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检验检测报告

TEST REPORT



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STFWT202011182

Product Name

3DProtective Mask

Trust Unit

Foshan COXO Medical Instrument Co.,Ltd.

Manufacturer

Test Category

Entrusted Inspection



江苏省特种安全防护产品质量监督检验中心

JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS



Test Report

STFWT202011182

Product Name	3DProtective Mask	Specification Type	KN95
		Trademark	---
Trust Unit	Foshan COXO Medical Instrument Co.,Ltd.	Tel	13062856052
Manufacturer	---	Sample Grade	FFP2
Sample Quantity	70 pcs	Sample Receiving Date	2020-04-24
Test Category	Entrusted inspection	Serial Number	---
Samples Conditions	Meet the testing requirements		
Document and Decide Accordance	EN 149: 2001+A1: 2009 《Respiratory protective devices -Filtering half masks to protect against particles-Requirements, testing, marking》		
Test Conclusion	<p>The samples were tested, the items tested meet the requirements of EN 149:2001+A1:2009 standard for FFP2 level.</p> <p style="text-align: right;">Signature Date: 2020-05-14</p>		
Remarks	<p>The head harness of the mask provided by the applicant is ear hanging. Compatibility with skin is not recognized by the center. The test data are only for reference. The sample is not marked for reuse and does not require testing for blocking performance. The test conclusion of this report is only for the items inspected and does not mean that the uninspected items or functions meet the requirements. The results apply to the sample as received.</p>		

Approver

陈敏

Examiner

杨森

Major tester

丁欣



7.5 MaterialPass¹

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.

Note1: Refer to Annex A for test data.

7.6 Cleaning and disinfectingN/A²

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.

Note2: Non-reusable respirator.

7.7 Practical performancePass³

The particle filtering half mask shall undergo practical performance tests under realistic conditions.

Note3: Refer to Annex A for test data.

7.8 Finish of parts

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 leakagePass⁴

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:

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

Note4: Refer to Annex A for test data.

7.9.2 Penetration of filter materialPass⁵

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

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

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Note5: Refer to Annex A for test data.

7.10 Compatibility with skinPass⁶

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.

Note6: Refer to Annex A for test data.

7.11 FlammabilityPass⁷

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.

Note7: Refer to Annex A for test data.

7.12 Carbon dioxide content of the inhalation airPass⁸

The carbon dioxide content of the inhalation air (dead space) shall not exceed an

Note8: Refer to Annex A for test data.



7.13 Head harnessPass⁹

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

Note9: Refer to Annex A for test data.

7.14 Field of visionPass¹⁰

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

Note10: Refer to Annex A for test data.

7.15 Exhalation valveN/A¹¹

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.

Note11: Valve-less respirator.

7.16 Breathing resistancePass¹²

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

Note12: Refer to Annex A for test data.



7.17 CloggingN/A¹³**7.17.2 Breathing resistance**N/A¹³

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

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

N/A¹³**Note13: Non-reusable respirator.****7.18 Demountable parts**N/A¹⁴

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

Note14: No demountable parts.

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Annex A: Summarization of Test Data

Clause		Result			Assessment
7.5	Material	Simulated wearing treatment	1#	No mechanical failure	Pass
			2#	No mechanical failure	
			3#	No mechanical failure	
		Temperature conditioned	4#	No mechanical failure	
			5#	No mechanical failure	
			6#	No mechanical failure	
7.9	Practical performance	As received	7#	No mechanical failure	Pass
			8#	No mechanical failure	
7.9.1	Total inward leakage	Individual exercise result			Pass
		As received	9#	47 out of the 50 individual exercise results $\leq 11\%$	
			10#	47 out of the 50 individual exercise results $\leq 11\%$	
			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 $\leq 11\%$	
		Temperature conditioned	14#	47 out of the 50 individual exercise results $\leq 11\%$	
			15#	47 out of the 50 individual exercise results $\leq 11\%$	
			16#	47 out of the 50 individual exercise results $\leq 11\%$	
			17#	47 out of the 50 individual exercise results $\leq 11\%$	
			18#	47 out of the 50 individual exercise results $\leq 11\%$	
		Individual wearer arithmetic means			
		As received	9#	9 individual wearer arithmetic means $\leq 8\%$	
			10#	9 individual wearer arithmetic means $\leq 8\%$	
			11#	9 individual wearer arithmetic means $\leq 8\%$	
			12#	9 individual wearer arithmetic means $\leq 8\%$	
			13#	9 individual wearer arithmetic means $\leq 8\%$	
		Temperature conditioned	14#	9 individual wearer arithmetic means $\leq 8\%$	
15#	9 individual wearer arithmetic means $\leq 8\%$				
16#	9 individual wearer arithmetic means $\leq 8\%$				
17#	9 individual wearer arithmetic means $\leq 8\%$				
18#	9 individual wearer arithmetic means $\leq 8\%$				

