TEST REPORT

GB2626-2006

Disposable masks - Requirements and test methods

Report Number.....: MT20200318-005-A

Date of issue.....: Mar. 25, 2020

Total number of pages.....: 11

Applicant

Name.....: Duanhdong Sky Power Medical Technology Co. Ltd

Address.....: 3 / F, Building D, 22 Dongyuan Road, East District, Zhongshan, Guangdong, China

Test specification

Standard.....: GB2626-2006

Test procedure .....: R

Procedure deviation.....: N/A

Non-standard test method.....: N/A

Test item description

Product description .....: KN95 Disposable Mask

Trade Mark.....: /

Model/Type reference.....: Planar

Manufacturer

Name.....: Duanhdong Sky Power Medical Technology Co. Ltd

Address.....: 3 / F, Building D, 22 Dongyuan Road, East District, Zhongshan, Guangdong, China

Testing laboratory

Name.....: Shenzhen XinWei Certification Service Co.,Ltd

Address.....: 501,5th Floor,Xusheng R&D Building,Gonghe Industrial Road, Xixiang Street, Baoan District, Shenzhen

Test case verdicts

Test case does not apply to the test object·····: N(N/A)

Test item does meet the requirement·····: P(Pass)

Test item does not meet the requirement·····: F(Fail)

Copy of marking plate:

KN95 Disposable Mask

Model: Planar

EN 149-2001

MADE IN CHINA

Duanhdong Sky Power Medical Technology Co. Ltd

3 / F, Building D, 22 Dongyuan Road, East District, Zhongshan, Guangdong, China

The markings above may be only a draft.For the final production samples,the additional markings which do not give rise to misunderstanding may be added.

Testing procedure and testing location:

Testing Laboratory.....: Shenzhen XinWei Certification Service Co.,Ltd

Address.....: 501,5th Floor,Xusheng R&D Building,Gonghe Industrial Road, Xixiang Street, Baoan District, Shenzhen

Date of Test.....: Mar. 18, 2020 to Mar. 25, 2020

Test by (name + signature) .....: Rex Chen

Reviewed by (name + signature) .....: Forlan Lu

Approved by (name + signature) ... .: Marin Wang

GB2626-2006			
Clause	Requirement-Test	Result-Remark	Verdict
4	Classification		N
	Classified into two types according to bacteria filtration efficiency and differential pressure and each type is further divided according to whether or not the masks are splash resistant		P
5	Requirements		P
	General		P
5.1.1	Materials and construction		P
	The disposable mask shall not disintegrate, split or tear during intended		P
5.1.2	Design		P
	The disposable mask shall have a means by which it can be fitted closely over the nose, mouth and chin of wearer and which ensures that the mask fits closely at the sides		N
5.2	Performance requirements		P
5.2.2	Bacterial filtration efficiency (BFE)		P
	When tested in accordance with Annex B, the bacterial filtration efficiency(BFE) of the disposable mask shall conform to the minimum value given for the relevant type in Table 1		P

Table 1 — Performance requirements

Test	Type I	Type IR	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 95	≥ 98	≥ 98
Differential pressure (Pa)	< 29,4	< 49,0	< 29,4	< 49,0
Splash resistance pressure (mm Hg)	Not required	≥ 120	Not required	≥ 120
NOTE Type IR and Type IIR are splash resistant types.				

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Clause	Requirement-Test	Result-Remark	Verdict
5.2.3	Breathability		--
	When tested in accordance with Annex C, the differential pressure of the disposable mask shall conform to the value given for the relevant type in Table 1 NOTE1 If the use of a respiratory protective device as disposable mask is required in an operating theatre and/or other medical settings, it might not fulfil the requirement with regard to differential as defined in this European Standard. In such cases NOTE 2 Differential Pressure is expressed in Pa 1 Pa equals 9,806 times pressure expressed in mm water		P
5.2.4	Splash resistance		--
	When tested in accordance with ASTM F1862, the resistance of the disposable mask to penetration of splashes of liquid shall conform to the minimum value given for the relevant type in Table 1.		P
6	Testing requirements		P
	Sample requirement		P
	Condition T:21℃±5℃ RH: 85%±5%	T:24.3^{0}C RH: 82.7%	P
7	Labelling and information		PP
	Annex I & 13 of MDD(93/42/EEC) specified the information that to be provided on the packaging in which the disposable mask is supplied.		P
	The following information shall be supplied in addition		P
	a) Number of the European standard	?	P
	b) Type of mask(as indicated in Table 1)	TYPE Ⅰ	P

