

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
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: 78 Pcs
C2 Sampling done by APPLUS+ with ID number : 21/32300112
Sample Received Date: Jan. 11, 2021
Testing Period: Jan. 11, 2021~ Jan. 17, 2021

Test Requirement:

According to the requirement of the Module C2 (SPC CE-062_EN M3 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:

may

Approved by:

Date:

2021-01-17

Summary of assessment*

Clause	Assessment
7.3 Visual inspection	Pass
7.5 Material	Pass
7.8 Finish of parts	Pass
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
7.16 Breathing resistance	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 %
Breathing resistance (30 L/min)	3.60 %
Breathing resistance (95 L/min)	2.20 %
Breathing resistance (160 L/min)	2.00 %

* 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 7.3 Visual inspection

Test Requirement	Results	Comment
Marking and the information supplied by the manufacturer, requirements refer to clause 9 and clause 10.	Comply	Pass

Clause 7.5 Material

(EN 149:2001+A1:2009, Clause 8.2 & 8.3.1 & 8.3.2)

Test Requirement	Results	Comment
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.	Comply	Pass
After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the face piece or straps.	Comply	Pass
When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.	Comply	Pass
Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comply	Pass

Clause 7.8 Finish of Parts

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

Test Requirement	Results	Comment
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

Clause 7.9.1 Total Inward Leakage
(EN 149:2001+A1:2009 Clause 8.5)

Test Requirement	Results	Comment
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	Pass

Appendix 1: Summarization of Test Data

Subject	Sample	Condition	Normal Breathing (%)	Head Side/Side (%)	Head Up/Down (%)	Speak Loudly (%)	Normal Breathing (%)	Mean (%)
Huang	1#	A.R.	4.2	4.3	4.4	4.6	4.3	4.36
Zhou	2#	A.R.	3.9	4.0	4.2	4.3	3.8	4.04
Ma	3#	A.R.	2.8	2.9	3.1	3.2	2.9	2.98
Wu	4#	A.R.	3.7	3.8	3.9	4.1	3.6	3.82
Li	5#	A.R.	4.6	4.7	4.8	4.9	4.5	4.70
Wu	6#	T.C.	5.2	5.3	5.4	5.6	5.3	5.36
Zhai	7#	T.C.	3.8	3.9	4.1	4.2	3.7	3.94
Zheng	8#	T.C.	4.5	4.6	4.7	4.9	4.4	4.62
Huang	9#	T.C.	4.2	4.3	4.4	4.5	4.3	4.34
Wu	10#	T.C.	5.1	5.2	5.3	5.4	5.2	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	Comment
The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.			Detail refer to Appendix 2	Pass
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#	0.74	/	Pass
		12#	0.73	/	
		13#	0.77	/	
	S.W.	17#	0.74	/	
		18#	0.78	/	
		19#	0.77	/	
	M.S. + T.C.	23#	/	0.82	
		24#	/	0.81	
		25#	/	0.82	
Paraffin oil test	A.R.	14#	0.49	/	
		15#	0.48	/	
		16#	0.48	/	
	S.W.	20#	0.49	/	
		21#	0.49	/	
		22#	0.50	/	
	M.S. + T.C.	26#	/	2.04	
		27#	/	1.62	
		28#	/	2.20	
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#	0.42%	Mean value 0.43%	Pass
	30#	0.44%		
	31#	0.43%		

Clause 7.16 Breathing Resistance

EN 149:2001+A1:2009, Clause 8.9)

Test Requirement				Results	Comment
The breathing resistances apply to valved and valveless filtering half masks and shall meet the requirements as the following table.				Detail refer to Appendix 4	Pass
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		

