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国检检测
CHINA COMPONENTS TEST

Test Report

Report No.: [2020] WSZ FHL NO.7298

Product Name Filtering half mask

Applicant Zhende Medical Co.,Ltd.

Manufacturer Zhende Medical Co.,Ltd.

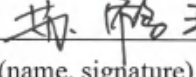
Test Type Entrusted inspection

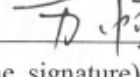
Jiangsu Guojian Testing Technology Co., Ltd.
3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China

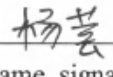


Test Report

Product name	Filtering half mask	Model name	ZD-001 11CM*16CM
		Brand	ZD
Laboratory/ Add.	Jiangsu Guojian Testing Technology Co., Ltd./ 3/F., Unit D, Xingye Building, Taihu International Tech-Park, Wuxi, Jiangsu, China		
Applicant/ Add/Tel	Zhende Medical Co.,Ltd./Gaobu Town, 312035, Shaoxing City, Zhejiang Province, China/18658517065		
Manufacturer/ Add/Tel	Zhende Medical Co.,Ltd./Gaobu Town, 312035, Shaoxing City, Zhejiang Province, China/18658517065		
Sample classification	FFP2	Sample number	GW7298-2020
Sample quantity	100 pcs	Date of receipt of sample	22/07/2020
Test type	Entrusted inspection	Article/Batch/Style number	20200717
Date (s) of performance of tests	25/07/2020~05/08/2020	Testing location	Same as the Laboratory
Sample state	Meeting the requirements of testing	Sample description	Refer to page 3
Test standard(s)	EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking		
Test items	Material, practical performance, finish of parts, compatibility with skin, flammability, carbon dioxide content of the inhalation air, head harness, field of vision, penetration of filter material, breathing resistance, total inward leakage		
Test conclusion	The samples upon testing comply with FFP2 classification requirements according to the standard EN 149:2001+A1:2009. The details of test results see on Pages 3-11. Date of issue: 06/08/2020		
Note	The test results presented in this report relate only to the submitted sample as received.		

Su Hequn 
Approver (name, signature)

Wan Heng 
Reviewer (name, signature)

Yang Ying 
Chief Tester (name, signature)

Sample description:	White, the filtering half mask is C-shaped, used to protect against particles, both solid and liquid aerosols
Test item particulars:	
Type of use	<input type="checkbox"/> re-useable particle filtering half mask <input checked="" type="checkbox"/> single shift only particle filtering half mask
Classes of devices.....	<input type="checkbox"/> FFP1 <input checked="" type="checkbox"/> FFP2 <input type="checkbox"/> FFP3
Exhalation valve(s).....	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Inhalation valve(s).....	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Designed to protect against both solid & liquid aerosols. :	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
Possible test case verdicts:	
- Test case does not be required to the test object.....: NRq (Not required)	
- Test case does not apply to the test object.....: N/A (Not Applicable)	
- Test object does meet the requirement.....: P (Pass)	
- Test object does not meet the requirement.....: F (Fail)	
General remarks:	
The test results presented in this report relate only to the submitted sample as received.	
This report shall not be reproduced, except in full, without the written approval of the issuing Laboratory can provide assurance that parts of a report are not taken out of context.	
Determination of the test results includes consideration of measurement uncertainty from the test equipment and methods.	
Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	
Environmental condition of the testing in this report:	
1) Unless otherwise specified, the ambient temperature for testing shall be 25 °C;	
2) T.C. Temperature conditioned:	
a) for 24 h to a dry atmosphere of 70 °C; b) for 24 h to a temperature of -30 °C;	
and return to room temperature 25 °C for 4 h between exposures and prior to subsequent testing.	

