



Test Report

On Behalf of

Shenzhen Meili Medical Devices Co., Ltd

KN95 protective mask

Model : KN95

Prepared for : **Shenzhen Meili Medical Devices Co., Ltd**
301Room 301, No. 33, Rifu Road, East District of Baishixia
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TEST REPORT EN 149 Respiratory protective devices. Filtering half masks to protect against particles.Requirements,testing,marking	
Report Reference No	TMC200314114-S
Checked by (printed name and signature) ... :	<i>Seven Liu</i> Seven Liu
Approved by (printed name and signature) ... :	Lemon Rao
Date of issue.....	March 20, 2020
Testing laboratory	TMC Testing Services(Shenzhen) Co., Ltd.
Address.....	1st Floor, Block A1, Zone A, Xinshidai Gongrong Industrial Park, No. 2, Shihuan Road, Shiyuan Street, Baoan District, Shenzhen, China
Applicant's name	Shenzhen Meili Medical Devices Co., Ltd
Address.....	301Room 301, No. 33, Rifu Road, East District of Baishixia Community, Fuyong Street, Bao'an District, Shenzhen City
Manufacturer's name	Shenzhen Meili Medical Devices Co., Ltd
Address.....	301Room 301, No. 33, Rifu Road, East District of Baishixia Community, Fuyong Street, Bao'an District, Shenzhen City
Factory's name	Same as applicant
Address.....	
Test specification:	
Standard.....	<input checked="" type="checkbox"/> EN 149:2001+A1:2009
Test procedure.....	CE
Non-standard test method.....	N/A
Test Report Form No	TMC200314114-S
TRF Originator.....	TMC
Master TRF.....	Dated 2019-01
Test item description	KN95 protective mask
Trade Mark.....	美丽
Model/Type reference.....	KN95
Ratings.....	--

Possible test case verdicts:

- test case does not apply to the test object ... N (Not apply)
- test object does meet the requirement.....P (Pass)
- test object does not meet the requirement..... F (Fail)

Testing

Date of receipt of test item March 10, 2020

Date(s) of performance of tests March 10, 2020 to March 21, 2020

General remarks:

The test results presented in this report relate only to the object tested.

This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.

“(See Enclosure #)” refers to additional information appended to the report.

“(See appended table)” refers to a table appended to the report.

General product information:

N/A

Copy of marking plate:

KN95 protective mask

Model:KN95

Standard: EN 149:2001+A1:2009

Classification: FFP2



Shenzhen Meili Medical Devices Co., Ltd

Made in China

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict

5	Classification		--
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices:		P
	- FFP1		N
	- FFP2	>95%	P
	- FFP3		N

6	Designation		--
	Particle filtering half masks meeting the requirements of this European Standard. Year of publication, classification, option	Particle filtering half mask EN149:2001+A1:2009 FFP2 NR.	P

7	Requirements		--
7.1	General		P
	All test all test samples shall meet the requirements.	Compled the requirement, see bellow	P
7.2	Nominal values and tolerances		P
	Unless otherwise specified,the values stated in this European Standard are experature limits.		P
7.3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	Clear marking is provided, see sample body	P
7.4	Packaging		P
	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.		P
7.5	Material		P
	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. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	Comfortable wearing, when releasing no hazards is produced.	P
7.6	Cleaning and disinfecting		N
	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.	It's is not re-usable.	N
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions.	Complied, see append test.	P
7.8	Finish of parts		P
	come into contact with the wearer shall have no sharp edges or burrs		P
7.9	Leakage	See append table 8.5	P
7.9.1	Total inward leakage		P