Appendix 4: Summarization of Test Data

Specimen	Condition	Inhalation(mbar)		Exhalation resistance(mbar)				
		At 30 L/min	At 95 L/min	At 160 L/min				
				A	B	C	D	E
32#	A.R.	0.40	1.05	1.72	1.72	1.71	1.70	1.70
33#		0.39	1.04	1.70	1.69	1.70	1.69	1.68
34#		0.40	1.04	1.71	1.71	1.70	1.69	1.69
35#	S.W.	0.40	1.04	1.71	1.70	1.71	1.70	1.69
36#		0.41	1.06	1.72	1.71	1.72	1.71	1.70
37#		0.41	1.05	1.72	1.72	1.71	1.71	1.70
38#	T.C.	0.35	0.97	1.64	1.63	1.64	1.63	1.62
39#		0.36	0.98	1.65	1.64	1.65	1.64	1.63
40#		0.35	0.98	1.64	1.64	1.63	1.63	1.62
/	T.C.+F.C.	/	/	/	/	/	/	/
/		/	/	/	/	/	/	/
/	F.C.	/	/	/	/	/	/	/

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

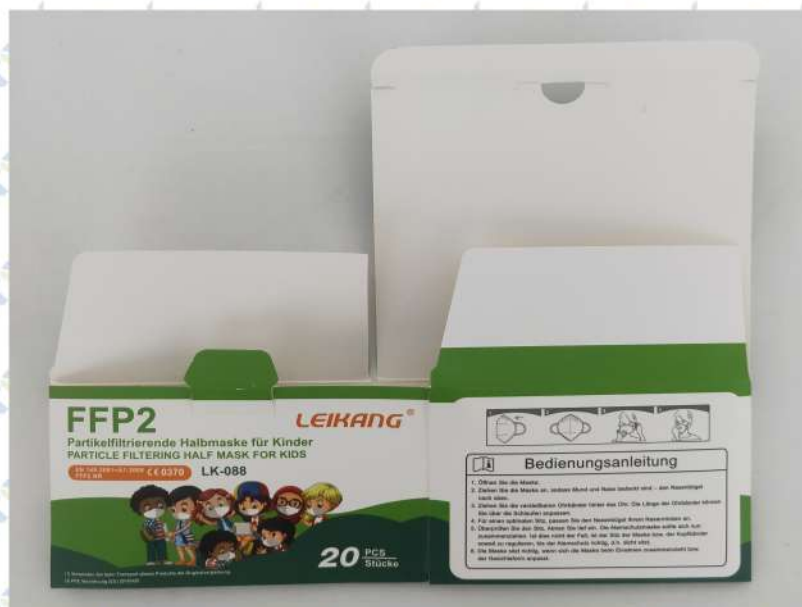


Fig.1

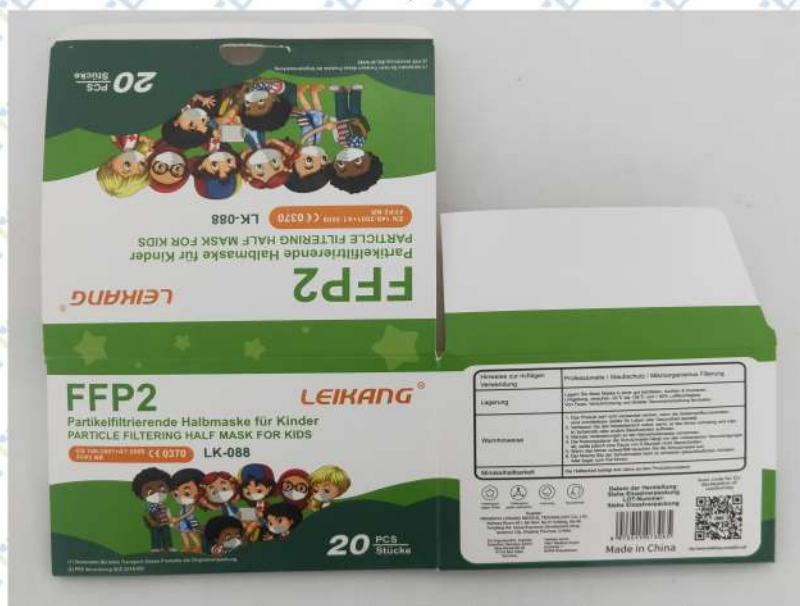


Fig.2



Fig.3



Fig.4



Fig.5



Fig.6

****End of Report****

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