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CNAS L5772

Test Report

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

Product: Fish-shaped Filtering half mask
Report No.: PTC20110406301C-EN01V01
Client: Dongguan Meio Medical Technology Co.,Ltd
Client Address: Room 901,unit 1,no.3 Huaide Songgang Industrial Zone,Humen Town,Dongguan,Guangdong Province
Manufacturer: Dongguan Meio Medical Technology Co.,Ltd
Manufacturer Address: No.7, Fazhan Road, Mowu village, Dongguan City, Guangdong Province
Contact: Mrs. Abby
Model(s): MY-002
Classification: FFP2 NR
Date of Tests: 2020.11.17~2020.11.24

Signed for and on Behalf of PTC

Prepare by:

Checked by:

Approved by:

Arme

Jue

Jim Mo



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Test Report

Report No.:PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 2 of 15

Summary of assessment

Clause	Assessment
7.3 Visual inspection	NOT TESTED
7.4 Packaging	PASS
7.5 Material	PASS
7.6 Cleaning and disinfecting	N/A
7.7 Practical performance	PASS
7.8 Finish of parts	PASS
7.9.1 Total inward leakage	PASS
7.9.2 Penetration of filter material	PASS
7.10 Compatibility with skin	PASS
7.11 Flammability	PASS
7.12 Carbon dioxide content of the inhalation air	PASS
7.13 Head harness	PASS
7.14 Field of vision	PASS
7.15 Exhalation valve	N/A
7.16 Breathing resistance	PASS
7.17 Clogging	N/A
7.18 Demountable parts	PASS
9 Marking	NOT TESTED

Remark:

PASS: comply with requirement of standard
N/A: not application
NOT TESTED: the clause were not required

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Test Report

Report No.:PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 3 of 15

Test Result:

Requirement	Test Result	Conclusion
7.3 Visual inspection The visual inspection shall also include the marking and the information supplied by the manufacturer.	Not tested	Not tested
7.4 Packaging 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.	In accordance with the requirement.	Pass
7.5 Material 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.	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.	Pass
7.6 Cleaning and disinfecting 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.	Single shift use only	N/A
7.7 Practical performance The particle filtering half mask shall undergo practical performance tests under realistic conditions	No imperfections	Pass
7.8 Finish of parts 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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Test Report

Report No.:PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 4 of 15

7.9.1 Total inward leakage

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

FFP2, Test results are shown in Annex A Table 7.9.1-A&B **Pass**

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.

7.9.2 Penetration of filter material

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%
FFP2	≤ 6%	≤ 6%
FFP3	≤ 1%	≤ 1%

FFP2, Test results are shown in Annex A Table 7.9.2. **Pass**

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.

No irritation or any other adverse effect to health. **Pass**

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.

Test results are shown in Annex A Table 7.11. **Pass**

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)

Test results are shown in Annex A Table 7.12. **Pass**

7.13 Head harness

The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.

Head harness can be donned and removed easily, adjustable or self-adjusting and **Pass**

The head harness shall be adjustable or self-adjusting and shall be

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Test Report

Report No.:PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 5 of 15

sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

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.

Pass the practical performance tests.

Pass

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.

No exhalation valve

N/A

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.

7.16 Breathing resistance

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

FFP2. Test results are shown in Annex A Table 7.16.

Pass

7.17 Clogging

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

Single shift use only.

N/A

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Test Report

Report No.:PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 6 of 15

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

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

7.18 Demountable parts

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand

Comply

Pass

9 Marking

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.

Not tested

Not tested

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

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Test Report

Report No.:PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 7 of 15

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.

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.

