

ZHEJIANG KEKANG MEDICAL TECHNOLOGY CO.,LTD
SOUTH VILLAGE,HONGQIAO TOWN(INSIDE YUEQINGSCIENCE & TECHNOLOGY INCUBATION
INNOVATION SERVICE CENTER),325608 YUEQING,CHINA

THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO.SL52035261588101TX DATE: 2020-07-28 ISSUED BY SGS (Shanghai) UPDATED SAMPLE INFORMATION.

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

Sample Description : (A)Face mask
Composition : (A)Non-woven;Wool jet;Hot air cotton
Sample Color : (A)WHITE
Style No. : KK-9501
Manufacturer : ZHEJIANG KEKANG MEDICAL TECHNOLOGY CO.,LTD
Supplier : ZHEJIANG KEKANG MEDICAL TECHNOLOGY CO.,LTD
Previous Report No. : SL52035298085001TX
Test Performed : Selected test(s) as requested by applicant
Sample Receiving Date : Jun 28, 2020
Testing Period : Jun 28, 2020 - Jul 28, 2020
Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Based on the results of the tests reported and the previous report SL52035298085001TX issued on Sep 14,2020, our Lab concluded that the recommendation level can be as below.

Sample No.	Recommendation Level
(A)	FFP2 NR

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

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Test Result

Personal Protective Equipment - Respiratory Protective Devices- Filtering Half Masks to Protect against Particles- Requirements, Testing, Marking

EN 149:2001+A1:2009

Clause 7.4 Packaging

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

Test Requirement	Results	Comment
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.	Comply	Pass

Clause 7.7 Practical Performance

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard.	No imperfections	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

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Clause 7.9.1 Total Inward Leakage

(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.	6.38	4.96	7.29	5.55	5.89	6.01
Luo	2	A.R.	7.92	7.12	5.86	7.88	6.25	7.01
Lu	3	A.R.	6.61	5.08	6.18	6.11	6.11	6.02
Wang	4	A.R.	4.20	5.06	5.58	6.95	5.16	5.39
Bao	5	A.R.	7.00	5.95	6.72	7.95	7.76	7.08
Ding	6	T.C.	4.52	5.19	5.76	6.06	6.75	5.66
Li	7	T.C.	5.58	4.94	7.90	7.96	7.89	7.45
Chen	8	T.C.	4.77	5.01	6.54	6.15	5.46	5.59
Song	9	T.C.	5.98	7.85	5.40	5.58	7.37	6.44
Ye	10	T.C.	7.47	7.97	7.11	7.02	7.27	7.37

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
Ding	134	150	110	52
Liu	120	135	117	50
Ye	126	137	105	52

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Clause 7.9.2 Penetration of Filter Material

(EN 149:2001+A1:2009, Clause 8.11 & EN 13274-7:2019)

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	Meet FFP1, Meet FFP2
Classification	Maximum penetration of test aerosol			
	Sodium chloride test 95 l/min % max.	Paraffin oil test 95 l/min % max.		
FFP1	20	20		
FFP2	6	6		
FFP3	1	1		

Appendix 2: Summarization of Test Data

Penetration of filter material

Aerosol	Condition	Sample No.	Penetration (%)
Sodium chloride test	As received	1	1.572
		2	1.638
		3	1.472
	Simulated wearing treatment	4	1.382
		5	1.462
		6	1.382
	Mechanical strength +Temperature conditioned	7	1.395
		8	1.876
		9	1.726
Paraffin oil test	As received	10	2.802
		11	2.714
		12	2.736
	Simulated wearing treatment	13	2.769
		14	2.793
		15	2.745
	Mechanical strength +Temperature conditioned	16	3.413
		17	4.580
		18	3.965

Flow conditioning : Single filter: 95.0 L/min



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Clause 7.13 Head Harness

(EN 149:2001+A1:2009, Clause 8.4 & 8.5)

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	

Clause 7.14 Field of Vision

(EN 149:2001+A1:2009, Clause 8.4)

Test Requirement	Results	Comment
The field of vision is acceptable if determined so in practical performance tests.	Comply	Pass

Clause 7.16 Breathing Resistance

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

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 5	Meet FFP1, Meet FFP2, Meet FFP3																						
<table border="1"> <thead> <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> </thead> <tbody> <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> </tbody> </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
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)