EN 149			
Clause	Requirement – Test	Result - Remark	Verdict
	The laboratory tests shall wearer to protect with high probability against the potential hazard to be expected.	Enough safe condition is Provide.	P
	Exercise results for total inward leakage shall be not greater than		P
	25 % for FFP1 11% for FFP2 5% for FFP3	FFP2, Not exceed 11%	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.		P
	22 % for FFP1 8 % for FFP2 2 % for FFP3.	FFP2, Not exceed 8%	P
7.9.2	Penetration of filter material		P
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.	see append table 7.92	P
7.10	Compatibility with shin		P
	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.		P
7.11	Flammability		P
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.		P
7.12	Carbon dioxide content of the inhalation air		P
	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0% (by volume).	<1.0%	P
7.13	Head harness		P
	Head harness shall be designed can be donned and removed easily and adjustable or selfadjusting and sufficiently robust to hold the particle.	Head harness is donned and removed easily	P
7.14	Field of vision		P
	Field of vision is acceptable in practical performance tests.	Clear field of vision when wearing	P
7.15	Exhalation valve(s)		N
	A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.	One valve provided	N
	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.	Clearly function	N
	Exhalation valve(s) shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.		N
	Exhalation valve housing is attached to the faceblank, and withstand axially a tensile force of 10 N applied for 10 s.		N
7.16	Breathing resistance		P
	Breathing resistances apply to valved and valveless and shall meet the requirements.		P
7.17	Clogging		N
	General		N

EN 149			
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	For single-use devices clogging test is an optional test.		N
	Devices designed to be resistant to clogging, shown by a slow increase		N
	The specified breathing resistances shall not be exceeded before the required dust load of 833 mg·h/m ³ .		N
7.17.2	Breathing resistance		N
7.17.2.1	Valved particle filtering half masks		N
7.17.2.2	Valveless particle filtering half masks		N
7.17.3	Penetration of filter materia		N
	All types claimed to meet the clogging requirement shall also meet the penetration requirements given in 7.9.2 after the treatment.		N
7.18	Demountable parts		N
	All demountable parts (if fitted) shall be readily connected and secured, where possible by hand.	No such demountable part	N
8	Testing		--
8.1	General		P
	No special measuring devices and methods are specified, commonly used devices and methods shall be used.		P
8.2	Visual inspection		P
	The visual inspection is carried out appropriate by the test house prior to laboratory or practical performance tests.		P
8.3	Conditioning		P
8.3.1	Simulated wearing treatment		P
	A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke.	25 cycles/min 2,0 l/stroke.	P
	For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head,	A saturator incorporated by breathing machine and the dummy head.	P
	The spilling out of the dummy's mouth and contaminating the particle filtering half mask the head shall be incline	Incline considered	P
8.3.2	Temperature conditioning		P
	Exposet masks to the following thermal cycle:		P
	a) for 24 h to a dry atmosphere of (70 ± 3) °C;		P
	b) for 24 h to a temperature of (-30 ± 3) °C;		P
	Allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing.	5h to paid for	P
8.3.4	Flow conditioning		P
	A total of 3 valved particle filtering half masks shall be tested, one as received and two temperature conditioned in accordance with 8.3.2.		P
9	Marking		--
9.1	Packaging		P

EN 149			
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	The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.	Complied, clearly marked	P
9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.		P
9.1.2	Type-identifying marking.		P
9.1.3	Classification: FFP1, FFP2, FFP3.	FFP2 NR	P
9.1.4	The number and year of publication of this European Standard.		P
9.1.5	At least the year of end of shelf life.		P
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.		P
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.	See product manual	P
9.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D".		N
9.2	Particle filtering half mask		P
	Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:		P
9.2.1	The name, trademark or other means of identification of the manufacturer or supplier.	Shenzhen Meili Medical Devices Co., Ltd	P
9.2.2	Type-identifying marking.		P
9.2.3	The number and year of publication of this European Standard.		P
9.2.4	The symbols FFP1, FFP2 or FFP3 according to class.	FFP2 NR	P
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the class designation (see 9.2.4).		N
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.		N

EN 149			
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Attachments: Test table

