中国认可
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检测
TESTING
CNAS L1225

TEST REPORT

Report No.:	4478420080549R1
Product Name:	Medical Surgical Mask
Product Model:	ZKM-02
Applicant:	Guangzhou Zhengkang Medical Equipment Co.,Ltd.

CHINA CERTIFICATION & INSPECTION GROUP SHENZHEN CO., LTD.
SHENZHEN HUATONGWEI INTERNATIONAL INSPECTION CO.,LTD.

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Add: Keji Nan No.12 Road, Hi-tech Park, Shenzhen, China
Tel: +86 755 2674 8019

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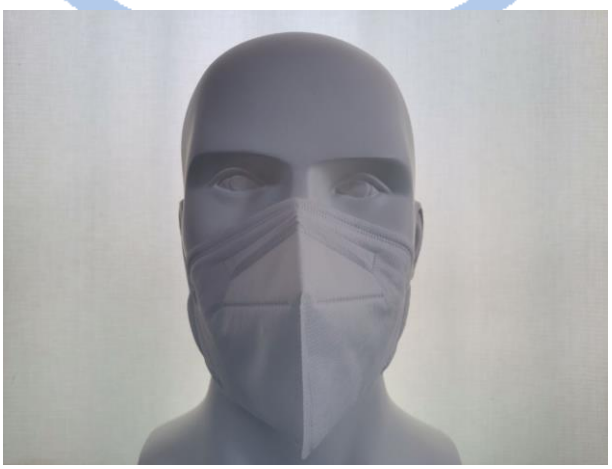
Date: 10 13, 2020

Test Report

APPLICANT	Guangzhou Zhengkang Medical Equipment Co.,Ltd.		
ADDRESS	Room 101，No. 9 ，Zhongxintang Road, Nanling, Taihe Town,Baiyun District, Guangzhou City, China		
MANUFACTURER	Guangzhou Zhengkang Medical Equipment Co.,Ltd.		
MANUFACTURER ADDRESS	Room 101，No. 9 ，Zhongxintang Road, Nanling, Taihe Town,Baiyun District, Guangzhou City, China		
SAMPLE NAME	Medical Surgical Mask		
SAMPLE MODEL	ZKM-02		
SAMPLE QUANTITY	120PCS		
LOT NUMBER	2020080502		
TYPE	Type IIR		
TEST REQUESTED	As specified by client, for details refer to next page(s).		
TEST METHOD	Please refer to next page.		
TEST RESULTS	Please refer to next page(s).		
RECEIVED DATE	08 26, 2020	TESTING PERIOD	08 26, 2020~09 09, 2020

SAMPLE PHOTO:

1-0



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Summary of Test Results

No.	Test Item		Test Standard	Test Result	Judgement
1	Bacterial Filtration Efficiency (BFE) Test		EN 14683:2019+AC:2019 (E) Annex B	Specimen 1#: 99.1% Specimen 2#: 99.5% Specimen 3#: 98.5% Specimen 4#: 98.4% Specimen 5#: 98.7%	Pass
2	Differential Pressure Test		EN 14683:2019+AC:2019 (E) Annex C	Max.:42.0Pa/cm^2	Pass
3	Synthetic Blood Penetration Test		ISO 22609:2004	Specimen 1#~32#: None seen	Pass
4	General	Materials and construction	EN 14683-2019+AC -2019	The medical face mask was no disintegrate, split or tear during using. the filter and layer materials are cleanliness.	Pass
		Design		The medical face mask can be fitted closely over the nose, mouth and chin of the wearer and the mask fits closely at the sides.	
5	*Microbial Cleanliness Test		ISO 11737-1: 2018	Specimen 1#: ＜1CFU/g Specimen 2#: ＜2CFU/g Specimen 3#: 1.5CFU/g Specimen 4#: 2.9CFU/g Specimen 5#: 4.8CFU/g	Pass

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Bacterial Filtration Efficiency (BFE) Test

1. Purpose

For evaluating the bacterial filtration efficiency (BFE) of mask.