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Test Report

Report No.:PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 8 of 15

Annex A: Summarization of Test Data

Table 7.9.1-A: Inward Leakage Test Data

Test specification: EN 149:2001+A1:2009 Clause 8.5

Subject	Sample No.	Condition	Walk (%)	Head Side/side (%)	Head up/down (%)	Talk (%)	Walk (%)	Mean (%)
Lv	1	A.R	2.6	3.0	3.0	3.3	4.2	3.2
Li	2	A.R	6.5	7.2	5.8	7.2	6.5	6.6
Zhong	3	A.R	4.8	6.4	6.1	5.5	6.9	5.9
Xu	4	A.R	3.4	4.3	5.7	6.4	5.4	5.0
Ma	5	A.R	3.5	2.4	3.6	3.4	1.4	2.9
Chen	6	T.C	2.6	3.7	3.6	3.7	4.4	3.6
Chen	7	T.C	4.4	4.2	3.8	3.8	3.3	3.9
Zhuo	8	T.C	1.7	2.2	2.6	3.0	2.8	2.5
Chen	9	T.C	4.4	6.7	1.8	4.1	6.0	4.6
Zhang	10	T.C	1.1	0.7	4.6	6.5	3.5	3.3

Table 7.9.1-B: Facial dimension

Subject	Face Length	Face Width	Face Depth	Mouth Width
Lv	113	139	104	53
Li	120	135	112	55
Zhong	108	135	106	56
Xu	120	150	120	70
Ma	130	170	130	80
Chen	110	160	90	40
Chen	115	145	110	50
Zhuo	103	146	100	50
Chen	110	145	95	40
Zhang	144	141	101	54

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Test Report

Report No.:PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 9 of 15

Table 7.9.2: Penetration of filter material

Test specification: EN 149:2001+A1:2009 Clause 8.11

Aerosol	Condition	Sample No.	Penetration (%)	Assessment
Sodium chloride test	As received	11	0.1	Pass
		12	0.1	
		13	0.1	
	Simulated wearing treatment	14	0.1	
		15	0.1	
		16	0.1	
	Mechanical strength + Temperature conditioned	17	0.1	
		18	0.3	
		19	0.2	
Paraffin oil test	As received	20	0.3	
		21	0.2	
		22	0.2	
	Simulated wearing treatment	23	0.3	
		24	0.2	
		25	0.4	
	Mechanical strength + Temperature conditioned	26	0.5	
		27	0.6	
		28	0.6	

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Test Report

Report No.:PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 10 of 15

Table 7.11: Flammability

Test specification: EN 149:2001+A1:2009 Clause 8.6

Condition	Sample No.	Result	Assessment
As received	29	No burn	Pass
	30	No burn	
Temperature conditioned	31	No burn	
	32	No burn	

Table 7.12: Carbon dioxide content of the inhalation air

Test specification: EN 149:2001+A1:2009 Clause 8.7

Condition	Sample No.	Result (%)		Assessment
As received	33	0.02	Mean value: 0.02	Pass
	34	0.02		
	35	0.02		

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Test Report

Report No.: PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 11 of 15

Table 7.16: Breathing resistance (mbar)

Test specification: EN 149:2001+A1:2009 Clause 8.9

As received	Flow Rate		36					37					38				
	Inhalation	30 l/min	0.16					0.18					0.15				
		95 l/min	0.67					0.66					0.65				
Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
		1.10	1.08	1.07	1.08	1.07	1.07	1.06	1.06	1.05	1.05	1.08	1.07	1.07	1.08	1.09	
Simulated wearing treatment	Flow Rate		39					40					41				
	Inhalation	30 l/min	0.20					0.21					0.20				
		95 l/min	0.74					0.75					0.75				
Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
		1.12	1.12	1.13	1.12	1.12	1.12	1.11	1.15	1.12	1.12	1.14	1.13	1.13	1.13	1.11	
Temperature conditioned	Flow Rate		42					43					44				
	Inhalation	30 l/min	0.17					0.19					0.19				
		95 l/min	0.66					0.71					0.72				
Exhalation	160 l/min	A	B	C	D	E	A	B	C	D	E	A	B	C	D	E	
		1.11	1.11	1.09	1.10	1.11	1.15	1.14	1.14	1.15	1.15	1.15	1.14	1.16	1.15	1.17	
Assessment	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

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Test Report

Report No.:PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 12 of 15

Test	Uncertainty
Total inward leakage	3.8%
Penetration of filter material(NaCl)	3.5%
Penetration of filter material(Paraffin oil)	4.2%
Carbon dioxide content of the inhalation air	4.5%
Breathing resistance(30L/min)	5.2%
Breathing resistance(95L/min)	5.4%
Breathing resistance(160)L/min)	6.0%

Remark: This report supersedes all previous documents bearing the test report number PTC20110406301C-EN01. Report number PTC20110406301C-EN01 was invalid.

