Test Report

Client Name	:	XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
Address	:	4th Floor, No.1 Building, No.6 Ji'an Road, Tong'an District, Xiamen, Fujian, China
Product Name	:	Single-use Surgical Mask Non-Sterile
Date	:	Mar. 21, 2020

Issued by : Monotek Technical Service Company Limited

EST REPORT

EN 14683

Medical face masks - Requirements and test methods

Report reference No.....:	MT20200318-011-A
Compiled by (+ signature).....:	Tony Xiao
Approved by (+ signature) .....:	Barry Zhou
Date of issue.....:	March 21, 2020
Contents .....:	10
Testing laboratory .....:	Monotek Technical Service Company Limited
Address.....:	Building A, No. 3, Huafa Road, Longgang District, Shenzhen, Guangdong, China.
Testing location .....:	Same as above
Applicant .....:	XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
Address .....:	4th Floor, No.1 Building, No.6 Ji'an Road, Tong'an District, Xiamen, Fujian, China
Test specification	
Standard .....:	EN 14683:2019
Test procedure .....:	Type test
Procedure deviation .....:	N.A.
Non-standard test method .....:	N.A.
Type of test object	
Description.....:	Single-use Surgical Mask Non-Sterile
Model.....:	GREENCARE
Trademark .....:	MP9017
Manufacturer .....:	Same as applicant
Address.....:	Same as applicant

Possible test case verdicts

— **test case does not apply to the test object.....:** N (Not applicable)

— test object does meet the requirement .....: P (Pass)

— test object does not meet the requirement .....: F (Fail)

Testing

Date of receipt of test item .....: Mar. 19, 2020

Date(s) of performance of test .....: Mar. 19, 2020 to Mar. 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 testing laboratory.

Models OH01-00 and OH01-01 are same except for model name

Marking information

XIAMEN PROBTAIN MEDICAL TECHNOLOGY CO.,LTD
Model: MP9017
Type II
EN 14683
CE

EN 14683			
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	Type II	P
5	Requirements		P
5.1	General		P
5.1.1	Materials and construction		P
	The surgical mask shall not disintegrate, split or tear during intended use	checked and found compliance	P
5.1.2	Design		P
	The surgical 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	checked and found compliance	P
5.2	Performance requirements		P
5.2.1	Bacterial filtration efficiency (BFE)		P
	When tested in accordance with Annex B, the bacterial filtration efficiency(BFE) of the surgical mask shall conform to the minimum value given for the relevant type in Table 1		P
	Table 1 — Performance requirements for surgical masks		--

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.				

5.2.2	Breathability		P

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	When tested in accordance with Annex C, the differential pressure of the surgical mask shall conform to the value given for the relevant type in Table 1 NOTE1 If the use of a respiratory protective device as surgical 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
5.2.3	Splash resistance		N
	When tested in accordance with ASTM F1862, the resistance of the surgical mask to penetration of splashes of liquid shall conform to the minimum value given for the relevant type in Table 1.		N
6	Testing requirements		P
	Sample requirement		P
	Condition T:20±2^{0}C RH: 65 2±%	T:21.5^{0}C RH: 66%	P
7	Labelling and information		P
	Annex I & 13 of MDD(93/42/EEC) specified the information that to be provided on the packaging in which the surgical mask is supplied.	Checked and found comliance	P
	The following information shall be supplied in addition		P
	a) Number of the European standard	EN 14683	P
	b) Type of mask(as indicated in Table 1)	Type II	P
Annex A	Information for users		P
	Majority of nuclei are between 0.5um and 12 um in diameter		P
	Designed to protect the working environment and not the wearer.		P
	Specifies the performance requirements and gives a test method for a special class of surgical masks offering protection against splashes.		P
	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.		P
	The filtration capacity of mask materials can vary depending on the filter media.		P
	The need for large groups of test subjects and observations.		P

