

Test Report

Applicant: Wenzhou Leikang Medical Technology Co.,Ltd
Address: Room 401, 4th floor, Building No.21, Wenzhou National University Science Park, No.89 Fengfang Rd. Economic Development Zone, Ouhai District, Wenzhou, Zhejiang Province, China

The following sample(s) was/were submitted and identified on behalf of the client as:

Product name: Filtering half mask
Model: LK-088、LK-088-1、LK-088-2、LK-088-3、LK-088-5、LK-088-6、LK-088-7、LK-088-8
Trade mark: LEIKANG
Manufacturer: Wenzhou Leikang Medical Technology Co.,Ltd
Address: Room 401, 4th floor, Building No.21, Wenzhou National University Science Park, No.89 Fengfang Rd. Economic Development Zone, Ouhai District, Wenzhou, Zhejiang Province, China
Classification: FFP2 NR
Sample quantity: 200 Pcs
C2 Sampling done by APPLUS+ with ID number : 23/32300406
Sample Received Date: Jan. 16, 2023
Testing Period: Jan. 16, 2023~ Feb. 02, 2023

Test Requirement:

According to the requirement of the Module C2 (SPC CE-062_EN M6 PPE) of Applus+, the test item(s) of the sample is according to the standard EN 149:2001+A1:2009.

Test Result(s): Please refer to the following page(s)

Test Method: Please refer to the following page(s)

Compiled by: _____

Reviewed by: _____

Approved by: _____

Date: _____

2023-02-02

Sample list

Sample No.	Model	Description
1#	LK-088-1	Black mask
2#	LK-088-1	Black mask
3#	LK-088-1	Black mask
4#	LK-088-1	Black mask
5#	LK-088-1	Black mask
6#	LK-088-5	Purple mask
7#	LK-088-5	Purple mask
8#	LK-088-5	Purple mask
9#	LK-088-5	Purple mask
10#	LK-088-5	Purple mask
11#	LK-088-6	Turquoise mask
12#	LK-088-6	Turquoise mask
13#	LK-088-6	Turquoise mask
14#	LK-088-2	Royal blue mask
15#	LK-088-2	Royal blue mask
16#	LK-088-2	Royal blue mask
17#	LK-088-3	Grey mask
18#	LK-088-3	Grey mask
19#	LK-088-3	Grey mask
20#	LK-088-7	Red mask
21#	LK-088-7	Red mask
22#	LK-088-7	Red mask
23#	LK-088	White mask
24#	LK-088	White mask
25#	LK-088	White mask
26#	LK-088	White mask
27#	LK-088	White mask
28#	LK-088	White mask
29#	LK-088-8	Tan mask
30#	LK-088-8	Tan mask
31#	LK-088-8	Tan mask

Summary of assessment*

Clause	Assessment
7.9.1 Total inward leakage	Pass
7.9.2 Penetration of filter material	Pass
7.12 Carbon dioxide content of the inhalation air	Pass
7.15 Exhalation valve(s)	N.A.
7.17 Clogging	N.A.
7.18 Demountable parts	Pass

Key

Pass	Requirement satisfied.
NRq	The clauses were not required.
Fail	Requirement not satisfied. Refer to the "Result details" section for more information.
N.A.	Requirement not applicable.

Test	Uncertainty
Total inward leakage	6.40 %
Penetration of filter material (NaCl)	1.60 %
Penetration of filter material (Paraffin Oil)	1.78 %
Carbon dioxide content of the inhalation air	5.34 %

* Assessment relates only to those specimens which were tested and subjects in this report.

