Star Care

Mascarilla Quirúrgica / Higiénica BFE 98%

Certificados

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Declaración de Conformidad

EC DECLARATION OF CONFORMITY

REGULATION 745/2017 ON MEDICAL DEVICE

Name and address of the manufacturer: /	Guangxi 3NOD Intelligent Health Technology Co., Ltd. Third Floor, Building D02, Guangxi 3NOD Smart Industrial Park, No.3 Gaoke Road, Beihai Industrial Park, Beihai 53600, China.
EC Authorized Representative:/	Caretechion GmbH Niederrheinstr 71,40474 Duesseldorf, Germany

We, as the manufacturer, are exclusive responsible for the declaration of conformity. Herewith declare that the state medical devicemeets the provisions of Medical Device Regulationof EU 2017/745:2017and its transportations in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Name of the medical device: /	Medical Face Masks
Type of Mask: /	Type IIR
Model:	BHKZ-001
UMDNSCode:/	12458
Basic UDI-DI:/	N/A
Intended purpose : /	The Medical Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material. These face masks are intended for use in infection control practices to reduce the potential exposure to blood and body fluids. This is a single use, disposable device(s), provided non-sterile.
Classification/	Rule1, Class I CND code:T020601Standard Surgical Face Masks according to annex VIII of directive EU 2017/745(MDR) /
CS reference: /	NA
Conformity assessment: /	Declare the conformity of the abovementioned products by issuing this EU Declaration of Conformity after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) 2017/745 / according to Article 52(7) of Regulation (EU) 2017/745 /

Beihai 2020-05-06 — General Manager

Place, date — Name and function

BH-CE-01-0102, A/0

1/1

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Certificado

Test Report No.: 721653517-2
Report Date: 17 April 2020

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	**Guangxi 3NOD Intelligent Health Technology Co., Ltd**
CLIENT ADDRESS	Third floor, building D02, guangxi 3nod Intelligent industrial park, no.3 gaoke road, beihai industrial park
TEST PERIOD	02-Apr-2020~11-Apr-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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Webpage: www.tuv-sud.cn

Regional Head Office:
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Certificado

Test Report No.: 721653517-2
Report Date: 17 April 2020

TEST REPORT

Sample Description	:	Medical face masks
Sample Quantity	:	60 pieces
Lot Number/Batch Code	:	/
Specification	:	BHKZ-001
Size	:	/
Style No.	:	Adult
Type of Mask	:	Type IIR
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
# = No comment;
N.D. = Not detected.

Photo of Samples

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Test Report No.: 721653517-2
Report Date: 17 April 2020

Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.8% Specimen 2#: 99.9% Specimen 3#: 99.7% Specimen 4#: 99.6% Specimen 5#: 99.7%
2	Differential Pressure Test	54.0 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~13#: None seen
4	Microbial Cleanliness Test	Specimen 1#: 25 CFU/g Specimen 2#: 15 CFU/g Specimen 3#: 22 CFU/g Specimen 4#: 13 CFU/g Specimen 5#: 18 CFU/g

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 : Medical face masks
   Specification : BHKZ-001
   Lot Number : /
   Sample Receiving Date : 2020-04-02

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

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6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre 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 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.
6.4.1 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.
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 ran, 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 facing towards the bacterial challenge (test area: 77cm²).
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 (37±2)°C for (20 to 52) 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 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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Test Report No.: 721653517-2
Report Date: 17 April 2020

8. Test results*

P Value / Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	26	42	0	0	0	0	0	0
2	65	105	0	0	0	0	0	0
3	206	221	0	0	0	0	0	0
4	269	387	0	0	0	2	0	1
5	963	1109	0	0	0	5	6	4
6	597	543	0	5	1	1	3	2
Total (T), CFU	2126	2407	<1	5	1	8	9	7
Average (C), CFU	$2.3x10^3 = (P_A+P_B) / 2$							
BFE ,%				99.8	99.9	99.7	99.6	99.7
Requirements	≥ 98							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

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Test Report No.: 721653517-2
Report Date: 17 April 2020

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	:	Medical face masks
Specification	:	BHKZ-001
Lot Number	:	/
Sample Receiving Date	:	2020-04-02

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)℃ 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 4.9cm², 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/cm²)	Average (Pa/cm²)	Requirements	Judgement
1#	57.0	54.0	< 60	Pass
2#	56.4			
3#	53.7			
4#	53.1			
5#	49.8			

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Test Report No.: 721653517-2
Report Date: 17 April 2020

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	:	Medical face masks
Specification	:	BHKZ-001
Lot Number	:	/
Sample Receiving Date	:	2020-04-02

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 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.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1 s 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).

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

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.

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Test Report No.: 721653517-2
Report Date: 17 April 2020

Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
11#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass

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Certificado

Test Report No.: 721653517-2
Report Date: 17 April 2020

Microbial Cleanliness Test

1. **Purpose**

   The purpose of the test was to measure microbial cleanliness of mask.