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	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.		P
	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.		P
	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.		P
Annex B	Method for intro determination of BFE		P
B.1	Principle		P
	A specimen of the mask material is clamped between a six-stage cascade impactor and an aerosol chamber.		P
	The bacterial filtration efficiency of the mask is given by the number of colony forming units passing units passing through the surgical mask material expressed as a percentage of the number of colony forming units in the challenge asrosol.		P
B.2	Reagents and material		P
B2.1.1	Tryptic soy agar		P
B2.1.2	Tryptic soy broth		P
B2.1.3	Peptone water		P
B2.1.4	Culture of Staphylococcus aureaus ATCC 209, growing on tryptic soy agar slants		P
B.3.	Apparatus		P
B3.1	Six stage cascade impactor.		P
B3.2	Nebulizer		P
B3.3	Aerosol chamber		P
B3.4	Flow meter		P
B3.5	Pressure gauge		P
B3.6	Erlenmeyer flasks		P
B3.	Peristaltic or syringe pump		P
B3.	Vacuum pump		P
B.4	Test specimens		P
	Cut from complete mask		P
	Each one shall be min. 100mm by 100mm.		P
	The number is min. 5		P
	Specimens taken form areas representative to incorporate all/any variation in construction		P

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B.5	Preparation of bacterial challenge		P
	B.2.4 shall be inoculated into 30ml trypic soy broth in an Erienmyer flask and incubated with mild shaking at temperature of 37 ±2^{0}C for 24 ±2 h		P
	The culture shall be diluted in peptone water to give a concentration of appro. 5x10^5 cuf/ml.		P
	The bacterial challenege 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
B.6.2	Deliver the bacterial challenge to the nebulizer		P
B.6.3	Perform a positive control run without a test specimen.		P
B.6.4	Place fresh plates in the impactor, fix a test specimen in place and repeat the above procedure.		P
B.6.5	Repeat this procedure for each test specimen.		P
B.6.6	After the last test specimen has been tested, perform a further positive control run.		P
B.6.7	Perform a negative control run by passing air, through the cascade impactor for 2 min.		P
B.6.8	Incubate all the plates at 37± 2 ^{0}C for 48± 4h.		P
B.6.9	Calculate the mean particle size of the bacterial challenge aerosol in accordance with the instructions of the cascade impactor manufacturer.		P
8.7	Calculation of BFE		P
	Using the equation B=(C-T)/C X 100		P
	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		P
B.8	Test report		P
	The following information shall be given		P
	a) number and date of the standard.	EN 14683: 2019	P
	b) Dimension of the test specimens.	6cm x 6cm	P
	c) Which side of the test specimen was towards the challenge aerosol	Inner side	P
	d) Flow rate during testing	28.3L/min	P
	e) Mean of the total plate counts of the 2 positive controls.	1.9X10^3 CFU	P
	f) Mean plate count of the negative control	Less than 1CUF	P

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	g) BFE for each test specimen	BFE#1: 99.7 BFE#2: 99.8 BFE#3: 99.8	P
Annex C	Method of determination of breathability		P
C.1	Principle		P
C.2	Apparatus		P
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.		P
C.4	Procedure		P
C4.1	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 adjusted to 8l/min.		P
C.4.3	The manometers M1 and M2 are read and recoded.		P
C.4.4	Above carried out on 5 different areas of the mask and the readings averaged.		P
C.5	Calculation of differential pressure		P
	differential pressure $\Delta P = (X_{m1} - X_{m2})/4,9$		P
C.6.	Test report		P
	The following information shall be given		P
	number and date of the standard.	EN 14683:2019	P
	Flow rate during testing	24.8L/min	P
	Differential pressure for each test specimen	Sample1:22.0 Sample2:22.6 Sample3:22.4	P
Annex ZA	Clause of this standard addressing essential requirements or other provisions of EU directive 93/42 concerning medical devices.		P

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Table ZA.1 — Correspondence between this European Standard and EU Directive 93/42/EEC Medical devices

Clause/subclause of this European Standard	Corresponding Essential Requirement of Directive 93/42/EEC	Comments
5.1.1	1, 2, 3, 4, 7.1, 8.1	
5.1.2	1, 2, 3, 7.1, 8.1	
5.2.1	3, 8.1	
5.2.2	3, 8.1, 9.2	
5.2.3	3, 8.1	
6	3, 8.1	
7	13	