Table 7.9.2		Penetration of test aerosol test					P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6
	Sodium chloride test 95 l/min		5.6	5.7	5.5	5.6	5.7
Paraffin oil test 95 l/min		5.4	5.6	5.7	5.7	5.6	5.5

Table 8.5		Leakage test				P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
	NaCl flow rate (L/min)		90	100	120	110
NaCl aerosol (um)		0.3	0.3	0.3	0.3	0.3
0.3Pumping flow rate (L/min)		30	30	30	30	30
NaCl concentration before mask (Mg/m3)		2	2	2	2	2
NaCl concentration after mask (Mg/m3)		0.05	0.06	0.07	0.08	0.06

Note: Test ark volume is 2m³
Average Leakage ratio is 8%<11%
Calculation formula as below :

$$P(\%) = \frac{C_2}{C_1} \times \left(\frac{t_{IN} + t_{EX}}{t_{IN}} \right) \times 100$$

Table 8.9.2		Exhalation resistance test				P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
	Inhalation gas velocity (L/min)		160	160	160	160
Maximum resistance (mbar)		2.45	2.47	2.45	2.46	2.46

Conclusion: Maximum permitted resistance < 3.0 mbar

Table 8.9.3		Inhalation resistance test				P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
	Inhalation gas velocity (L/min)		30	30	30	30
Maximum resistance (mbar)		0.42	0.44	0.44	0.45	0.43

Conclusion: Maximum Inhalation resistance < 0.7 mbar

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Table 8.9.3.2		Inhalation resistance test				P
Item	Models	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5
	Inhalation (L/min)		95	95	95	95
Maximum resistance (mbar)		2.12	2.14	2.16	2.15	2.14
Conclusion: Maximum Inhalation resistance < 2.4mbar						

Photo Documentation

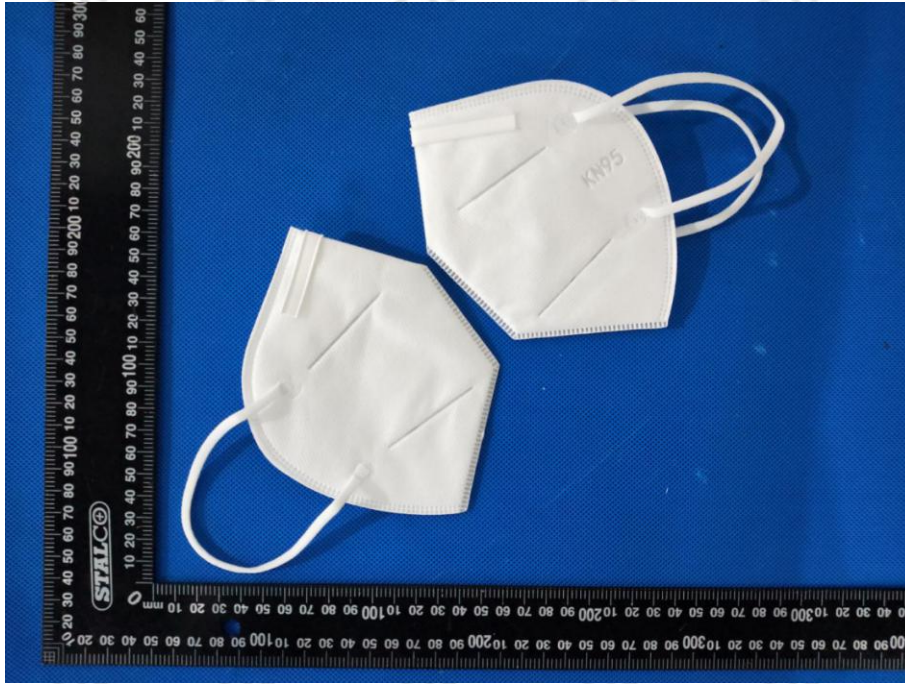


Photo 1 Overview

- End of Test Report -