2. Sample description was given by client

Sample description: Single-use surgical mask with ear loop
Lot Number : 2020080502
Sample Receiving Date :2020-08-26

3. Test Method

EN 14683:2019+AC:2019(E) 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.
Prior to testing, condition all test specimens for a minimum of 4 h at (21±5)°C and (85±5)% relative humidity.

6. Procedure

1.1 Preparation of the bacterial challenge: Dilute the cultutre in peptone water to achieve a concentration of approximately 5×10^5 CFU/mL.
1.2 Adjust the flow rate through the Anderson sampler to 28.3 L/min.
1.3 Deliver the challenge to the nebulizer using a syringe pump. Purge tubing and nebulizer of air bubbles.
1.4 Perform a positive control run without a test specime 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.
1.4.1 Initiate the aerosol challenge by turning on the air pressure and pump connected to the nebulizer. Immediaterly begin sampling the aerosol using the Anderson sampler.
1.4.2 Time the challenge suspension to be delivered to the nebulizer for 1 min.
1.4.3 Time the air pressure and Anderson sampler to run for 2 min.
1.4.4 At the conclusion of the positive control ran, remove plates from the Anderson sampler.
1.5 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 facing towards the bacterial challenge (test area: 77cm^2).
1.6 Repeat the challenge procedure for each test specimen.
1.7 Repeat a positive control after completion of the sample set.
1.8 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.
1.9 Incubate agar plates at (37±2)°C for (20 to 52) h.
1.10 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 manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE=(C-T) / C \times 100$$

T is the total plate count for the test specimen.
C is the mean of the total plate counts for the two positive controls.

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8.Test results

Specimens	***T***	**Results（%）**
Specimen 1#	18	99.1
Specimen 2#	10	99.5
Specimen 3#	29	98.5
Specimen 4#	31	98.4
Specimen 5#	25	98.7
Requirements	≥ 98	
Remarks	Positive Control: 1.95×10^3CFU Negative Control: ＜1CFU	

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Differential pressure Test

1. Purpose

The purpose of the test was to measure the differential pressure of masks.

2. Sample description was given by client

Sample description: Single-use surgical mask with ear loop
Lot Number : 2020080502
Sample Receiving Date :2020-08-26

3. Test Method

EN 14683:2019+AC:2019(E) Annex C

4. Apparatus and materials

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

6. Procedure

6.1 Without a specimen in place, the holder is closed and the differential manometer is zeroed. The pump is started and the flow of air adjusted to 8 L/min.

6.2 The pretreated specimen is placed across the orifice (total area 4.9cm^2, test area diameter 25mm) and clamped into place so as to minimize air leaks.

6.3 Due to the presence of an alignment system the tested area of the specimen should be perfectly in line and across the flow of air.

6.4 The differential pressure is read directly.

6.5 The procedure described in steps 6.1-6.4 is carried out on 5 different areas of the mask and readings averaged.

Results:

Specimen	Test Results (Pa/cm^2)	Maximum (Pa/cm^2)	Requirements	Judgement
1#	42.0	42.0	< 60	Pass
2#	40.0			
3#	37.0			
4#	41.2			
5#	41.5			

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Synthetic Blood Penetration Test

1. Purpose

For evaluation of resistance of masks to penetration by a fixed volume of synthetic blood at a high velocity.

2. Sample description was given by client

Sample description: Single-use surgical mask with ear loop
Lot Number : 2020080502
Sample Receiving Date: 2020-08-26

3. Test Method

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 32 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.
5.3 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).

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.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1s difference in spurt duration (g)		
	Min.	Target	Max.
120	3.002	3.063	3.124

6.10 Adjust the reservoir pressure and repeat steps 6.7 to 6.9 until the weight difference is within the target range.

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).