Amendments to report

Version	Date of issue	Changes
PTC20110406301C-EN01V01	2020.11.30	Manufacturer Address

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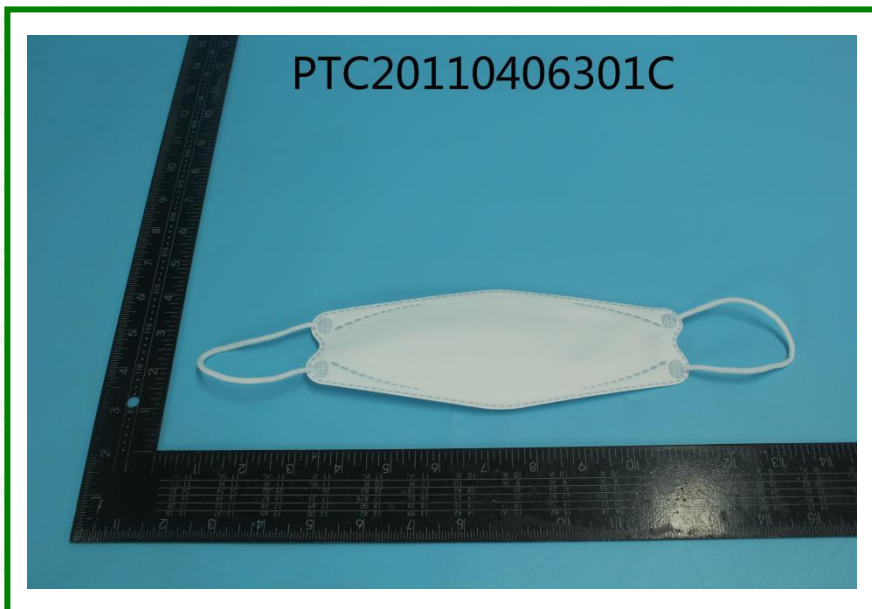
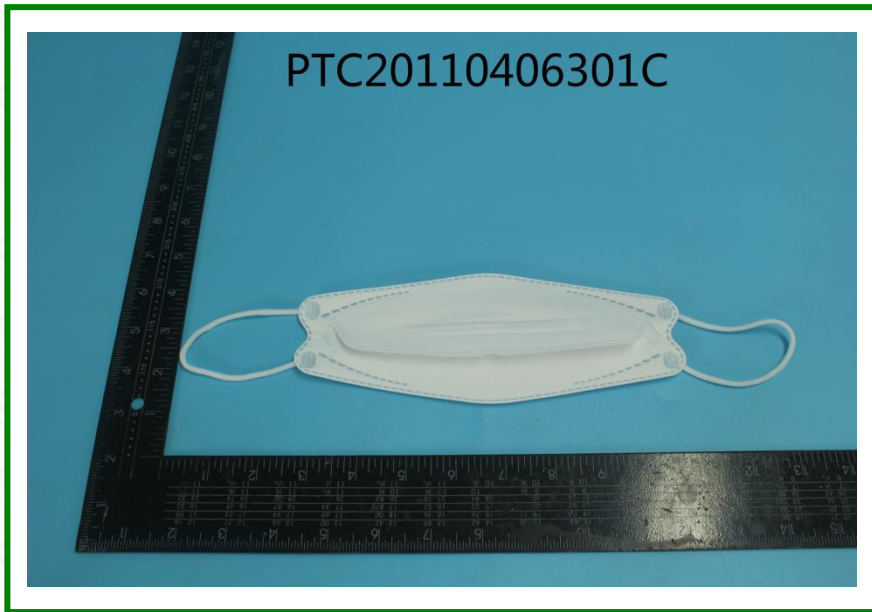
Test Report