S.No. (Cl.No.)	Test item		Unit	Technical requirements	Test result	Single item decision
1 (7.3)	Visual inspection	Marking/ information	—	Marking and the information supplied by the manufacturer, requirements refer to Cl.9 and Cl.10	The clause were not required	NRq
2 (7.4)	Packaging	Visual inspection	—	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.	The clause were not required	NRq
3 (7.5)	Material	Visual inspection	—	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.	Materials were suitable withstand handling and wear.	Pass
			—	After undergoing S.W., none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.	Sample 1: neither facepiece nor straps have mechanical failure	
			—		Sample 2: neither facepiece nor straps have mechanical failure	
			—		Sample 3: neither facepiece nor straps have mechanical failure	
			—	After undergoing S.W. and T.C., none of the particle filtering half masks shall not collapse.	Sample 4: no collapse	
			—		Sample 5: no 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.	Sample 6: no collapse				
—		Not constitute a hazard or nuisance for the wearer				
4 (7.6)	Cleaning and disinfecting	—	Particle filtering half mask designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. Testing shall be done in accordance with 8.4 and 8.5.	<input type="checkbox"/> Fulfil the requirements after testing, or <input checked="" type="checkbox"/> The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer	N/A	
		—	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. Testing shall be done in accordance with 8.11.	<input type="checkbox"/> Tests results refer to S. No. 7(7.9.2), or <input checked="" type="checkbox"/> The Particle filtering half mask is NOT re-usable according to information supplied by manufacturer		

S.No. (Cl.No.)	Test item	Unit	Technical requirements	Test result	Single item decision		
5 (7.7)	Practical performance	Head harness comfort	—	Head harness should be comfort.	Sample 1: has the feeling of comfortable wearing	Pass	
					Sample 2: has the feeling of comfortable wearing		
		Security of fastenings	—	Fastenings are safe and reliable	Sample 1: All fastenings are firm		
					Sample 2: All fastenings are firm		
		Field of vision	—	Field of vision is acceptable	Sample 1: Having a wider visual field		
					Sample 2: Having a wider visual field		
6 (7.8)	Finish of parts	Visual inspection	—	Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.	Parts of the device have no sharp edges and burrs	Pass	
7 (7.9.2)	Leakage— Penetration of filter material	Sodium chloride	—	$\leq 6\%$	A.R. ¹⁾ 0.1% 0.1% 0.2%	Pass	
					S.W. ¹⁾ 0.1% 0.1% 0.1%		
					M.S+ T.C. ²⁾ 0.3% 0.4% 0.3%		
		Paraffin oil	—	$\leq 6\%$	A.R. ¹⁾ 0.1% 0.1% 0.1%	Pass	
					S.W. ¹⁾ 0.2% 0.1% 0.1%		
					M.S+ T.C. ²⁾ 0.4% 0.4% 0.3%		
		¹⁾ average penetration over a time of 30s, beginning 3 min after the start of the test reported ²⁾ max. penetration during exposure test reported; Note: The penetration of the filter of the particle filtering half mask shall meet the requirements below: Maximum penetration of sodium chloride aerosol test 95 L/min max. FFP1: 20%, FFP2: 6%, FFP3: 1% Maximum penetration of paraffin oil aerosol test 95 L/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%					

S.No. (Cl.No.)	Test item	Unit	Technical requirements	Test result		Single item decision
8 (7.10)	Compatibility with skin	—	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.	A.R.	5 pcs all don't cause irritation	Pass
				T.C.	5 pcs all don't cause irritation	
9 (7.11)	Flammability	—	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.	A.R.	The Sample is burning. Burning time:0.4s	Pass
					The Sample is burning. Burning time:0.5s	
				T.C.	The Sample is burning. Burning time:0.4s	
					The Sample is burning. Burning time:0.5s	
10 (7.12)	Carbon dioxide content of the inhalation air	—	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume). Remark: 3 half masks (S1, S2 and S3) A.R. tested.	Sample 1	0.7031%	Pass
				Sample 2	0.7015%	
				Sample 3	0.7023%	
				average	0.70%	
11 (7.13)	Head harness	—	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.	A.R.	All of 5 pieces particle filtering half mask meet the requirements	Pass
				T.C.	All of 5 pieces particle filtering half mask meet the requirements	
12 (7.14)	Field of vision	—	The field of vision is acceptable if determined so in practical performance tests.	The two samples both have a wider visual field		Pass

