

National Quality Supervision and Testing Center for Personal Protective Equipment (Beijing)

No.55 Taoranting Street, Xicheng District, Beijing, China. Phone: +86 10 63519250

Phone: +86 10 63519250 Fax: +86 10 63519250

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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

Report No: 2014-W-191

Client: Polygard (Zhangzhou) PPE CO., Ltd.

Contact: Ye Xiaolin

Model (s): 8200

Date(s) of tests: 2014.9.20-2014.10.31

DESCRIPTION OF SAMPLES

General Information Model Main Components
8200 Cup-shaped respirator body

Manufacturer Polygard (Zhangzhou) PPE CO., Ltd.

Manufacturer Address Inner Dashijie Logistics Center, Pinghe County, Zhangzhou City, Fujian Province, China.

Signed: Issued: 2014.11.5

杨文芬 Yang Wenfen Authorized Signatory, Lab Director

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Test Results

7.3 Visual inspection

Pass¹

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

Note1: The visual inspection was carried out as per required by the standard.

7.4 Package

Pass

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.

7.5 Material

Pass²

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^3

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

Pass⁴

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

FFP3

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

Pass⁵

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

Note5: Refer to Annex A for test data.

7.9.2 Penetration of filter material

Pass⁶

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

Sodium chloride test 95 l/min

FFP1 $\leq 20\%$ FFP2 $\leq 6\%$

≤1%

Paraffin oil test 95 l/min ≤20%

≤6% ≤6% ≤1%

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Note6: Refer to Annex A for test data.

7.10 Compatibility with skin

Pass⁷

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

Pass⁸

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

Pass⁹

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume) **Note9: Refer to Annex A for test data.**

7.13 Head harness Pass¹⁰

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.

Note10: Refer to Annex A for test data.

7.14 Field of vision Pass¹¹

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

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

Pass¹³

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.

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7.17 Clogging N/A¹⁴

7.17.2 Breathing resistance

Pass

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

Pass

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	€20%	€20%
FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note14: Non-reusable respirator.

7.18 Demountable parts

N/A¹⁵

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand **Note15: No demountable parts.**

9 Marking Pass

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.

10 Information to be supplied by the manufacturer

Pass

- 10.1 Information supplied by the manufacturer shall accompany every smallest commercial available package.
- **10.2** Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.
- 10.3 The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on

application/limitations;

the meaning of any colour coding;

checks prior to use;

donning, fitting;

use:

maintenance (e.g. cleaning, disinfecting), if applicable;

storage;

the meaning of any symbols/pictograms used

- **10.4** The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.
- 10.5 Warning shall be given against problems likely to be encountered, for example:

fit of particle filtering half mask (check prior to use);

it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal; air quality (contaminants, oxygen deficiency);

use of equipment in explosive atmosphere.

10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded.

10.7 For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift.

End of Test Results

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Annex A: Summarization of Test Data

