A.R.	6.48	6.59	6.78	6.84	6.55		
3	A.R.	5.97	5.98	6.31	6.19	6.31	6.2	
4	A.R.	9.03	9.32	9.30	9.33	9.46	9.3	
5	A.R.	6.89	7.37	7.22 6.91		7.12	7.1	
6	T.C.	6.34	6.91	6.39	6.48 7.14	6.44 7.51	6.5	
7	T.C.	7.11	7.56	7.23			7.3	
8	T.C.	7.00	7.14	7.19 7.18		7.22	7.1	
9	T.C.	7.12	7.20	7.29	7.32	7.31	7.2	
10	T.C.	7.04	7.15	7.31	7.41	7.31	7.2	
	No. 1 2 3 4 5 6 7 8 9	No. Condition 1 A.R. 2 A.R. 3 A.R. 4 A.R. 5 A.R. 6 T.C. 7 T.C. 8 T.C. 9 T.C.	No. Condition Walk(%) 1 A.R. 8.25 2 A.R. 6.48 3 A.R. 5.97 4 A.R. 9.03 5 A.R. 6.89 6 T.C. 6.34 7 T.C. 7.11 8 T.C. 7.00 9 T.C. 7.12	No. Condition Walk(%) Side/side(%) 1 A.R. 8.25 8.77 2 A.R. 6.48 6.59 3 A.R. 5.97 5.98 4 A.R. 9.03 9.32 5 A.R. 6.89 7.37 6 T.C. 6.34 6.91 7 T.C. 7.11 7.56 8 T.C. 7.00 7.14 9 T.C. 7.12 7.20	No. Condition Walk(%) Side/side(%) up/down(%) 1 A.R. 8.25 8.77 8.70 2 A.R. 6.48 6.59 6.78 3 A.R. 5.97 5.98 6.31 4 A.R. 9.03 9.32 9.30 5 A.R. 6.89 7.37 7.22 6 T.C. 6.34 6.91 6.39 7 T.C. 7.11 7.56 7.23 8 T.C. 7.00 7.14 7.19 9 T.C. 7.12 7.20 7.29	No. Condition Walk(%) Side/side(%) up/down(%) Talk(%) 1 A.R. 8.25 8.77 8.70 8.37 2 A.R. 6.48 6.59 6.78 6.84 3 A.R. 5.97 5.98 6.31 6.19 4 A.R. 9.03 9.32 9.30 9.33 5 A.R. 6.89 7.37 7.22 6.91 6 T.C. 6.34 6.91 6.39 6.48 7 T.C. 7.11 7.56 7.23 7.14 8 T.C. 7.00 7.14 7.19 7.18 9 T.C. 7.12 7.20 7.29 7.32	No. Condition Walk(%) Side/side(%) up/down(%) Talk(%) Walk(%) 1 A.R. 8.25 8.77 8.70 8.37 8.42 2 A.R. 6.48 6.59 6.78 6.84 6.55 3 A.R. 5.97 5.98 6.31 6.19 6.31 4 A.R. 9.03 9.32 9.30 9.33 9.46 5 A.R. 6.89 7.37 7.22 6.91 7.12 6 T.C. 6.34 6.91 6.39 6.48 6.44 7 T.C. 7.11 7.56 7.23 7.14 7.51 8 T.C. 7.00 7.14 7.19 7.18 7.22 9 T.C. 7.12 7.20 7.29 7.32 7.31	

Table 7.9.1-B Facial dimension

Subject	Face length	Face Width	Face Depth	Mouth Width		
Yi	> 120	130	109	59		
Gong	122	140	115	65		
Yu	119	160	139	55		
Hu	112	122	119	- 63		
Xu	Xu 110 130		118	60		
Deng	115	119	110	59		
Zhang	112	123	113	55		
Liu	103	130	100	50		
Zhi	118	139	130	63		
Fang	115	129	120	50		
Chen	116	150	132	56		
Lv	110	121	110	53		