6.18For standard synthetic blood, the timer duration can be estimated using the formula: (p is the density of the test fluid.) $t = 0.5 + (2\times p$ - g at 0.5 s) / (g at 1.5 s - g at 0.5 s).

6.19 Record the timer setting to use as the starting point for subsequent testing.

6.20Mount 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.

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Results:

ISO 22609, 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 (16.0 kPa)

Specimen	Test Results	Judgement	Specimen	Test Results	Judgement
1#	None Seen	Pass	17#	None Seen	Pass
2#	None Seen	Pass	18#	None Seen	Pass
3#	None Seen	Pass	19#	None Seen	Pass
4#	None Seen	Pass	20#	None Seen	Pass
5#	None Seen	Pass	21#	None Seen	Pass
6#	None Seen	Pass	22#	None Seen	Pass
7#	None Seen	Pass	23#	None Seen	Pass
8#	None Seen	Pass	24#	None Seen	Pass
9#	None Seen	Pass	25#	None Seen	Pass
10#	None Seen	Pass	26#	None Seen	Pass
11#	None Seen	Pass	27#	None Seen	Pass
12#	None Seen	Pass	28#	None Seen	Pass
13#	None Seen	Pass	29#	None Seen	Pass
14#	None Seen	Pass	30#	None Seen	Pass
15#	None Seen	Pass	31#	None Seen	Pass
16#	None Seen	Pass	32#	None Seen	Pass

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Microbial Cleanliness Test

1.0 Purpose

To describe the population of viable microorganisms present on or in product

2.0 Reference

Medical face masks - Requirements and test methods EN 14683-2019

Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products ISO 11737-1: 2018

3.0 Equipment and reagents

3.1 Instruments

Vertical pressure steam sterilizer (SHB026), Steel Straight Scale (SHB076), Electronic Balance (SHB016), Clean bench (SHB015), Bench type low speed large capacity centrifuge (SHB021), Inverted microscope (SHB005), Constant Temperature Vibrator (SHB007), Biochemical incubator(SHB024), Biochemical incubator(SHB025)

3.2 Reagents

SDA（Beijing Land Bridge Technology Co., Ltd，Lot No:20190912）,TSA（HOPEBIO,Lot No:20190 613）,Sodium chloride-peptone buffer（Beijing Land Bridge Technology Co., Ltd，Lot No:20190820）

4.0 Experiment design and dose

4.1 Sample preparation

According to the table above, 5 samples were randomly selected for the experiment.

4.2 Test method

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, 5g/l NaCl and 2 g/l Tween 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℃ and 7 days at 25℃ for TSA and SDA plates respectively. The total bioburden is expressed by addition of the TSA and SDA counts.

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5.0 Statistical method

Count according to the principle of colony count.

6.0 Results of the test

Culture start time		2020-08-27 14:00			
Culture end time		2020-08-30 14:00	2020-09-03 14:00	Total bioburden (cfu/per sample)	Total biomass (cfu/g)
sample number	weight	Aerobe (cfu/100ml)	Fungi (cfu/100ml)		
1	6.1	< 1	< 1	< 6	< 1
2	6.2	3	< 1	< 12	< 2
3	6.2	2	1	9	1.5
4	6.2	5	1	18	2.9
5	6.2	8	2	30	4.8
According to EN 14683-2019 standard, the total biomass of surgical masks should be ≤30cfu/g。					

7.0 Conclusion

Under the conditions of this study, the test article met the criteria.

8.0 Record

All raw data pertaining to this study and a copy of the final report are to be stored in the designated archive files at Huatongwei.

9.0 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation

Note：
This report is only responsible for the test result of submitted samples
* The inspection basis of mark * is not within the scope of CNAS recognition of the laboratory or the test results are provided to qualified outsourcing institutions
Based on the report No.: 4478420080549modify, and the original report invalid.

Approved by: Date:2020-10-13