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Clause	Requirement-Test	Result-Remark	Verdict
Annex A	Information for users	See the manual specification	P
	Majority of nuclei are between 0.5um and 12 um in diameter		N
	Designed to protect the working environment and not the wearer		N
	Specifies the performance requirements and gives a test method for a special class of disposable masks offering protection against splashes		N
	Protection degree depends on a number of factors, such as the filtration capacity and efficiency of the material and the fit of mask on the wearer's face.		N
	The filtration capacity of mask materials can vary depending on the filter media		N
	The need for large groups of test subjects and observations.		N
	A further factor to be considered is the capacity of the mask to absorb moisture form the exhaled air and thereby to maintain its performance over a long period of time.		N
	The contamination risk resulting from hand contact with a used mask means that it is essential that the mask is taken off and disposed of when no longer worn over nose and mouth.		N
	In summary, to use an appropriate mask is an effective means to protect the working environment from droplet contamination from nose and throat during health care procedures.		N
Annex B	Method for intro determination of BFE		P
B.1	Principle		--
	A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber.		P

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Clause	Requirement-Test	Result-Remark	Verdict
	An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum.		P
	The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.		P
B.2	Reagents and materials		P
B.2.1	General		P
	B.2.2 and B.2.3 describe commercially available solutions of tryptic soy agar and tryptic soy broth. Other variants may be suitable.		P
B.2.2	Tryptic soy agar		P
B.2.3	Tryptic soy broth		P
B.2.4	Peptone water		P
B.2.5	Culture of Staphylococcus aureus ATCC 6538, growing on tryptic soy agar slants		P
B.3	Apparatus		--
B.3.1	Six stage cascade impactor		P
B.3.2	Nebulizer		P
B.3.3	Aerosol chamber		N
B.3.4	Flow meters		N
B.3.5	Pressure gauge		P
B.3.6	Erlenmeyer flasks		P
B.3.7	Peristaltic or syringe pump		P
B.3.8	Vacuum pump		N
B.4	Test specimens		N
	cut from complete masks		N
	Each specimen shall be minimum 100 mm by 100 mm		N

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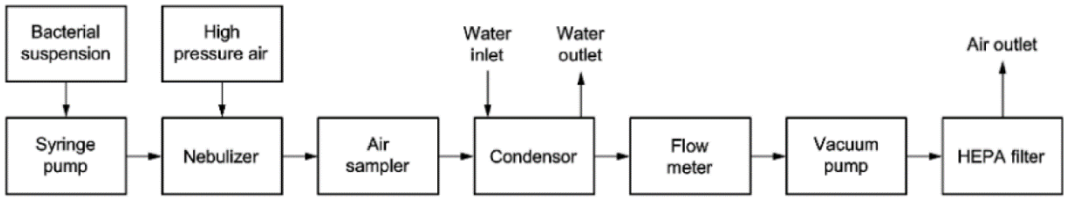
Clause	Requirement-Test	Result-Remark	Verdict
	The number of specimens that shall be tested is minimum 5 (five)		N
	Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for the time required to bring them into equilibrium with atmosphere prior to testing.		N
B.5	Preparation of bacterial challenge		P
	B.2.4 shall be inoculated into 30ml tryptic soy broth in an Erlenmeyer flask and incubated with mild shaking at temperature of 37 ±20C for 24 ±2 h.		P
	The culture shall then be diluted in peptone water to give a concentration of approximately 5 x 10^5cfu/ml.		P
	The bacterial challenge shall be maintained at 2200 ±500 cuf per test.		P
	The mean particle size in the bacterial challenge shall be maintained at 3 ±0.3 um		P
B.6	Procedure		P
B.6.1	Assemble the apparatus as shown in below figure.		P
 **Figure B.1 — Principle of BFE test apparatus**			
B.6.2	Deliver the bacterial challenge to the nebulizer		N
B.6.3	Perform a positive control run without a test specimen.		N
B.6.4	Place fresh plates in the impactor, fix a test specimen in place and repeat the above procedure.		N
B.6.5	Repeat this procedure for each test specimen.		N

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Clause	Requirement-Test	Result-Remark	Verdict
B.6.6	After the last test specimen has been tested, perform a further positive control run.		N
B.6.7	Perform a negative control run by passing air, through the cascade impactor for 2 min.		N
B.6.8	Incubate all the plates at 37± 2 0C for 48± 4h.		N
B.6.9	Calculate the mean particle size of the bacterial challenge aerosol in accordance with the instructions of the cascade impactor manufacturer.		N
8.7	Calculation of bacterial filtration efficiency		--
	Using the equation B=(C-T)/C X 100		N
	Where C is the mean of the total plate counts for the 2 positive control runs T is the total plate count for the test specimen		N
B.8	Test report		--
	The following information shall be given		--
	a) number and date of this European Standard;	EN 149-2001	P
	b) lot number or batch code of the masks tested;	Planar	P
	c) dimensions of the test specimens and the size of the area tested;	95mm x 175mm	P
	which side of the test specimen was facing towards the challenge aerosol;	The side without metal bars	P
	flow rate during testing;		N
	f) mean of the total plate counts of the two positive controls;		N
	g) mean plate count of the negative controls;		N
	h) bacterial filtration efficiency for each test specimen.		P

