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YHUK Product Certificate Document

Type IIR Surgical Mask

Date: 2020/04/25

Test Report

Report No. : Z-Y-0055-2020



Company: Beijing Biosis Healing Biological Technology Co., Ltd

Sample name : Medical Surgical Mask

Model: BH-EGF-17.5×9.5

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Sample name	Medical Surgical Mask		sample number	/
	Submitted sample(√)	Sampling		
Trademark	/		Model	BH-EGF-17.5×9.5
Company	Beijing Biosis Healing Biological Technology Co., Ltd		Test category	Registration inspection
Address	No.6 plant west, Valley No.1 Bio-medicine Industry Park, Daxing District, 102600 Beijing, PEOPLE'S REPUBLIC OF CHINA.		Product ID	620022301
Production units	Beijing Biosis Healing Biological Technology Co.,Ltd		Sampling sheet number	/
The unit to be inspected	Beijing Biosis Healing Biological Technology Co.,Ltd		producing date	02/23/2020
Sampling unit	/		Number of sample	50
Sampling site	/		Sampling basic No.	/
Sampling time	/		Detection location	In the laboratory of the inspection center at Tongzhou
Date received	February 24, 2020		Date of Test	From February 24, 2020 to March 02, 2020
Inspection item	Appearance, mask band, particle filtration efficiency, bacterial filtration efficiency (BFE),differential pressure, et al.			
Inspection standard	Technical requirements for medical device products of Medical Surgical Mask from Beijing Biosis Healing Biological Technology Co.,Ltd			
Inspection conclusion	The tested samples meet the requirements of Medical Surgical Mask from Beijing Biosis Healing Biological Technology Co.,Ltd			
Date of issuance, March 04, 2020				
Remark	1) “--”in the report indicate that this item does not apply, “/”in the report represent this blank.			

Name of approver : Hu GuangfuReviewer Yue HuaTestor Zhang YapingTitle of approver:Deputy Director

Test Report

Report No. : Z-Y-0055-2020 Product ID 620022301

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Serial number	Inspection item	Inspection clause	Standards requirements	Inspection result	Single conclusion
1	Size	2.1	The mask should cover the wearer's nose, mouth and jaw	Meet the requirement	Conformity
			The design conforms with the regulations of Table 1 of technical requirements for medical device products of Medical Surgical Mask from Beijing Biosis Healing Biological Technology Co.,Ltd		Conformity
			Length (17.5±1)cm	Maximum deviation +0.3cm	Conformity
			Width (9.5±1)cm	maximum deviation +0.3cm	Conformity
2	Appearance	2.2	The appearance of the mask should be neat and intact, and the surface must be free from damage and stains.	Meet the requirement	Conformity
3	Nose clip	2.3.1	Masks must be fitted with a nose clip made of a plastic material.	Meet the requirement	Conformity
		2.3.2	The length of nose clip should not shorter than 8cm.	Minimum value is 9.6cm	Conformity
4	Mask band	2.4.1	Mask band should be easy to wear	Meet the requirement	Conformity
		2.4.2	The breaking strength of the connection point between each mask band and the mask body should not be less than 10N.	>10N	Conformity
5	Bacterial filtration efficiency(BFE)	2.5.1	The bacterial filtration efficiency of thee masks should be more than 95%.	Minimum value is 99.7%.	Conformity
6	Particle filtration efficiency(PFE)	2.5.2	The non-oily particles filtration efficiency of thee masks should be more than 30%.	Minimum value is 93.2%.	Conformity
7	Differential pressure(ΔP)	2.6	The pressure difference between the two sides of the mask for gas exchange should not be greater than 49Pa.	Maximum value is 36.7Pa.	Conformity