Clause		Result				
		Simulated	1#	No mechanical failure		
		wearing	2#	No mechanical failure		
7.5	Material	treatment	3#	No mechanical failure	Pass	
1.5	Material	Temperature	4#	No mechanical failure	1 ass	
		conditioned	5#	No mechanical failure		
		conditioned	6#	No mechanical failure		
7.9	Practical	1#		No mechanical defect	Pass	
	performance	2#		No mechanical defect	1 455	
			1 1	Individual exercise result	1	
			9# 47 out of the 50 individual exercise results $\leq 11\%$			
			10#	48 out of the 50 individual exercise results $\leq 11\%$		
		As received	11#	47 out of the 50 individual exercise results $\leq 11\%$		
			12#	47 out of the 50 individual exercise results $\leq 11\%$		
			13#	47 out of the 50 individual exercise results ≤ 11%	1	
			14#	48 out of the 50 individual exercise results ≤ 11%		
			15#	46 out of the 50 individual exercise results ≤ 11%		
		Temperature	16#	46 out of the 50 individual exercise results \le 11%	1	
		conditioned	17#	47 out of the 50 individual exercise results $\leq 11\%$	1	
	m . 1.		18#		+	
7.9.1	Total inward		11	47 out of the 50 individual exercise results ≤ 11%	Pass	
	leakage			ividual wearer arithmetic means	-	
			9#	9 individual wearer arithmetic means≤ 8%	-	
		As received	10#	9 individual wearer arithmetic means≤ 8%		
			yed 11# 9 individual wearer arithmetic means≤ 8%			
			12#	9 individual wearer arithmetic means≤ 8%		
			13#	8 individual wearer arithmetic means≤ 8%		
			14#	8 individual wearer arithmetic means≤ 8%	1	
		15# 8 individual wearer arithmetic means < 8%				
		Temperature	16#	9 individual wearer arithmetic means≤ 8%		
		conditioned	17#	9 individual wearer arithmetic means≤ 8%	-	
			18#	8 individual wearer arithmetic means \$ 8%	-	
			11			
			19#	Sodium chloride test(95L/min) 1.27%	-	
					-	
		As received	20#	1.42%	-	
			21#	1.51%	4	
		Simulated	19#	1.49%		
		wearing	20#	1.51%]	
		treatment	21#	1.19%		
			25#	1.49%		
		M.S+T.C	26#	1.51%		
	Penetration of		27#	1.62%] _	
7.9.2	filter material			Paraffin oil test(95L/min)	Pass	
			28#	1.81%		
		As received	29#	1.92%	1	
		115 Total (cd	30#	1.87%	1	
		~	31#		1	
		Simulated	-	1.72%	_	
		wearing treatment	32#	1.69%	-	
		пеаннени	33#	1.79%		
			34#	1.91%	1	
		M.S+T.C	35#	1.82%]	
	1		36#	1.79%	I	

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Clause		Result					Assessment		
				9#	No irritation or any other adverse effect to health				
				10#	No	irritation or any other	r adverse effect to health		
		As rec	As received		No	irritation or any other	r adverse effect to health		
				12#	No	No irritation or any other adverse effect to health			
7.10	Compatibility			13#	No	irritation or any other	r adverse effect to health	Pass	
7.10	with skin			14#	No	irritation or any other	r adverse effect to health	1 433	
		Tempe	ratura	15#	No	irritation or any other	r adverse effect to health		
		condit		16#	No	irritation or any other	r adverse effect to health		
				17#		•	r adverse effect to health		
				18#	No		r adverse effect to health		
		As rec	eived	37#		Didn'			
7.11	Flammability			38#		Didn'		Pass	
		Tempe		39#		Didn'		1 433	
		condit	ioned	40#		Didn'	t burn		
	Carbon dioxide		1			As received			
7.12	content of the	1#		2#		3#	Mean value	Pass	
	inhalation air	0.4%		0.5%		0.4%	0.4%		
						As received			
		9#	Head harness can be donned and removed easily, adjustable and						
		9#	have sufficiently robust to hold the particle filtering half mask firmly.						
		10#	Head harness can be donned and removed easily, adjustable and						
		10//	have sufficiently robust to hold the particle filtering half mask firmly.						
		11#		ad 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						
7.13	Head harness	have sufficiently robust to hold the particle filtering half mask firmly.						Pass	
			Temperature conditioned						
		14#					ed easily, adjustable and		
							e filtering half mask firmly. ed easily, adjustable and		
		15#							
			have sufficiently robust to hold the particle filtering half mask firmly. Head harness can be donned and removed easily, adjustable and						
		16#	have sufficiently robust to hold the particle filtering half mask firmly.						
			Head harness can be donned and removed easily, adjustable and						
		17#	have sufficiently robust to hold the particle filtering half mask firmly.						
		104	Head harness can be donned and removed easily, adjustable and						
		18#	have sufficiently robust to hold the particle filtering half mask firmly.						
7 14	Eigld of white	1#			Passe	d the practical perfor	mance tests	D.	
7.14	Field of vision	2#			Passe	d the practical perfor	mance tests	Pass	