S.No. (Cl.No.)	Test item	Unit	Technical requirements	Test result	Single item decision
13 (7.15)	Exhalation valve(s)	—	A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	No exhalation valve(s)	N/A
			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.	No exhalation valve(s)	
			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.	No exhalation valve(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.	No exhalation valve(s)	
14 (7.17)	Clogging— Breathing resistance & Penetration of filter material	—	Optional for single shift use devices, mandatory for re-usable devices. Tested by Cl. 7.17.1/2/3.	<input type="checkbox"/> Tests results refer to Table C&D, or <input checked="" type="checkbox"/> Tests not requested for single shift use face mask	N/A
15 (7.18)	Demountable parts	—	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	No demountable parts	N/A

Table A- Leakage—Total Inward Leakage

S.No. (Cl.No.)	Test item	Unit	Technical requirements ¹⁾	Test result						Single item decision	
				Exercises	E1 (%)	E2 (%)	E3 (%)	E4 (%)	E5 (%)		TIL (%)
16 (7.9.1)	Leakage— Total inward leakage	—	At least 46 out of the 50 individual exercise results shall be not greater than 11% ; And in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 8% .	A.R.	5.8	6.4	6.6	6.7	6.0	6.3	Pass
					5.4	6.1	6.2	6.5	5.7	6.0	
					5.3	6.0	6.1	6.0	5.6	5.8	
					6.1	6.6	6.7	7.0	6.3	6.5	
					5.5	6.3	6.5	6.7	5.9	6.2	
				T.C.	6.2	6.8	6.9	6.8	6.4	6.6	
					5.9	6.7	6.8	6.9	6.4	6.5	
					6.1	7.1	7.0	7.0	6.5	6.7	
					6.2	6.8	6.9	7.0	6.2	6.6	
					6.0	6.5	6.9	6.9	6.2	6.5	

Note 1:
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
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.

Table A-1- Test subjects—Facial dimension

Test Subject No.	Length of face (mm)	Width of face (mm)	Depth of face (mm)	Width of mouth (mm)
1	120	130	109	59
2	122	140	115	65
3	119	160	139	55
4	112	122	119	63
5	110	130	118	60
6	115	119	110	59
7	112	123	113	55
8	103	130	100	50
9	118	139	130	63
10	120	135	125	50

Table B- Breathing Resistance

S.No (CLNo.)	Test item		Unit	Technical requirements ¹⁾	Test result					Single item decision	
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side		Lying on the right side
17 (7.16)	Breathing resistance	Inhalation 30 L/min	mbar	≤ 0.7	A.R.	0.5	0.5	0.6	0.5	0.5	Pass
						0.5	0.5	0.6	0.6	0.5	
						0.5	0.5	0.6	0.5	0.5	
					S.W.	0.5	0.5	0.5	0.5	0.5	
						0.6	0.5	0.5	0.5	0.5	
						0.5	0.5	0.6	0.5	0.5	
		T.C.		0.5	0.5	0.5	0.6	0.6			
				0.5	0.6	0.6	0.6	0.6			
				0.6	0.6	0.6	0.6	0.6			
		Inhalation 95 L/min		A.R.	1.6	1.5	1.5	1.6	1.5	Pass	
					1.6	1.6	1.6	1.6	1.6		
					1.6	1.5	1.5	1.6	1.6		
	S.W.		1.6	1.5	1.5	1.6	1.6				
			1.6	1.5	1.6	1.5	1.6				
			1.5	1.5	1.5	1.5	1.5				
	T.C.		1.6	1.5	1.6	1.5	1.5				
			1.6	1.5	1.5	1.5	1.5				
			1.6	1.5	1.6	1.5	1.6				
	Exhalation 160 L/min	A.R.	2.6	2.5	2.5	2.5	2.6	Pass			
			2.4	2.5	2.5	2.5	2.4				
			2.5	2.4	2.4	2.5	2.5				
S.W.		2.6	2.5	2.5	2.6	2.5					
		2.6	2.5	2.5	2.6	2.6					
		2.6	2.5	2.6	2.5	2.6					
T.C.		2.6	2.5	2.6	2.5	2.5					
		2.5	2.5	2.5	2.6	2.6					
		2.5	2.6	2.6	2.5	2.5					