8	Ability of synthetic blood to penetrate masks	2.7	The synthetic blood is sprayed to the outer side of the mask at a pressure of 16.0kPa(120mmHg), and the inner side of the mask should not show blood.	No penetration	Conformity
9	Flame retardancy	2.8	Masks should be made of non-flammable materials, and the burning time of the mask after leaving the flame is not more than 5 seconds.	0 second	Conformity
10	Microbial index	2.9	The masks should meet the requirements of microbial indicators in YY0460-2011, as shown in the table below.	Meet the requirement	
Total number of bacterial colonies, cfu/g		≤ 100	<20 cfu/g	Conformity	
E.coli		Cannot be detected	Failed to detect	Conformity	
Pseudomonas aeruginosa		Cannot be detected	Failed to detect	Conformity	
Staphylococcus aureus		Cannot be detected	Failed to detect	Conformity	
Hemolytic streptococcus		Cannot be detected	Failed to detect	Conformity	
Fungus		Cannot be detected	Failed to detect	Conformity	

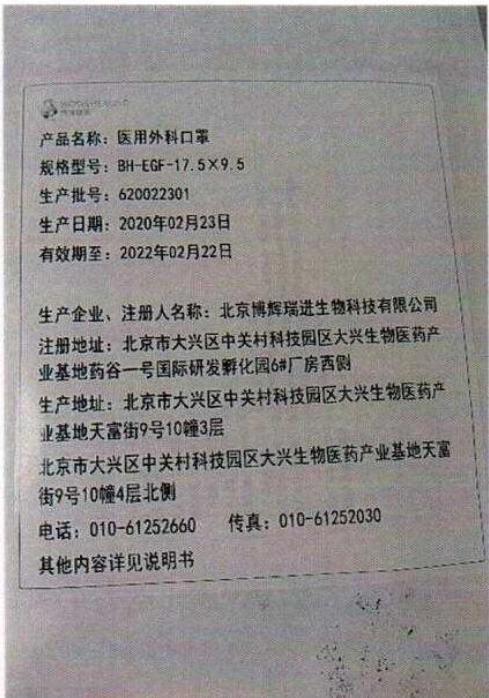


Photo page of Test Report

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Photoes and descriptions



Descriptions of samples

/

Model and other descriptions

/





SUBJECT Physical & Microbiological Test

TEST LOCATION TÜV SÜD China

TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai 201108, P.R. China

CLIENT NAME Beijing Biosis Healing Biological Technology Co., Ltd.

CLIENT ADDRESS No.6 plant west, Valley No.1 Bio-medicine Industry Park, Daxing District, 102600
Beijing, PEOPLE'S REPUBLIC OF CHINA

TEST PERIOD 12-Mar-2020~23-Mar-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By



(Leo Liu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

Chemical/Microbiology Laboratory:
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No.151 Heng Tong Road Shanghai
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Differential pressure of a medical face mask

1.Purpose

The purpose of the test was to measure the differential pressure of a medical face mask.

2.Sample description was given by the client

Medical Surgical Mask
Type : BH-EG-17.5X9.5
Lot : 620021301

3.References

EN 14683:2019

4.Apparatus

Differential pressure testing instrument

5.Test specimen

5.1 Test specimen are complete masks or shall be cut from masks. Each specimen shall be able to provide 5 different circular test areas of 2.5 cm in diameter.

5.2 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.

6. Procedure

- 6.1 The test specimen is placed across the 2.5 cm diameter orifice(total area 4.9 cm²) and clamped into place so as to minimize air leaks and that the tested area of the specimen will be in line and across the flow of air.
- 6.2 The pump is started and the that tested area of the specimen will be in line and across the flow of air.
- 6.3 The manometers M1 and M2 are read and recorded.
- 6.4 The procedure described in steps 6.1~6.3 is carried out on 5 different areas of the mask and readings averaged.

7. Calculation

For each test specimen calculate the different pressure ΔP as follows:

$$\Delta P = \frac{(X_{m1} - X_{m2})}{4.9}$$

X_{m1} : is pressure in Pa, manometer M1, mean of 5 test areas, low pressure side of the material;

X_{m2} : is pressure in Pa, manometer M2, mean of 5 test areas, high pressure side of the material;

4.9 is the cm² area of the test material;

ΔP is the different pressure per cm² of the test material expressed in Pa.



