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Test Report for

EN 14683:2019

Medical face masks-Requirements and test methods

Testing Laboratory:
CCIC Huatongwei International Inspection（Suzhou) Co.,Ltd.
Testing Location:
Room 101,Building G,Ruoshui Road 388,Industrial Park, Suzhou, Jiangsu,China

Overview

Manufacturer	Anhui Yimeijian Medical Supplies Co.LTD No.8, North Feilong Road, Xinjie Town, Tianchang City, Anhui Province, China
the test devices	Medical Face Masks
Report No.:	CSTBE20030005
Model Name.:	YMJ1, YMJ2, YMJ3

Signatures

Tested by: Teddy Yao

Supervised by Tom Li

Approved by: Bobby Lu 2020-03-25

EN 14683:2019			
Clause	Requirement + Test	Result - Remark	Verdict
5.1	General		P
5.11	Materials and construction		P
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric. The medical face mask shall not disintegrate, split or tear during intended use. In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Considered	P
5.1.2	Design		P
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.	Considered	P
	Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	Considered	P
5.2	Performance requirements		P
5.2.1	General		P
	All tests shall be carried out on finished products or samples cut from finished products.		P
5.2.2	Bacterial filtration efficiency (BFE)		P
	When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	The Bacterial Filtration Efficiency ≥ 98% See appended Table 1 for YMJ1 The Bacterial Filtration Efficiency ≥ 98% See appended Table 4 for YMJ2 The Bacterial Filtration Efficiency ≥ 98% See appended Table 7 for	P

		for YMJ3	
	For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE.	Not such masks	N/A
	When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually. The lowest performing panel or area shall determine the BFE value of the complete mask.		N/A
5.2.3	Breathability		P
	When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.	The differential pressure <40 Pa/cm^2 See appended Table 2 for type YMJ1 See appended Table 5 for type YMJ2 See appended Table 8 for type YMJ3	P
	If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).	Considered	P
5.2.4	Splash resistance		N/A
	When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.	Type IIR for YMJ3	P
5.2.5	Microbial cleanliness (Bioburden)		P
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Table 1).	The bioburden of the medical mask was <30 CFU/g See appended Table 3 for type YMJ1 See appended Table 6 for	P

		type YMJ2 See appended Table 9 for type YMJ3	
	To determine the mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D.	Compliance	P
	The number of masks that shall be tested is minimum 5 of the same batch/lot.	5pcs masks tested	P
	Other test conditions as described in EN ISO 11737-1:2018 may be applied.		P
	In the test report, indicate the total bioburden per individual mask and based on the mask weight, the total bioburden per gram.	See appended Table 3	P
5.2.6	Biocompatibility		P
	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact. The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime. The results of testing should be documented according to the applicable parts of the EN ISO 10993 series. The test results shall be available upon request.	The biocompatibility of mask was evaluated in following report: CSTBR20030093 CSTBR20030094 CSTBR20030095 for YMJ1and YMJ2 CSTBR20030096 CSTBR20030097 CSTBR20030098 for YMJ3	P
5.2.7	Summary of performance requirements		P
	Table 1 — Performance requirements for medical face masks		P
6	Marking, labelling and packaging		P
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied	Considered	P
	The following information shall be supplied:		P
	a) number of this European Standard;	EN 14683:2019	P
	b) type of mask (as indicated in Table 1).	Type II for YMJ1 and YMJ2 Type IIR for YMJ3	P

	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.	Compliance	P

Bacterial Filtration Efficiency (BFE) Test

Summary:
The bacterial filtration efficiency (BFE) test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of staphylococcus aureus(ATCC6538) was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 1.7-3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) at (3,0 ± 0,3) μm The test method complies with EN14683:2019 Annex B

The Differential Pressure test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate.
The differential pressure test was designed to comply with EN 14683:2019 Annex C.