Report No.:PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 13 of 15

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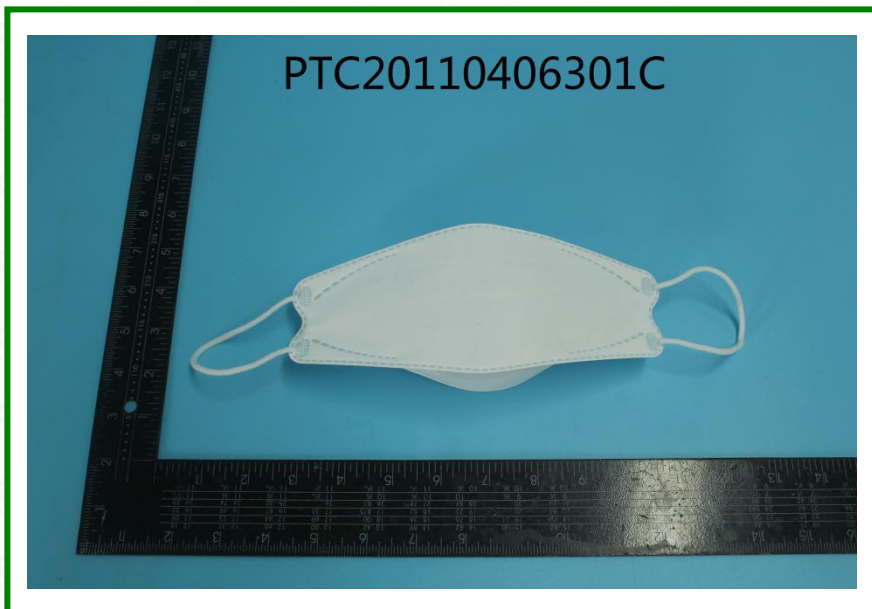


Test Report

Report No.:PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 14 of 15



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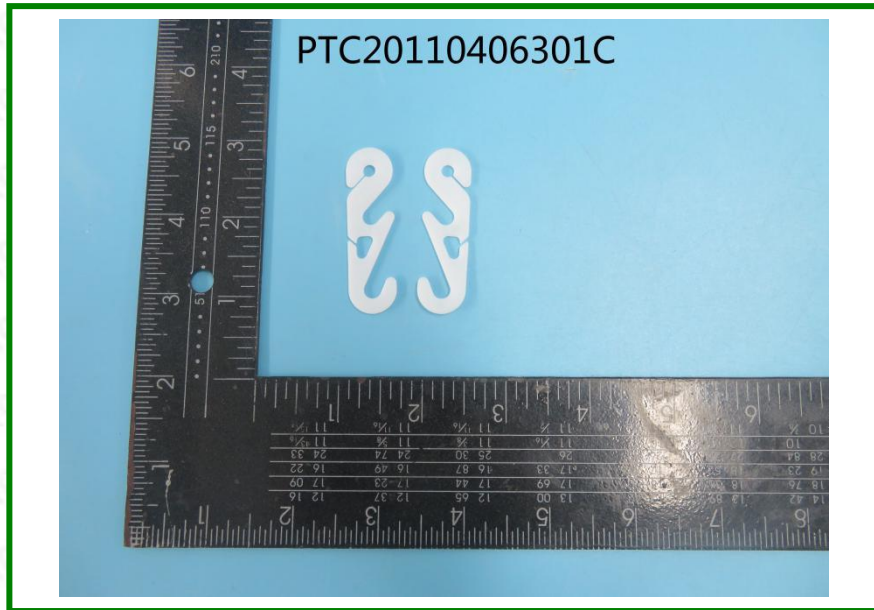


Test Report

Report No.:PTC20110406301C-EN01V01

Issue Date: Nov.30, 2020

Page 15 of 15



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