8. Test results

Test Items*		Test Results	Test Methods
Different Pressure Test (Pa/cm ²)	1	39.4	EN 14683:2019
	2	37.9	
	3	41.5	
	4	40.6	
	5	38.7	

Note: The test report is the test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.



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Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the Bacterial Filtration Efficiency (BFE) of medical face mask material.

2. Sample description was given by the client

Medical Surgical Mask

Type : BH-EG-17.5X9.5

Lot : 620021301

3. References

EN 14683:2019 Annex B

4. Apparatus and materials

- 4.1 *Staphylococcus aureus* ATCC 6538
- 4.2 Peptone water
- 4.3 Tryptic Soy Broth(TSB)
- 4.4 Tryptic Soy Agar(TSA)
- 4.5 Bacterial filtration efficiency test apparatus
- 4.6 Six-stage viable particle Anderson sampler
- 4.7 Flow meters

5. Test specimen

- 5.1 As requested by client, take a total of 5 test specimens.
- 5.2 Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

- 6.1 Preparation of the bacterial challenge: Dilute the culture in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
- 6.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
- 6.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
- 6.4 Perform a positive control run without a test specimen to determine the number of viable aerosol particles being generated. The mean particle size (MPS) of the aerosol will also be calculated from the results of these positive control plates.
 - 6.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediately begin sampling the aerosol using the Anderson sampler.
 - 6.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
 - 6.4.3 Time the air pressure and Anderson sampler to run for 2 min.
 - 6.4.4 At the conclusion of the positive control run, remove plates from the Anderson sampler.
- 6.5 Place new agar plates into Anderson sampler and clamp the test specimen into the top of the Anderson sampler, with the inside of the specimen in contact with the challenge.
- 6.6 Repeat the challenge procedure for each test specimen.
- 6.7 Repeat a positive control after completion of the sample set.



- 6.8 Perform a negative control run by collecting a 2 min sample of air from the aerosol chamber. No bacterial challenge should be pumped into the nebulizer during the collection of the negative control.
- 6.9 Incubate agar plates at (35±2)°C for (48±4) h.
- 6.10 Count each of the six-stage plates of the Anderson sampler.

7. Calculation

Total the count from each of the six plates for the test specimens and positive controls, as specified by the manufacturer of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE(\%) = \frac{C-T}{C} \times 100$$

where:

C= average plate count total for positive controls

T= plate count total for sample

8. Test results

Test Items*	Test Results		Test Methods
Bacterial Filtration Efficiency(BFE)(%) <i>Staphylococcus aureus</i> ATCC 6538	1	99.6	EN 14683:2019 Annex B
	2	99.9	
	3	99.8	
	4	99.7	
	5	99.7	

Note:

- 1.Control average: 2388 CFU.
- 2.Mean particle size:3.0 μm.
- 3.Testing side: outside of specimen
- 4.Testing area: 39.5cm².
- 5.The test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.

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Synthetic Blood Penetration Test for Masks

1.Purpose

For evaluating the resistance of medical face masks to penetration by a fixed volume of synthetic blood at a high velocity.

2.Sample description was given by the client

Medical Surgical Mask

Type : BH-EG-17.5X9.5

Lot : 620021301

3.References

EN 14683:2019

ISO 22609:2004

4.Apparatus and materials

- 4.1 Synthetic blood
- 4.2 Tensiometer
- 4.3 Synthetic blood penetration test apparatus
- 4.4 Targeting plate
- 4.5 Air pressure source
- 4.6 Ruler
- 4.7 Balance
- 4.8 Controlled temperature and humidity chamber

5.Test specimen

5.1 As requested by client, take a total of 13 test specimens.

5.2 Prior to testing, condition all test specimens for a minimum of 4h at (21±5)°C and (85±5) % relative humidity.

6.Procedure

- 6.1 Prepare the synthetic blood (40~44 mN/m) for the test.
- 6.2 Determine the density of the synthetic blood.
- 6.3 Fill the reservoir with new synthetic blood.
- 6.4 Position the test specimen 30.5 cm (12 in.) from the exit of the canula.
- 6.5 Set the reservoir pressure to the approximate pressure.
- 6.6 Place the targeting plate approximately 1 cm away from the mask.
- 6.7 Set the valve timer to 0.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).

