

Test Report No.: 178140628a 001

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Client: Dongguan Kangya Medical Technology Co.,Ltd
Room 101, No.3 Daxin industrial street, changping village,
daojiao town, Dongguan city, Guangdong province

Sample Description As Declared :

No. Of Sample : 90 Pcs
Product Description : Filtering half mask
Lot No./Batch code : 2020-05-11-01
Model No. : 10217
Colour : White
Country of Origin : China
Sales Destination(country) : EU(country name not provided)
Product End Use : Disposable protective mask
Test type : Partial test
Product type : Single shift use only
Claimed Classification : FFP2 NR

Sample obtaining method: Sending by customer**Sample Receiving date:** 2020-05-19**Delivery condition:** Apparent good, Samples tested as received**Test Period:** 2020-05-20 to 2020-07-02**Test specification:****Test result:**

Particulate respirator-half facepiece

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

Please refer to result page

For and on behalf of**TÜV Rheinland / CCIC (Qingdao) Co., Ltd.**

2020-07-02

Alex Zhou / General Manager

Date

Name/Position

Sample information is provided by customer. Test result is drawn according to the kind and extent of tests performed.
This test report relates to the above mentioned test sample. Without permission of the test center this test report is not
permitted to be duplicated in extracts. This test report does not entitle to carry any safety mark on this or similar products.

Material list

Material	Color	Location
Textile	White	White folding mask

Note:

	Shading shows the clauses requested
NRq	The clauses were not requested.
Pass	Requirement satisfied.
Ltd	Testing requested was insufficient completely to verify compliance with the clause. Refer to the "result details section for more information.
Fail	Requirement not satisfied. Refer to the "result details section for more information.
NAs	Assessment not carried out.
NAP	Requirement not applicable.
NT	Requested but not tested due to early termination following failure.

Result:

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

- 7.4 Package[^]** **NRq**
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.
- 7.5 Material[^]** **PASS¹**
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.
- 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.
- Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.
- Note 1: In accordance with the requirement.
Specimens -14, -15, -16 were conditioned in accordance with 8.3.1, None of the specimens conditioned suffered mechanical failure or collapse.
Specimens -01, -02, -03 were conditioned in accordance with 8.3.2, None of the specimens conditioned suffered collapse.
- 7.6 Cleaning and disinfecting[^]** **NAP²**
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.
- With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.
- Note 2: Single shift use only.

7.7 Practical performance^
PASS³

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

Note 3: No imperfections.

Specimen and subject details:

Specimen	Subject
-41	LCF
-42	YZF

7.8 Finish of parts^
PASS⁴

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

Note 4: None of the specimens used in limited laboratory testing undertaken showed the evidence of sharp edges or burrs.

7.9.1 Total inward leakage^
PASS⁵

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

Test Requirement	Results	Comment
<p>The total inward leakage consists of three components: face seal leakage, exhalation value leakage(if exhalation value fitted) and filter penetration. 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</p> <p>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</p>	Detail refer to Appendix 1	Meet FFP1 Meet FFP2

Appendix 1: Summarization of Test Data
Inward Leakage Test Data

Subject	Sample No.	Condition	Walk(%)	Head Side/side(%)	Head up/down(%)	Talk(%)	Walk(%)	Mean(%)
Zhou	1	A.R.	5.56	4.50	5.44	4.48	5.81	5.16
Luo	2	A.R.	5.62	6.10	6.39	6.02	6.33	6.09
Lu	3	A.R.	4.36	6.53	5.37	4.65	5.67	5.32
Wang	4	A.R.	3.49	4.72	3.42	4.29	4.94	4.17
Bao	5	A.R.	4.90	7.32	4.35	6.49	7.66	6.14
Ding	6	T.C.	4.11	5.17	5.05	4.83	4.66	4.76
Li	7	T.C.	4.67	6.68	7.36	6.75	6.50	6.39
Chen	8	T.C.	4.65	6.18	3.36	6.53	4.20	4.98
Song	9	T.C.	4.70	6.28	5.54	5.75	5.84	5.62
Ye	10	T.C.	6.14	7.67	6.06	7.43	6.08	6.68

Facial Dimension(mm)

Subject	Face length	Face Width	Face Depth	Mouth Width
Chen	125	150	120	58
Lu	115	132	107	48
Zhou	115	135	106	52
Li	125	130	107	46
Luo	125	136	100	43
Zheng	128	140	112	55
Wang	120	147	103	48
Song	120	140	100	50
Bao	130	134	104	50

7.9.2 Penetration of filter material^
PASS

The penetration of the filter of the particle filtering half mask shall meet the requirements of below:

Classification	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP 1	≤ 20%	≤ 20%
FFP 2	≤ 6%	≤ 6%
FFP 3	≤ 1%	≤ 1%

Table 7.9.2- Penetration of filter material

Test specification: EN149-2001 Clause 8.11

Test specification: EN 1472007 Class 0.1					
Aerosol	Condition	Sample No.	Penetration (%)		Assessment
			After 3 minutes	Max. during exposure	
Sodium chloride test	A.R.	-26	0.53		PASS
		-27	0.52		
		-28	0.53		
	S.W.	-14	0.87		
		-15	0.94		
		-16	0.93		
	M.S. + T.C.	-20	1.70	1.84	
		-21	1.57	1.58	
		-22	1.56	1.77	
Paraffin oil test	A.R.	-29	0.85		
		-30	0.89		
		-31	0.87		
	S.W.	-17	0.40		
		-18	0.40		
		-19	0.40		
	M.S. + T.C.	-23	1.03	2.60	
		-24	2.60	3.10	
		-25	2.62	3.14	
Maximum permitted		6			
Flow conditioning:		Single filter: 95.0 L/min			

7.10 Compatibility with skin^
PASS⁶

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.