As received	Flow rate(l/min)		1					2					3				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30	0.4	0.5	0.4	0.5	0.5	0.4	0.4	0.5	0.4	0.4	0.5	0.4	0.5	0.4	0.5
		95	1.8	1.9	1.8	1.9	1.9	1.8	1.8	1.8	1.9	1.9	1.8	1.8	1.9	1.9	1.8
Exhalation		160	2.0	2.1	2.0	2.1	2.0	2.1	2.1	2.0	2.1	2.1	2.0	2.0	2.1	2.1	2.1
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	0.4	0.5	0.4	0.5	0.5	0.4	0.4	0.5	0.5	0.4	0.5	0.4	0.4	0.5	0.4
		95	1.9	1.9	1.8	1.8	1.9	1.9	1.8	1.8	1.9	1.9	1.8	1.9	1.9	1.9	1.8
Exhalation		160	2.1	2.2	2.2	2.1	2.1	2.2	2.1	2.1	2.2	2.2	2.1	2.1	2.2	2.1	2.2
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	0.4	0.4	0.5	0.4	0.4	0.5	0.4	0.4	0.5	0.4	0.4	0.5	0.4	0.5	0.4
	95	1.8	1.7	1.8	1.8	1.9	1.7	1.7	1.8	1.9	1.9	1.7	1.9	1.8	1.8	1.7	

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

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	No demountable parts	N.A.

Test	Uncertainty
Total inward leakage	3.4%
Penetration of filter material	4.8%
Carbon dioxide content of the inhalation air	3.9%
Breathing resistance (30L/min)	5.9%
Breathing resistance (95L/min)	4.9%
Breathing resistance (160L/min)	4.3%

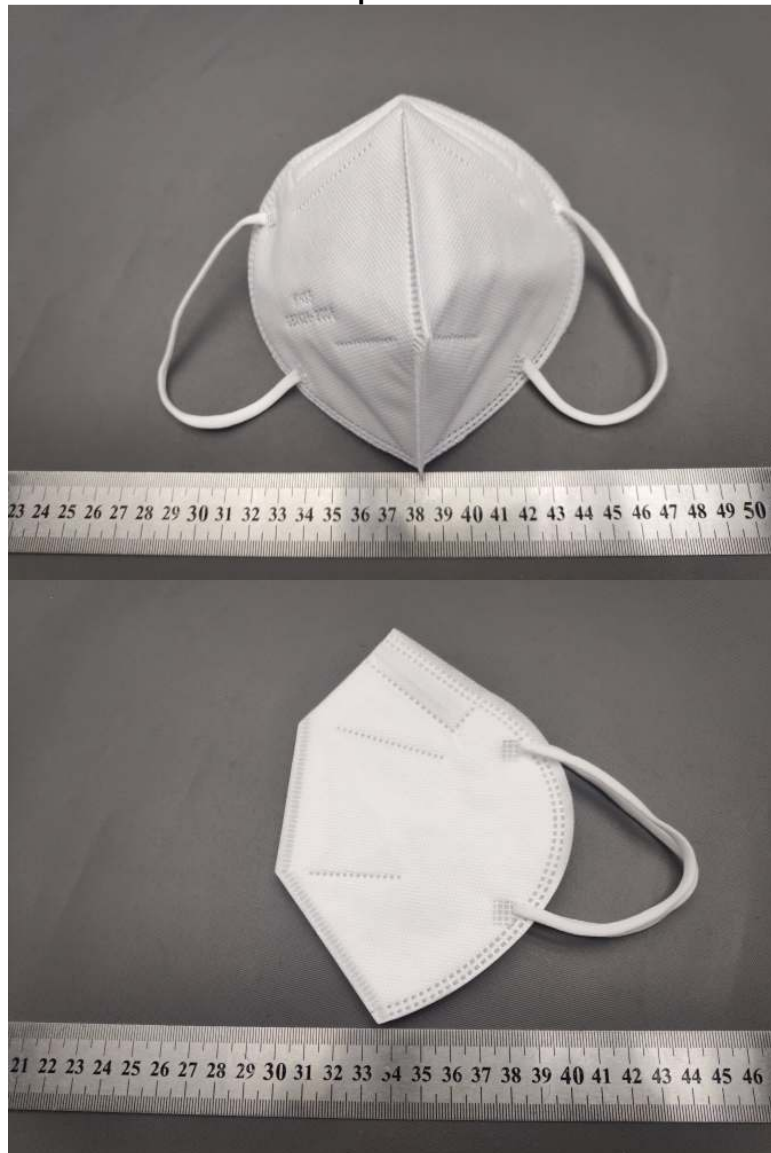


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Sample Photo



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