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- 6.8 Set the valve timer to 1.5 s. Collect and weigh the amount of fluid delivered (before the targeting hole).
- 6.9 Calculate the difference in weight of the two spurts. For a test fluid with a density of 1.003, Table 1 gives the target difference in weight plus lower and upper limits for a velocity range within 2% of the target.
- 6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.

Table 1 Target weight differences

Fluid Pressure (mmHg)	Weight difference for 1 s difference in spurt duration (g)		
	Min.	Target	Max.
80	2.456	2.506	2.556
120	3.002	3.063	3.124
160	3.466	3.537	3.607

- 6.11 Record the weight difference for the spurts exiting the nozzle.
- 6.12 Record the pressure in the reservoir.
- 6.13 Set the valve time to 0.5 s. Collect and weigh the amount of fluid passing through the targeting hole.
- 6.14 Set the valve time to 1.5 s. Collect and weigh the amount of fluid passing through the targeting hole.
- 6.15 The difference in weight between the 0.5 s and 1.5 s spurts through the targeting plate shall be within +2 %, -5 % of the difference in weight from the nozzle.
- 6.16 If the differential weight is less than 95 % of the weight difference exiting the nozzle, check the aim of the stream to make sure it is passing cleanly through the targeting hole.
- 6.17 If the differential weight is more than 102 % of the weight difference exiting the nozzle, repeat the weight measurements exiting the nozzle (steps 6.7 to 6.11).
- 6.18 For standard synthetic blood, the timer duration can be estimated using the formula:
$$(p \text{ is the density of the test fluid.}) t = 0.5 + (2 \times p - g \text{ at } 0.5 \text{ s}) / (g \text{ at } 1.5 \text{ s} - g \text{ at } 0.5 \text{ s}).$$
- 6.19 Record the timer setting to use as the starting point for subsequent testing.
- 6.20 Mount a test specimen on the specimen holding fixture. If the mask contains pleats, spread the pleats out when mounting the mask onto the fixture to present a single layer of material as the target area.
- 6.21 Squirt the synthetic blood onto the test specimen for the calculated time. Ensure that the synthetic blood hits the target area of mask.
- 6.22 Inspect the inside surface for synthetic blood penetration within 10 s of squirting the synthetic blood against the target area.
- 6.23 Report the results (none / penetration) for each test specimen at the test pressure.



7. Test results

Test Items*		Test Results	Test Methods
Penetration of Synthetic Blood Pressure: 120 mmHg (16.0 kPa)	1	None Seen	EN 14683:2019 ISO 22609:2004
	2	None Seen	
	3	None Seen	
	4	None Seen	
	5	None Seen	
	6	None Seen	
	7	None Seen	
	8	None Seen	
	9	None Seen	
	10	None Seen	
	11	None Seen	
	12	None Seen	
	13	None Seen	

Note: The test results issued by the testing institution as requested by the consignor, it shall not determine the legitimacy of the product.





Cleanliness of Microbial (Bioburden) Test for Masks

1. Purpose

For determination of a population of microorganisms.