Note 1: Limitation may need be changed according to classification, refer to Table 2 — Breathing resistance of EN 149:2001 +A1:2009 for the Technical requirements.

Table C- Clogging Test—Breathing resistance

S.No (Cl.No)	Test item ¹⁾²⁾		Unit	Technical requirements ¹⁾²⁾ (mbar)	Test result						Single item decision
					Exercises	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	
18 (7.17)	Clogging test—	Inhalation 95 L/min	mbar	—	A.R.						N/A
					T.C.						
	Breathing resistance	Exhalation 95 L/min	mbar	—	A.R.						N/A
					T.C.						

Note 1: Valved particle filtering half masks

After clogging the inhalation resistances shall not exceed FFP1: 4 mbar FFP2: 5 mbar FFP3: 7 mbar at 95 L/min continuous flow;
The exhalation resistance shall not exceed 3 mbar at 160 L/min continuous flow.

Note 2: 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 95 L/min continuous flow.

Table D- Clogging Test—Penetration of filter material

S.No (Cl.No)	Test item	Unit	Technical requirements	Test result		Single item decision
19 (7.17)	Clogging test- Penetration of filter material	Paraffin oil	—	—	A.R. T.C. T.C.	N/A

Note: Maximum penetration of test aerosol test 95 L/min max. FFP1: 20%, FFP2: 6%, FFP3: 1%

Abbreviations :

A.R. As received

M.S. Mechanical strength

S.W. Simulated wearing treatment

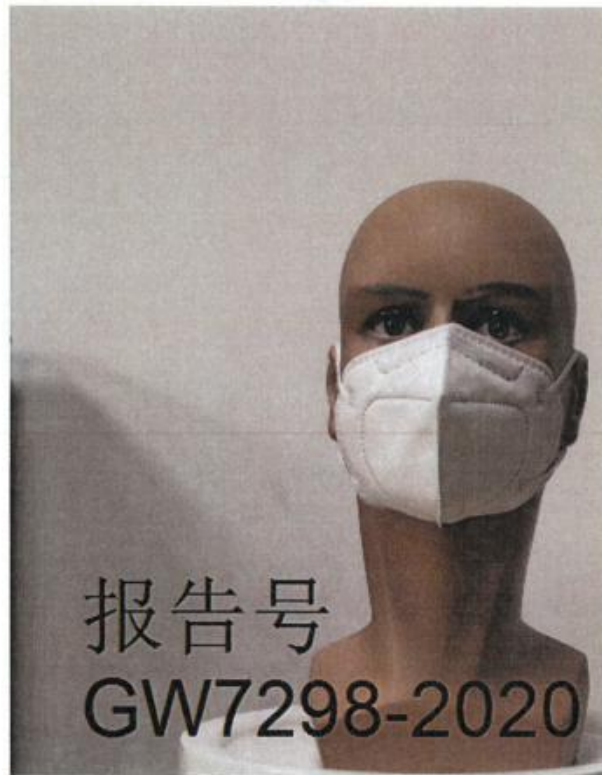
T.C. Temperature conditioned

F.C. Flow conditioned

C.D. Cleaning and Disinfecting

Annex A- Estimates of the uncertainty of measurement

Test item	Uncertainty
Total inward leakage	2.98%
Penetration of filter material	1.00%
Flammability	1.00%
Carbon dioxide content of the inhalation air	0.93%
Breathing resistance	1.90%

Annex B- Sample Photo

The end