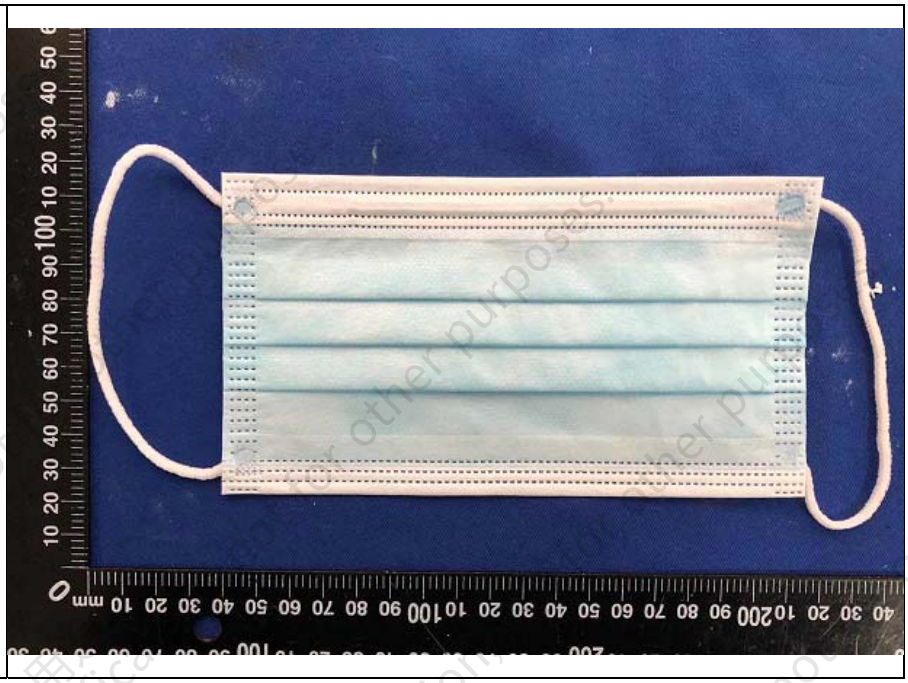
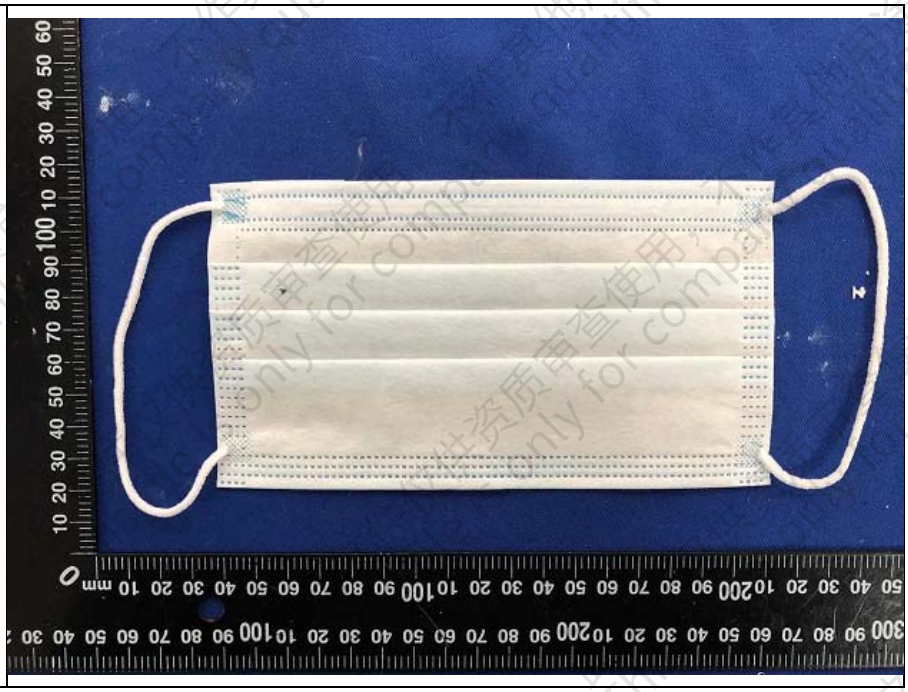
Photo 1	

Photo 2	

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