2. Sample description was given by the client

Medical Surgical Mask
Type : BH-EG-17.5X9.5
Lot : 620021301

3. References

EN 14683:2019
EN ISO 11737-1:2018

4. Apparatus and materials

- 4.1 Orbital shaker
- 4.2 Sterile 500 mL bottle
- 4.3 Extraction liquid (1 g/L Peptone, 5 g/L NaCl and 2 g/L Tween 20)
- 4.4 Tryptone soya agar (TSA)
- 4.5 Sabouraud dextrose agar (SDA) with chloramphenicol
- 4.6 Filtration equipment
- 4.7 Sterilized membrane (0.45μm)

5. Test specimen

5.1 As requested by client, take a total of 5 masks.

6. Procedure

- 6.1 Weight each mask prior testing.
- 6.2 The full mask is aseptically removed from the packaging and placed in a stomacher bag.
- 6.3 Pour into 100 mL extraction liquid and process 5 min in a stomacher individually by highest speed.
- 6.4 After this extraction step, 100 mL of the extraction liquid is filtered through a 0.45μm filter and laid down on a TSA plate for the total visible aerobic microbial count. Another 100mL aliquot of the same extraction liquid is filtered in the same way and the filter plated on SDA with chloramphenicol for fungi enumeration.Additionally,plate 10mL,1mL and 0.1mL of the extraction liquid both for TSA and SDA with chloramphenicol.
- 6.5 The plates are incubated for 3 d at 30°C and 7d at 25 °C for TSA and SDA plates respectively.
- 6.6 The colonies formed on incubation are counted.

7. Calculation

The total bioburden is expressed by addition of the TSA and SDA counts. Microbial cleanliness is based on the mask weigh, which is the total bioburden per gram tested.



8. Test results

Test Items*		Test Results	Test Methods
Microbial cleanliness (CFU/g)	1	9.6	EN 14683:2019 EN ISO 11737-1:2018
	2	5.2	
	3	2.6	
	4	1.7	
	5	0.9	

Note:

1.*denotes this test was carried out by external laboratory assessed as competent.

2.This report is for internal use only by the client.

-END OF THE TEST REPORT-



Declaration of Conformity

**Manufacturer
Address**

BEIJING BIOSIS HEALING BIOLOGICAL TECHNOLOGY CO., LTD
No.6 plant west, Valley No.1 Bio-medicine Industry Park, Daxing District,
102600 Beijing, PEOPLE'S REPUBLIC OF CHINA.

**European
Representative**

SHANGHAI INTERNATIONAL HOLDING CORP.GMBH (EUROPE)
EIFESTRASSE 80, 20537 HAMBURG, GERMANY

We, the manufacturer, herewith declare that the products

Medical Surgical Mask

BH-EGF- (12×7,14.5×9,17.5×9.5)
BH-BDF- (12×7,14.5×9,17.5×9.5)

meet the provisions of Directive 93/42/EEC and 2007/47/EC which apply to them.
The medical device has been assigned to class I according to Annex IX of the
Directive 93/42/EEC. It bears the mark



WE, AS THE MANUFACTURER,
ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY

Valid from: 2020 - 03 - 03
Valid until: 2024 - 05 - 27

Standard NO. EN 14683-2019 Type IIR

Bo Zhao
Signature of General Director



Product Service



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Certificate

No. Q5 101395 0001 Rev. 00

Holder of Certificate: **Beijing Biosis Healing Biological Technology Co., Ltd.**

No.6 plant west
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102600 Beijing
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Beijing Biosis Healing Biological Technology Co., Ltd.
No.6 plant west, Valley No.1 Bio-medicine Industry Park, Daxing District, 102600 Beijing, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design, Development, Production, Distribution and Sales of
Disposable Circular Stapler, Disposable Linear Stapler and Reloads,
Disposable Hemorrhoidal Stapler, Disposable Linear Cutter Stapler
and Reloads, Disposable Circumcision Stapler, Wound Protector,
Disposable Skin Staplers, Disposable Specimen Retrieval Bag,
Disposable Laparoscope trocar, Disposable Endoscopic Linear
Cutter Stapler and Reloads, Disposable Hemorrhoid Ligator, Veress
needle, Scar Silicon gel, Chitosan Gel, Clip Appliers and Removers,
Band-aid, Ligating clips, Surgical Mesh.

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.:

BJ1823301

Valid from:

2019-04-15

Valid until:

2022-04-14

Date, 2019-04-15

Stefan Preiß