



中国认可
国际互认
检测
TESTING
CNAS L10118



国检检测
CHINA COMPONENTS TEST

Test Report

(2020) WSZ FHL NO.W0614

Product Name Orphila P2195

Client Qingdao Orphila Medical Technology Co.,Limited

Manufacturer Qingdao Orphila Medical Technology Co.,Limited

Test Type Entrusted inspection


Jiangsu Guojian Testing Technology Co., Ltd.



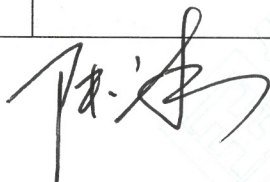
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Product name	Orphila P2195	Specification	OM-KP95-P2
		Brand	—
Client/Add/Tel	Qingdao Orphila Medical Technology Co.,Limited / ROOM 501 BUILDNG 1 NO 18. HONG KONG MIDDLE ROAD, SHINAN DISTRICT, QINGDAO SHANDONG, CHINA/—		
Manufacturer/Add/Tel	Qingdao Orphila Medical Technology Co.,Limited / ROOM 501 BUILDNG 1 NO 18. HONG KONG MIDDLE ROAD, SHINAN DISTRICT, QINGDAO SHANDONG, CHINA/—		
Sample grade	FFP2	Sample number	GW0614-2020
Sample quantity	110 pcs	Receiving date of sample	14/05/2020
Test type	Entrusted inspection	Article number/Batch number/Style number	—
Test date	14/05/2020~22/05/2020	Testing sites	Testing room
Sample state	Meeting the requirements of testing	Sample description	—
Test standard(s)	EN 149:2001+A1:2009 Respiratory protective devices-Filtering half masks to protect against particles- Requirements,testing, marking		
Test items	Visual inspection, practical performance, finish of parts, compatibility with skin, flammability, carbon dioxide content of the inhalation air, material, head harness, field of vision, penetration of filter material, breathing resistance, total inward leakage		
Test conclusion	<p>The sample upon testing, the test items meet the requirements of the EN 149:2001+A1:2009 standard. The detail of test results see on Pages 2-5.</p> <p style="text-align: right;">Issue date: 27/05/2020</p>		
Note	<p>For the entrusted sample test, the technical responsibilities are undertaken for the test results of the supplied samples only.</p>		

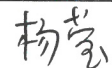
Approver:



Reviewer:



Chief Tester:




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S.No.	Test item	Unit	Technical requirements	Test result	Single item decision
1	Visual inspection	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.	Packaging withstands mechanical damage and contamination.	Qualified
		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.	Materials withstand handling and wear.	
2	Practical performance	Head harness comfort	— Head harness should be comfort.	Sample 1 has the feeling of comfortable wearing	Qualified
				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	
3	Finish of parts	—	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	Qualified
4	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	Qualified
				T.C. 5 pcs all don't cause irritation	
5	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:0.1s	Qualified
				T.C. The Sample is burning. Burning time:0.1s	

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S.No.	Test item	Unit	Technical requirements	Test result				Single item decision	
6	Carbon dioxide content of the inhalation air	—	$\leq 1.0\%$ (by volume)	Sample 1	0.6300%			Qualified	
				Sample 2	0.6310%				
				Sample 3	0.6320%				
				Average value	0.63%				
7	Material	—	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				Qualified	
				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 1: no collapse						
			Sample 2: no collapse						
Sample 3: no collapse									
8	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	A.R.	All of 5 pieces particle filtering half mask meet the requirements			Qualified	
				T.C.	All of 5 pieces particle filtering half mask meet the requirements				
9	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				Qualified	
10	Penetration of filter material	Sodium chloride	—	$\leq 6\%$	A.R.	0.4%	0.5%	0.5%	Qualified
					S.W.	0.5%	0.6%	0.5%	
					M.S+T.C.	0.8%	0.7%	0.7%	
	Paraffin oil	—	$\leq 6\%$	A.R.	2.7%	2.6%	2.7%	Qualified	
				S.W.	2.5%	2.6%	2.7%		
				M.S+T.C.	5.9%	5.9%	5.9%		

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S.No.	Test item		Unit	Technical requirements	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
11	Breathing resistance	Inhalation 30 L/min	mbar	≤0.7	A.R.	0.4	0.4	0.5	0.4	0.4	Qualified
						0.4	0.4	0.5	0.4	0.4	
						0.4	0.4	0.5	0.4	0.4	
					S.W.	0.4	0.4	0.4	0.4	0.4	
						0.4	0.4	0.4	0.4	0.5	
						0.5	0.4	0.4	0.4	0.4	
					T.C.	0.4	0.4	0.4	0.5	0.5	
						0.4	0.4	0.5	0.4	0.4	
						0.4	0.4	0.5	0.4	0.4	
	Inhalation 95 L/min	mbar	≤2.4	A.R.	1.3	1.3	1.4	1.3	1.3	Qualified	
					1.3	1.3	1.3	1.4	1.3		
					1.3	1.3	1.2	1.3	1.3		
				S.W.	1.3	1.3	1.2	1.2	1.3		
					1.3	1.3	1.2	1.3	1.3		
					1.3	1.2	1.3	1.3	1.3		
				T.C.	1.3	1.2	1.2	1.2	1.3		
					1.3	1.3	1.3	1.2	1.2		
					1.2	1.2	1.3	1.3	1.3		
Exhalation 160 L/min	mbar	≤3.0	A.R.	1.8	1.9	1.9	1.9	1.9	Qualified		
				1.9	1.9	1.9	1.9	1.9			
				1.9	2.0	1.9	2.0	2.0			
			S.W.	1.9	1.9	1.8	1.8	1.8			
				1.8	1.9	1.9	1.9	1.9			
				1.9	1.9	1.8	1.8	1.8			
			T.C.	1.8	1.8	1.9	1.9	1.9			
				1.9	1.9	1.8	1.8	1.8			
				1.8	1.9	1.9	1.9	1.9			

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S.No.	Test item	Unit	Technical requirements	Test result							Single item decision	
				Exercises	E1 (%)	E2 (%)	E3 (%)	E4 (%)	E5 (%)	TIL (%)		
12	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.	1#	6.3	6.7	7.0	6.8	6.3	6.6	Qualified
					2#	6.2	7.0	7.1	7.1	6.4	6.8	
					3#	6.1	7.1	7.4	7.2	6.6	6.9	
					4#	6.2	6.8	6.7	6.9	6.2	6.6	
					5#	6.2	7.0	7.1	7.0	6.3	6.7	
				T.C.	6#	6.6	7.2	7.4	7.1	6.6	7.0	
					7#	6.0	6.4	6.4	6.6	6.0	6.3	
					8#	5.8	6.4	6.8	6.6	6.0	6.3	
					9#	6.3	6.7	6.8	6.9	6.4	6.6	
					10#	6.8	7.4	7.4	7.7	7.0	7.3	
Note	_____											

_____ The end _____