Clause		Result		Assessment		
7.9.2	Penetration of filter material/%	Sodium chloride test(95L/min)		Pass		
		As received	19#		0.18	
			20#		0.19	
			21#		0.24	
		Simulated wearing treatment	22#		0.27	
			23#		0.29	
			24#		0.34	
		M.S.+T.C.	25#		0.41	
			26#		0.43	
			27#		0.49	
					Paraffin oil test(95L/min)	
		As received	28#		1.24	
			29#		1.33	
			30#		1.29	
		Simulated wearing treatment	31#		1.44	
			32#		1.49	
			33#		1.58	
		M.S.+T.C.	34#		1.89	
35#	1.99					
36#	1.78					
7.10	Compatibility with skin	As received	9#	No irritation or any other adverse effect to health	Pass	
			10#	No irritation or any other adverse effect to health		
			11#	No irritation or any other adverse effect to health		
			12#	No irritation or any other adverse effect to health		
			13#	No irritation or any other adverse effect to health		
		Temperature conditioned	14#	No irritation or any other adverse effect to health		
			15#	No irritation or any other adverse effect to health		
			16#	No irritation or any other adverse effect to health		
			17#	No irritation or any other adverse effect to health		
18#	No irritation or any other adverse effect to health					
7.11	Flammability	As received	37#	Didn't burn	Pass	
			38#	Didn't burn		
		Temperature conditioned	39#	Didn't burn		
			40#	Didn't burn		



Clause		Result				Assessment
7.12	Carbon dioxide content of the inhalation air/%	As received				Pass
		41#	42#	43#	Mean value	
		0.55	0.54	0.53	0.54	
7.13	Head hardness	As received				Pass
		9#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		10#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		11#	Head 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 have sufficiently robust to hold the particle filtering half mask firmly.			
		Temperature conditioned				
		14#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		15#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		16#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
		17#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.			
18#	Head harness can be donned and removed easily, adjustable and have sufficiently robust to hold the particle filtering half mask firmly.					
7.14	Field of vision	As received	7#	Passed the practical performance tests		Pass
			8#	Passed the practical performance tests		



Clause		Result			Assessment			
		Inhalation		Exhalation				
		30 l/min	95 l/min	160 l/min				
7.16	Breathing resistance (mbar)	As received			Pass			
		41#	A	0.3		1.1	1.6	
			B	0.3		1.1	1.6	
			C	0.3		1.1	1.6	
			D	0.3		1.2	1.7	
			E	0.3		1.1	1.6	
		42#	A	0.3		1.1	1.6	
			B	0.3		1.2	1.7	
			C	0.3		1.1	1.6	
			D	0.3		1.1	1.6	
			E	0.3		1.1	1.6	
		43#	A	0.3		1.1	1.6	
			B	0.3		1.1	1.6	
			C	0.3		1.2	1.7	
			D	0.3		1.1	1.6	
			E	0.3		1.1	1.6	
		Simulated wearing treatment				Pass		
		44#	A	0.3			1.1	1.6
			B	0.3			1.1	1.6
			C	0.3			1.1	1.6
			D	0.3			1.2	1.7
			E	0.3			1.1	1.6
		45#	A	0.3			1.1	1.6
			B	0.3			1.2	1.7
			C	0.3			1.1	1.6
			D	0.3			1.1	1.6
			E	0.3			1.2	1.6
		46#	A	0.3			1.1	1.6
			B	0.3			1.1	1.6
			C	0.4			1.2	1.7
D	0.3		1.1	1.6				
E	0.3		1.1	1.6				



Clause		Result				Assessment			
		Inhalation		Exhalation					
7.16	Breathing resistance		30 l/min	95 l/min	160 l/min	Pass			
		Temperature conditioned							
		47#	A	0.3	1.1		1.6		
			B	0.3	1.2		1.7		
			C	0.3	1.1		1.6		
			D	0.3	1.1		1.6		
			E	0.3	1.1		1.6		
		48#	A	0.3	1.1		1.6		
			B	0.3	1.1		1.6		
			C	0.3	1.1		1.6		
			D	0.4	1.2		1.7		
			E	0.3	1.1		1.6		
		49#	A	0.3	1.1		1.6		
			B	0.3	1.1		1.6		
			C	0.4	1.2		1.7		
			D	0.3	1.1		1.6		
			E	0.3	1.1		1.6		
		7.16	Breathing resistance	A: facing directly ahead B: facing vertically upwards C: facing vertically downwards D: lying on the left side E: lying on the right side					
		Remarks : M.S.: Mechanical strength; T.C.: Temperature conditioning; N/A: Not applicable							

Original Sample



==== End of Report ====



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