Table -7.9.2 Penetration of filter material

Test specification: EN 149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment		
		11	0.084			
	As received	eceived 12				
TEXT !	TEVI .	13	0.097			
2/	- HERV	14	0.185	19		
	Simulated wearing treatment	15	0.246	-1/8		
		16	0.229			
Mecha		17	0.411			
	Mechanical strength+ Temperature conditioned	18	0.374	16 K		
	表 ()	19	0.462	12/2		
Sodium chloride test Mechanical Paraffin oil test Mechanical	387	20	0.945	Pass		
	As received	21	1.09			
		22	0.997	1		
		23	1.24			
	Simulated wearing treatment	24	1.41			
		25	1.55	3,5		
		26	1.72	,		
	Mechanical strength+ Temperature conditioned	27	1.98			
	2/4	28	2.24	35		

Table 7.11 Flammability

Test specification: EN 149-2001 Clause 8.6

Condition	Condition Sample No. Result						
87.	29	Burn for 1 s	7.				
As received 30	30	Burn for 1 s					
Temperature	31	Burn for 1 s	Pass				
conditioned	32	Burn for 1 s	- 6				

Table 7.12 Carbon dioxide content of the inhalation air

Test specification: EN 149-2001 Clause 8.7

Condition	Sample No.	Resi	Assessment	
	33	0.43%	2	
As received	34	0.43%	Mean value 0.4%	Pass
	35	0.46%	美色八	

Table 7.16 Breathing resistance (mbar)

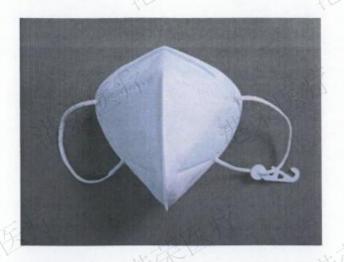
Test specification: EN 149-2001 Clause 8.9

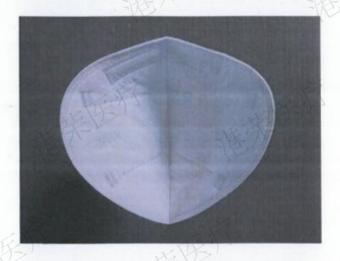
7 -	Flow rate				36	0	CK.	37				25	K.	38			
			A	В	C	D	E	Α	В	C	D	E	A	В	C	D	E
As received	101 100	30 1/min	0.4	0.6	0.6	0.5	0.4	0.5	0.6	0.6	0.5	0.5	0.4	0.5	0.6	0.6	0.5
	Inhalation	95 1/min	1.7	1.8	2.0	1.9	1.7	1.8	1.8	2.0	2.0	1.9	1.8	1.8	2.1	2.0	1.9
	Exhalation	160 l/min	2.1	2.1	2.3	2.2	2.1	2.1	2.2	2.4	2.3	2.2	2.2	2.2	2.4	2.4	2.1
Simulated wearing treatment					39			40				41					
	Flow rate	rate	A	В	C	D	Е	A	В	C	D	E	A	В	С	D	E
	Inhalation	30 l/min	0.5	0.5	0.6	0.6	0.6	0.5	0.6	0.6	0.5	0.5	0.4	0.5	0.6	0.6	0.5
		95 1/min	1.8	2.0	2.0	1.9	1.8	1.7	2.0	2.1	2.0	1.9	1.8	1.9	2.1	2.0	1.8
255	Exhalation	160 l/min	2.1	2.3	2.4	2.2	2.2	2.3	2.3	2.5	2.4	2.2	2.2	2.2	2.4	2.4	2.1
200	Flow rate		42				43				44 - /						
T	Flow	rate	A	В	С	D	E	A	В	C	D	E	Α	В	C	D	E
Temperature conditioned	Tub detion	30 1/min	0.5	0.6	0.6	0.5	0.5	0.4	0.5	0.6	0.6	0.5	0.5	0.5	0.6	0.5	0.5
conditioned	Inhalation	95 l/min	1.8	2.0	2.1	2.0	1.8	1.9	1.9	2.1	2.0	2.0	1.8	1.9	2.1	2.0	1.9
	Exhalation	160 l/min	2.2	2.3	2.5	2.4	2.1	2.3	2.2	2.4	2.4	2.3	2.2	2.2	2.5	2.4	2.3
Assessment		21		24						Pass							

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



ANNEX B PHOTOS OF SAMPLES







End of Annex B

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国家劳动保护用品属量监督检验中心(北京)