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Clause				Resu	Assessment			
				Inhal	lation	Exhalation		
				30L/min	95L/min	160L/min		
				_				
			A	0.3mbar	1.2mbar	0.6mbar		
			В	0.3mbar	1.2mbar	0.6mbar		
		1#	C	0.3mbar	1.3mbar	0.7mbar		
			D	0.2mbar	1.3mbar	0.6mbar		
			E	0.3mbar	1.2mbar	0.6mbar		
			A	0.3mbar	1.2mbar	0.6mbar		
			В	0.3mbar	1.2mbar	0.7mbar		
		2#	C	0.4mbar	1.3mbar	0.6mbar		
			D	0.4mbar	1.3mbar	0.6mbar		
			E	0.3mbar	1.3mbar	0.6mbar		
			A	0.3mbar	1.2mbar	0.6mbar		
		41#	В	0.3mbar	1.2mbar	0.6mbar	Pass	
	Breathing		C	0.3mbar	1.2mbar	0.6mbar		
7.16			D	0.3mbar	1.2mbar	0.6mbar		
7.10	resistance		E	0.3mbar	1.2mbar	0.6mbar		
			Simulated wearing treatment					
			A	0.4mbar	1.2mbar	1.3mbar		
			В	0.4mbar	1.2mbar	1.3mbar		
		42#	C	0.4mbar	1.2mbar 1.3mba	1.3mbar		
				D	0.3mbar	1.2mbar	1.3mbar	
			E	0.4mbar	1.3mbar	1.3mbar		
			A	0.4mbar	1.2mbar	1.2mbar		
			В	0.4mbar	1.2mbar	1.2mbar		
		43#	C	0.4mbar	1.3mbar	1.2mbar		
			D	0.4mbar	1.2mbar	1.2mbar		
			E	0.3mbar	1.2mbar	1.3mbar		
			A	0.4mbar	1.2mbar	1.3mbar		
			В	0.4mbar	1.2mbar	1.3mbar		
		44#	C	0.4mbar	1.3mbar	1.3mbar		
			D	0.3mbar	1.2mbar	1.3mbar		
			E	0.3mbar	1.2mbar	1.3mbar		

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Cl	ause			Assessment			
					Inhalation Exhalation		
				30L/min	95L/min	160L/min	
			A	0.3mbar	1.2mbar	1.3mbar	
			В	0.3mbar	1.1mbar	1.3mbar	
		45#	C	0.3mbar	1.2mbar	1.3mbar	
			D	0.3mbar	1.3mbar	1.3mbar	
			E	0.3mbar	1.2mbar	1.3mbar	
			A	0.3mbar	1.2mbar	1.3mbar	
			В	0.3mbar	1.2mbar	1.3mbar	
		46#	C	0.3mbar	1.2mbar	1.3mbar	
			D	0.3mbar	1.2mbar	1.3mbar	
			E	0.3mbar	1.2mbar	1.3mbar	
			A	0.3mbar	1.2mbar	1.2mbar	
			В	0.3mbar	1.3mbar	1.3mbar	
		47#	C	0.3mbar	1.3mbar	1.3mbar	
			D	0.3mbar	1.3mbar	1.3mbar	
			E	0.3mbar	1.2mbar	1.3mbar	
	Breathing						
7.16	resistance		A	0.3mbar	bar 1.2mbar 1.3mbar	1.3mbar	Pass
		48#	В	0.3mbar	1.2mbar	1.3mbar	
			C	0.3mbar	1.2mbar	1.3mbar	
			D	0.3mbar	1.2mbar	1.3mbar	
			E	0.3mbar	1.2mbar	1.3mbar	
			A	0.4mbar	1.2mbar	1.3mbar	
			В	0.4mbar	1.3mbar	1.3mbar	
		49#	C	0.3mbar	1.3mbar	1.3mbar	
			D	0.3mbar	1.3mbar	1.3mbar	
			E	0.3mbar	1.3mbar	1.2mbar	
			A	0.3mbar	1.3mbar	1.3mbar	
		50#	В	0.3mbar	1.2mbar	1.3mbar	
			C	0.3mbar	1.2mbar	1.3mbar	
			D	0.3mbar	1.2mbar	1.3mbar	
			E	0.3mbar	1.3mbar	1.3mbar	
		A: facing direct B: facing verti C: facing verti D: lying on the E: lying on the	cally upw cally dow e left side	vards vnwards			

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ANNEX B PHOTOS OF SAMPLES





End of Annex B