Condition parameters: Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for a minimum of 4 h to bring them into equilibrium with atmosphere prior to testing

Type of test Article: YMJ 1
Test Article quantity: 5 pcs
BFE Area tested: (Each specimen shall be minimum 100 mm × 100 mm)
BFE Flow Rate: 28.3 L/min
MPS Mean particle size: 3.0μm

Test Result:

Test Article Number	Percent BEF(%)	Comments
1	99.1	≥98
2	98.7	≥98
3	98.3	≥98
4	99.2	≥98
5	98.6	≥98

Table 1

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:
$B = (C - T) / C \times 100$
Where
C is the mean of the total plate counts for the two positive control runs;
T is the total plate count for the test specimen

Differential Pressure test

Condition parameters: Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for a minimum of 4 h to bring them into equilibrium with atmosphere prior to testing

Type of test Article: YMJ 1
Test Article quantity 5 pcs;
Test Article Dimensions: 4.9 cm^2 (25 mm diameter orifice);
Differential Pressure Flow Rate: 8 L/min;

Test Result:

Test Article Number	ΔP (Pa/cm^2)	Comments
1	28.9	<40
2	27.1	<40
3	27.9	<40
4	26.5	<40
5	27.8	<40

Table 2

For each test specimen calculate the differential pressure ΔP/cm^2 of each tested area as follows:
ΔP = (X m1 – X m2)/4,9
Where
X m1 is the pressure in Pa, measured by manometer M1 – low pressure side of the material;
X m2 is the pressure in Pa, measured by manometer M2 – high pressure side of the material;
ΔP is the differential pressure per cm 2 of test material expressed in Pa.

Microbial cleanliness (Bioburden)Test

Summary:

To determine the mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D of EN 14683:2019.

Test procedure

Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l polysorbate surfactant 20 [e.g. ween 20, Alkest TW 20]).

The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 µm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30 °C and 7 days at (20 to 25) °C for TSA and SDA plates respectively.

Type of test Article: YMJ 1
Test Article quantity: 5 pcs

Result:

Test Article Num	Weight (g)	Aerobic CFU/mask	Fungal CFU/mask	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.1	22	21	43	13.9
2	3.1	22	20	42	13.5
3	3.1	22	21	43	13.9
4	3.0	19	20	39	13.0
5	3.0	20	21	41	13.7

Table 3

When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g

Bacterial Filtration Efficiency (BFE) Test

Summary:
The bacterial filtration efficiency (BFE) test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of staphylococcus aureus(ATCC6538) was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 1.7-3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) at (3,0 ± 0,3) μm The test method complies with EN14683:2019 Annex B

The Differential Pressure test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate.
The differential pressure test was designed to comply with EN 14683:2019 Annex C.

Condition parameters: Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for a minimum of 4 h to bring them into equilibrium with atmosphere prior to testing

Type of test Article: YMJ 2
Test Article quantity: 5 pcs
BFE Area tested: (Each specimen shall be minimum 100 mm × 100 mm)
BFE Flow Rate: 28.3 L/min
MPS Mean particle size: 3.0μm

Test Result:

Test Article Number	Percent BEF(%)	Comments
1	98.9	≥98
2	99.1	≥98
3	98.4	≥98
4	99.2	≥98
5	99.4	≥98

Table 4

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:
$B = (C - T) / C \times 100$
Where
C is the mean of the total plate counts for the two positive control runs;
T is the total plate count for the test specimen

Differential Pressure test

Condition parameters: Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for a minimum of 4 h to bring them into equilibrium with atmosphere prior to testing

T Type of test Article: YMJ 2
Test Article quantity 5 pcs;
Test Article Dimensions: 4.9 cm^2 (25 mm diameter orifice);
Differential Pressure Flow Rate: 8 L/min;

Test Result:

Test Article Number	ΔP (Pa/cm^2)	Comments
1	27.3	<40
2	28.5	<40
3	27.8	<40
4	29.2	<40
5	28.7	<40

Table 5

For each test specimen calculate the differential pressure ΔP/cm^2 of each tested area as follows:
ΔP = (X m1 – X m2)/4,9
Where
X m1 is the pressure in Pa, measured by manometer M1 – low pressure side of the material;
X m2 is the pressure in Pa, measured by manometer M2 – high pressure side of the material;
ΔP is the differential pressure per cm 2 of test material expressed in Pa.

Microbial cleanliness (Bioburden)Test

Summary:

To determine the mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D of EN 14683:2019.

Test procedure

Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l polysorbate surfactant 20 [e.g. ween 20, Alkest TW 20]).

The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 µm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30 °C and 7 days at (20 to 25) °C for TSA and SDA plates respectively.