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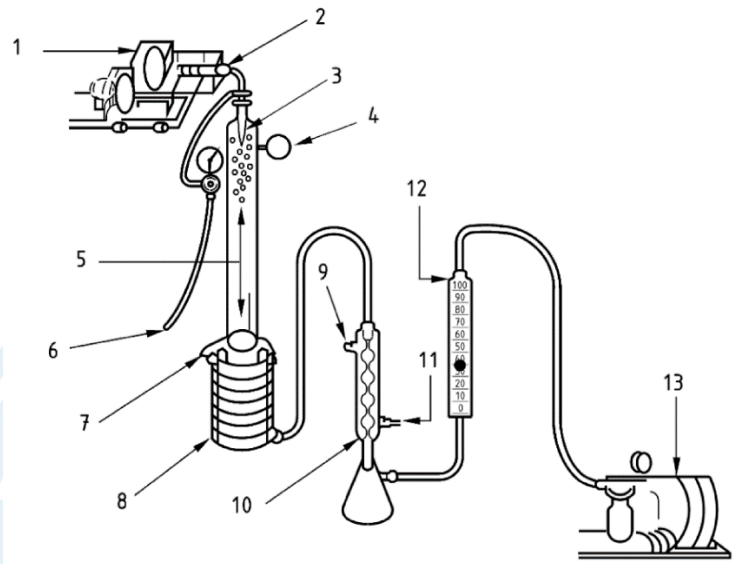
Clause	Requirement-Test	Result-Remark	Verdict



Annex C	Method of determination of breathability		----
C.1	Principle		----
C.2	Apparatus		----
C.2.1	Flow meter		P
C.2.2	Manometers M1 and M2		P
C.2.3	Electric vacuum pump		P
C.2.4	Valve		P
C.3	Test specimen		P
	Complete mask or cut from masks		P
	Each one shall be able to provide 5 different circular test areas of 2.5cm in diameter.		P
	The number of test specimens is 5.	5	P
C.4	Procedure		--
C.4.1	Specimen placed across the 2.5cm diameter orifice and clamped so that the tested area will be in line and across the air flow		P
C.4.2	The pump is started and the flow of air adjusted to 8 l/min.		P

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Clause	Requirement-Test	Result-Remark	Verdict
C.4.3	The manometers M1 and M2 are read and recoded.		P
C.4.4	The procedure described in steps C.4.1 through C.4.3 is carried out on 5 (or appropriate number of) different areas of the mask and the readings averaged.		P
C.5	Calculation of differential pressure		P
	For each test specimen calculate the differential pressure L1P as follows: $\Delta P = (X_{m1} - X_{m2})/4,9$		P
C.6	Test report		--
	The following information shall be given in the test report		--
	a. number and date of this European Standard;		N
	b. lot number or batch code of the masks tested		N
	c. flow rate during testing		N
	d. differential pressure for each test specimen		N

Photo Documentation

Fig.1

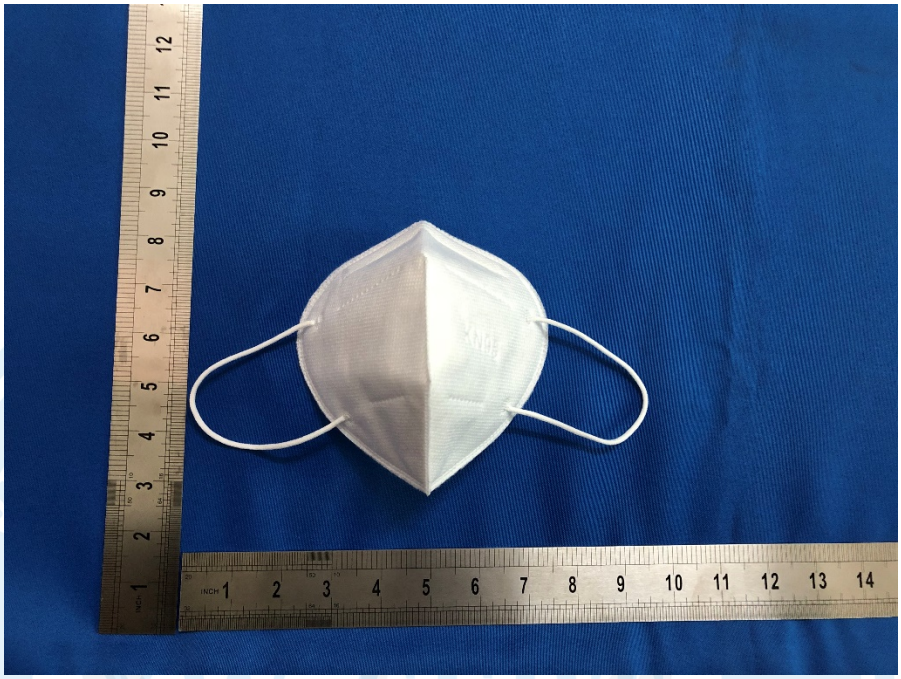

Fig.2