Test Result

Respiratory Protective Devices — Filtering Half Masks to Protect against Particles — Requirements,
Testing, Marking
(EN 149:2001+A1:2009)

Clause 7.9.1 Total Inward Leakage

(EN 149:2001+A1:2009 Clause 8.5)

Test Requirement	Results
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	Detail refer to Appendix 1

Appendix 1: Summarization of Test Data

Subject	Sample	Condition	Normal Breathing (%)	Head Side/Side (%)	Head Up/Down (%)	Speak Loudly (%)	Normal Breathing (%)	Mean (%)	Comment
Huang	1#	A.R.	4.1	4.3	4.2	4.7	4.0	4.26	Pass
Zhou	2#	A.R.	3.7	3.9	4.1	4.5	3.6	3.96	
Ma	3#	A.R.	2.6	2.8	3.2	3.3	2.7	2.92	
Wu	4#	A.R.	3.9	4.1	4.3	4.5	3.7	4.10	
Li	5#	A.R.	4.8	5.0	4.9	5.1	4.4	4.84	
Wu	6#	T.C.	5.0	5.1	5.3	5.5	4.8	5.14	Pass
Zhai	7#	T.C.	3.7	3.9	4.3	4.5	3.6	4.00	
Zheng	8#	T.C.	4.2	4.7	4.9	5.1	4.2	4.62	
Huang	9#	T.C.	4.5	4.8	5.0	5.3	4.7	4.86	
Wu	10#	T.C.	4.9	5.2	5.4	5.7	5.0	5.24	

Facial Dimension:

Subject	Length of Face (mm)	Width of Face (mm)	Depth of Face (mm)	Width of Mouth (mm)
Huang	130	140	125	53
Zhou	100	148	125	55
Ma	120	158	110	50
Wu	110	148	121	44
Li	112	146	112	50
Wu	120	154	128	54
Zhai	135	165	125	53
Zheng	106	155	112	54
Huang	105	157	118	51
Wu	112	172	118	55

Clause 7.9.2 Penetration of Filter Material

(EN 149:2001+A1:2009, Clause 8.11)

Test Requirement			Results
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.			Detail refer to Appendix 2
Classification	Maximum penetration of test aerosol(%)		
	Sodium chloride test 95 L/min	Paraffin oil test 95 L/min	
FFP1	20	20	
FFP2	6	6	
FFP3	1	1	

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)		Assessment
			Average in 30s after 3 min	Max. during exposure	
Sodium chloride test	A.R.	11#	0.43	/	Pass
		12#	0.42	/	
		13#	0.42	/	
	S.W.	17#	0.58	/	Pass
		18#	0.55	/	
		19#	0.51	/	
	M.S. + T.C.	23#	/	0.66	Pass
		24#	/	0.70	
		25#	/	0.77	
Paraffin oil test	A.R.	14#	0.66	/	Pass
		15#	0.64	/	
		16#	0.63	/	
	S.W.	20#	0.69	/	Pass
		21#	0.69	/	
		22#	0.67	/	
	M.S. + T.C.	26#	/	0.93	Pass
		27#	/	0.88	
		28#	/	0.86	
Flow rate of test aerosol: 95.0 L/min					

Clause 7.12 Carbon Dioxide Content of The Inhalation Air
(EN 149:2001+A1:2009, Clause 8.7)

Test Requirement	Results	Comment
The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1.0 % (by volume).	Detail refer to Appendix 3	Pass

Appendix 3: Summarization of Test Data

Carbon Dioxide Content of The Inhalation Air

Condition	Sample No.	Result		Assessment
A.R.	29#	0.46%	Mean value: 0.45%	Pass
	30#	0.45%		
	31#	0.45%		

Clause 7.15 Exhalation Valve(s)

(EN 149:2001+A1:2009, Clause 8.2 & 8.9.1 & 8.3.4 & 8.8)

Test Requirement	Results	Comment
a) A particle filtering half mask may have one or more exhalation valve(s), which shall function correctly in all orientations.	No valves.	N.A.
b) 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 valves.	
c) Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300L/min over a period of 30 s.	No valves.	
d) When the exhalation valve housing is attached to the face blank, it shall withstand axially a tensile force of 10N applied for 10 s.	No valves.	