Note 6: Specimens -41, -42, -43, -44, -45 (A.R.) and specimens -04, -05, -06, -07, -08 (T.C.) were tested. No irritation or any other adverse effect to health.

7.11 Flammability^
PASS

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.

Table 7.11- Flammability

Test specification: EN149-2001 Clause 8.6

Condition	Sample No.	Result	Assessment
A.R.	-32	Burn for 0.3 s	PASS
	-33	Burn for 0.4 s	
T.C.	-09	Burn for 0.5 s	
	-10	Burn for 0.5 s	

7.12 Carbon dioxide content of the inhalation air^
PASS

The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume).

Table 7.12- Carbon dioxide content of the inhalation air

Test specification: EN149-2001 Clause 8.7

Condition	Sample No.	Result	Assessment
A.R.	-32	0.44%	PASS
	-33	0.46%	
	-34	0.47%	
Maximum permitted		1.0%	

7.13 Head harness^
PASS⁷

Test Requirement	Results	Comment
The head harness shall be designed so that the particle filtering half mask can be donned and removed easily.	Comply	Pass
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 total inward leakage requirements for the device.	Comply	

7.14 Field of vision^
PASS⁸

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

Note 8: Specimens -41 and -42 (A.R.) were tested. Pass the practical performance tests and no adverse comments.

7.15 Exhalation valve^
NAp

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.

7.16 Breathing resistance^
PASS⁹

Test Requirement				Results	Comment																						
<p>The penetration of the filter of the particle filtering half mask shall meet the requirements of the following table.</p> <table><tr><th rowspan="3">Classification</th><th colspan="3">Maximum permitted resistance (mbar)</th></tr><tr><th colspan="2">Inhalation</th><th>Exhalation</th></tr><tr><th>30 l/min</th><th>95 l/min</th><th>160 l/min</th></tr><tr><td>FFP1</td><td>0.6</td><td>2.1</td><td>3.0</td></tr><tr><td>FFP2</td><td>0.7</td><td>2.4</td><td>3.0</td></tr><tr><td>FFP3</td><td>1.0</td><td>3.0</td><td>3.0</td></tr></table>				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	Detail refer to Appendix 5	Meet FFP1, Meet FFP2, Meet FFP3
					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 5: Summarization of Test Data

Breathing resistance (mbar)

	Flow rate(l/min)		1					2					3				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
As received	Inhalation	30	0.3	0.4	0.3	0.4	0.3	0.3	0.4	0.4	0.3	0.3	0.4	0.4	0.3	0.4	0.3
		95	1.0	1.2	1.1	1.0	1.1	1.0	1.2	1.1	1.0	1.1	1.2	1.1	1.0	1.2	1.1
	Exhalation	160	2.3	2.5	2.4	2.3	2.3	2.4	2.5	2.3	2.4	2.3	2.4	2.3	2.4	2.3	2.4
Simulated wearing treatment	Flow rate(l/min)		4					5					6				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30	0.5	0.4	0.5	0.4	0.4	0.5	0.4	0.4	0.5	0.4	0.5	0.5	0.4	0.5	0.5
		95	1.2	1.1	1.3	1.1	1.3	1.3	1.2	1.1	1.2	1.1	1.3	1.2	1.1	1.1	1.2
	Exhalation	160	2.4	2.5	2.4	2.4	2.4	2.5	2.4	2.4	2.5	2.5	2.4	2.5	2.5	2.4	2.4
Temperature conditioned	Flow rate(l/min)		7					8					9				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30	0.3	0.4	0.3	0.3	0.3	0.4	0.3	0.4	0.4	0.3	0.3	0.3	0.4	0.4	0.3
		95	0.9	1.1	0.9	1.0	1.0	1.1	0.9	1.0	1.1	0.9	1.0	1.1	1.1	0.9	1.0
	Exhalation	160	2.2	2.3	2.4	2.2	2.2	2.3	2.4	2.2	2.3	2.3	2.2	2.4	2.3	2.3	2.4

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

7.17 Clogging[^]

NRq¹⁰

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 95 l/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 95 l/min continuous flow.

7.17.3 Penetration of filter material

Classification	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP 1	≤ 20%	≤ 20%
FFP 2	≤ 6%	≤ 6%
FFP 3	≤ 1%	≤ 1%

Note 10: Single shift use only.

7.18 Demountable parts[^]

NAp¹¹

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

Note 11: No demountable parts were used.

9 Marking^**NRq****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. 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 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". ID 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(see 9.2.4).

Example FFP3 NR D, FFP2 R D.

9.2.6 Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.

10 Information to be supplied by the manufacturer^**NRq**

- 10.1 Information supplied by the manufacturer shall accompany every smallest commercial available package.
- 10.2 Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination.
- 10.3 The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on
- application/limitations; the meaning of any colour coding; checks prior to use; donning fitting; use; maintenance(e.g. cleaning, disinfecting), if applicable; storage; the meaning of any symbols/pictograms used of the equipment.
- 10.4 The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.
- 10.5 Warning shall be given against problems likely to be encountered, for example:
- fit of particle filtering half mask (check prior to use);
 - it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal;
 - air quality (contaminants, oxygen deficiency);
 - use of equipment in explosive atmosphere.
- 10.6 The information shall provide recommendations as to when the particle filtering half mask shall be discarded.
- 10.7 For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift.

Remark: "^" indicates that the test is sub-contracted to the lab China Academy of Safety Science and Technology which complies with the requirement of ISO/IEC 17025:2017, the registration No. CNAS L0118.

Photo:



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