Type of test Article: YMJ 2
Test Article quantity: 5 pcs

Result:

Test Article Num	Weight (g)	Aerobic CFU/mask	Fungal CFU/mask	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.0	19	18	37	12.3
2	3.1	24	21	45	14.5
3	3.1	26	21	47	15.2
4	3.0	21	19	40	13.3
5	3.1	22	20	42	13.5

Table 6

When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g

Bacterial Filtration Efficiency (BFE) Test

Summary:
The bacterial filtration efficiency (BFE) test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of staphylococcus aureus(ATCC6538) was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 1.7-3.0 x 10^3 colony forming units (CFU) with a mean particle size (MPS) at (3,0 ± 0,3) µm The test method complies with EN14683:2019 Annex B

The Differential Pressure test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate.
The differential pressure test was designed to comply with EN 14683:2019 Annex C.

Condition parameters: Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for a minimum of 4 h to bring them into equilibrium with atmosphere prior to testing

Type of test Article: YMJ 3
Test Article quantity: 5 pcs
BFE Area tested: (Each specimen shall be minimum 100 mm × 100 mm)
BFE Flow Rate: 28.3 L/min
MPS Mean particle size: 3.0µm

Test Result:

Test Article Number	Percent BEF(%)	Comments
1	99.2	≥98
2	98.4	≥98
3	98,6	≥98
4	98.7	≥98
5	99.1	≥98

Table 7

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:
$B = (C - T) / C \times 100$
Where
C is the mean of the total plate counts for the two positive control runs;
T is the total plate count for the test specimen

Differential Pressure test

Condition parameters: Each test specimen shall be conditioned at (21 ± 5) °C and (85 ± 5) % relative humidity for a minimum of 4 h to bring them into equilibrium with atmosphere prior to testing

Type of test Article: YMJ 3
Test Article quantity 5 pcs;
Test Article Dimensions: 4.9 cm^2 (25 mm diameter orifice);
Differential Pressure Flow Rate: 8 L/min;

Test Result:

Test Article Number	ΔP (Pa/cm^2)	Comments
1	27.1	<40
2	28.3	<40
3	28.3	<40
4	27.6	<40
5	27.8	<40

Table 8

For each test specimen calculate the differential pressure ΔP/cm^2 of each tested area as follows:
ΔP = (X m1 – X m2)/4,9
Where
X m1 is the pressure in Pa, measured by manometer M1 – low pressure side of the material;
X m2 is the pressure in Pa, measured by manometer M2 – high pressure side of the material;
ΔP is the differential pressure per cm 2 of test material expressed in Pa.

Microbial cleanliness (Bioburden)Test

Summary:

To determine the mask's bioburden according to EN ISO 11737-1:2018, refer to the procedure as described in Annex D of EN 14683:2019.

Test procedure

Weigh each mask prior testing. The full mask is aseptically removed from the packaging and placed in a sterile 500 ml bottle containing 300 ml of extraction liquid (1 g/l Peptone, 5 g/l NaCl and 2 g/l polysorbate surfactant 20 [e.g. ween 20, Alkest TW 20]).

The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm. After this extraction step, 100 ml of the extraction liquid is filtered through a 0,45 µm filter and laid down on a TSA plate for the total viable aerobic microbial count. Another 100 ml aliquot of the same extraction liquid is filtered in the same way and the filter plated on Sabouraud Dextrose agar (SDA) with chloramphenicol for fungi enumeration. The plates are incubated for 3 days at 30 °C and 7 days at (20 to 25) °C for TSA and SDA plates respectively.

Type of test Article: YMJ 3
Test Article quantity: 5 pcs

Result:

Test Article Num	Weight (g)	Aerobic CFU/mask	Fungal CFU/mask	Total Bioburden (CFU/mask)	Total Bioburden (CFU/g)
1	3.2	25	17	42	13.1
2	3.1	20	19	39	12.6
3	3.2	21	20	41	12.8
4	3.1	22	18	40	12.9
5	3.1	19	20	39	12.6

Table 9

When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g

Synthetic Blood Penetration Resistance test (Splash Resistance)

Summary: The procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this Procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm, A test volume of 2mL of synthetic blood was employed using the targeting plate method
This test method was designed to comply with ISO22069:2004 as referenced in EN 14683:2019

Type of test Article: YMJ 3
Number of Test Articles Tested: 32
Number of Test Articles Passed: 30
Test Side: Outside
Pre-Conditioning: Minimum of 4 hours at (21 ± 5) °C and (85 ± 10) % relative humidity (RH)
Test Conditions: 18.8°C and 32%RH

Results: Per ISO22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when≥29 of 32 test articles show passing results.

Test Pressure: 120 mmHg(16.0kPa)

Test Article Number:	Synthetic Blood Penetration
1-16,18-26,28-32	None Seen
17,27	Yes

Table 10

END OF EN 14683 REPORT