Clause 7.17 Clogging

(EN 149:2001+A1:2009, Clause 8.9 & 8.10)

Test Requirement	Results	Comment																			
Clause 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 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.	Requirement not applicable.	N.A.																			
Test Requirement	Results	Comment																			
Clause 7.17.3 Penetration of filter material All types (valved and valveless) of particle filtering half masks claimed to meet the clogging requirement shall also meet the requirements.	Requirement not applicable.	N.A.																			
<table><tr><td rowspan="4">Classification</td><td colspan="2">Maximum penetration of test aerosol</td></tr><tr><td>Sodium chloride test 95 L/min</td><td>Paraffin oil test 95 L/min</td></tr><tr><td>%</td><td>%</td></tr><tr><td>max.</td><td>max.</td></tr><tr><td>FFP1</td><td>20</td><td>20</td></tr><tr><td>FFP2</td><td>6</td><td>6</td></tr><tr><td>FFP3</td><td>1</td><td>1</td></tr></table>			Classification	Maximum penetration of test aerosol		Sodium chloride test 95 L/min	Paraffin oil test 95 L/min	%	%	max.	max.	FFP1	20	20	FFP2	6	6	FFP3	1	1	
Classification				Maximum penetration of test aerosol																	
				Sodium chloride test 95 L/min	Paraffin oil test 95 L/min																
				%	%																
			max.	max.																	
FFP1			20	20																	
FFP2	6	6																			
FFP3	1	1																			

Clause 7.18 Demountable Parts

(EN 149:2001+A1:2009, Clause 8.2)

Test Requirement	Results	Comment
All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	Comply	Pass

Sample photo(s):



Fig.1 (LK-088-1)



Fig.2 (LK-088-1)



Fig.3 (LK-088-1)

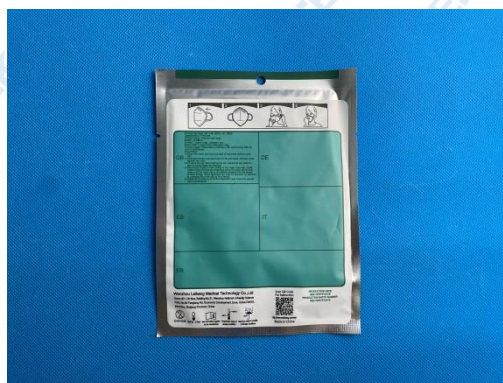


Fig.4 (LK-088-1)



Fig.5 (LK-088-1)



Fig.6 (LK-088-1)



Fig.7 (LK-088-5)



Fig.8 (LK-088-5)



Fig.9 (LK-088-5)



Fig.10 (LK-088-5)



Fig.11 (LK-088-5)



Fig.12 (LK-088-5)



Fig.13 (LK-088-6)



Fig.14 (LK-088-6)



Fig.15 (LK-088-6)

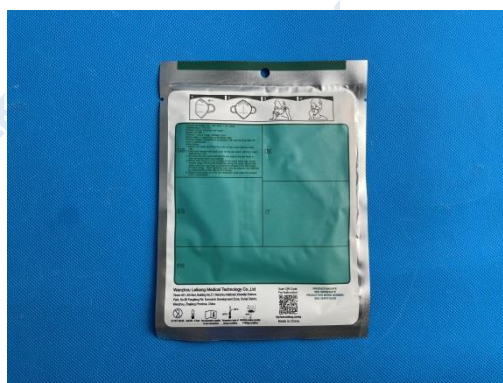


Fig.16 (LK-088-6)



Fig.17 (LK-088-6)



Fig.18 (LK-088-6)



Fig.19 (LK-088-2)



Fig.20 (LK-088-2)



Fig.21 (LK-088-2)



Fig.22 (LK-088-2)



Fig.23 (LK-088-2)



Fig.24 (LK-088-2)



Fig.25 (LK-088-3)



Fig.26 (LK-088-3)



Fig.27 (LK-088-3)



Fig.28 (LK-088-3)



Fig.29 (LK-088-3)



Fig.30 (LK-088-3)



Fig.31 (LK-088-7)



Fig.32 (LK-088-7)



Fig.33 (LK-088-7)



Fig.34 (LK-088-7)



Fig.35 (LK-088-7)



Fig.36 (LK-088-7)



Fig.37 (LK-088)



Fig.38 (LK-088)



Fig.39 (LK-088)



Fig.40 (LK-088)



Fig.41 (LK-088)



Fig.42 (LK-088)



Fig.43 (LK-088-8)



Fig.44 (LK-088-8)



Fig.45 (LK-088-8)



Fig.46 (LK-088-8)



Fig.47 (LK-088-8)



Fig.48 (LK-088-8)

****End of Report****

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