2. **Sample description was given by client**

   Sample description : Medical face masks
   Specification : BHKZ-001
   Lot Number : /
   Sample Receiving Date : 2020-04-02

3. **Test Method**

   According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

4. **Apparatus and materials**

   4.1 Orbital shaker.
   4.2 0.45 um filter.
   4.3 Tryptic Soy Agar (TSA).
   4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
   4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
   4.6 Extraction apparatus.

5. **Test specimen**

   5.1 As requested by client, take a total of 5 mask samples.
   5.2 Mask samples for testing are provided in the original primary packaging.
   5.3 Condition at (18 to 26)℃ and (45 to 65)% relative humidity during testing.

6. **Procedure**

   6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
   6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
   6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
   6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um 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 SDA for fungi enumeration.
   6.5 The plates are incubated for 3 days at 30℃ and 7 days at (20 to 25)℃ for TSA and SDA plates respectively.
   6.6 Calculate the colonies of each agar plate.

7. **Calculation**

   For each test specimen calculate the microbial cleanliness as follows by counting the total colonies of the TSA and SDA plates.

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Test Report No.: 721653517-2
Report Date: 17 April 2020

Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	13	12	25	According to EN ISO 11737-1:2018 the microbial cleanliness of the mask shall be ≤30 CFU/g tested.	Pass
2#	9	6	15		
3#	9	13	22		
4#	9	4	13		
5#	13	5	18		

Note:

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

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

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Star Care

Physical & Microbiological Test

Test Report No.: 721653518-9
Report Date: 20 April 2020

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	**Shenzhen 3NOD electronics co., Ltd**
CLIENT ADDRESS	3rd floor,zone1,building14,hengmingzhu technology industrial park , xinqiao tongfuyu industrial park,shajing street,baoan district, shenzhen
TEST PERIOD	02-Apr-2020~11-Apr-2020

Prepared By

Bella Xu

(Bella Xu)
Report Drafter

Authorized By

Leo Liu

(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.

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Physical & Microbiological Test

Test Report No.: 721653518-9
Report Date: 20 April 2020

TEST REPORT

Sample Description	:	Medical face masks
Sample Quantity	:	60 pieces
Lot Number/Batch Code	:	/
Specification	:	KZM-001
Size	:	/
Type of Mask	:	Type IIR
Brand Name	:	/

Remark: The above information was provided by applicant.

Summary of Test Results

No.	Test Item	Test Standard	Judgement
1	Bacterial Filtration Efficiency (BFE) Test	EN 14683:2019+AC:2019(E) Annex B	Pass
2	Differential Pressure Test	EN 14683:2019+AC:2019(E) Annex C	Pass
3	Synthetic Blood Penetration Test	ISO 22609:2004	Pass
4	Microbial Cleanliness Test	EN 14683:2019+AC:2019(E) Annex D	Pass

Note: Pass = Meet customer requirements;
Fail = Fail customer requirements;
# = No comment;
N.D. = Not detected.

Photo of Samples

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Physical & Microbiological Test

Test Report No.: 721653518-9
Report Date: 20 April 2020

Results

No.	Test Item	Test Result
1	Bacterial Filtration Efficiency (BFE) Test	Specimen 1#: 99.4% Specimen 2#: 99.8% Specimen 3#: 99.6% Specimen 4#: 99.9% Specimen 5#: 99.7%
2	Differential Pressure Test	55.3 Pa/cm^2
3	Synthetic Blood Penetration Test	Specimen 1#~13#: None seen
4	Microbial Cleanliness Test	Specimen 1#: 10 CFU/g Specimen 2#: 9 CFU/g Specimen 3#: 18 CFU/g Specimen 4#: 13 CFU/g Specimen 5#: 17 CFU/g

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 : Medical face masks
Specification : KZM-001
Lot Number : /
Sample Receiving Date : 2020-04-02

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

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Mascarilla Quirúrgica / Higiénica BFE 98%

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6. Procedure

6.1 Preparation of the bacterial challenge: Dilute the cultutre 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 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.
6.4.1 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.
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 ran, 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 facing towards the bacterial challenge (test area: 77cm²).
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 (37±2)°C for (20 to 52) 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 manufacture of Anderson sampler. The filtration efficiency percentages are calculated as follows:

$$BFE=(C-T)/C\times100$$

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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Physical & Microbiological Test

Test Report No.: 721653518-9
Report Date: 20 April 2020

8. Test results*

P Value / Stage Number	Positive Control (A)	Positive Control (B)	Negative Control	Specimen 1#	Specimen 2#	Specimen 3#	Specimen 4#	Specimen 5#
1	31	34	0	0	0	0	0	0
2	66	112	0	0	0	0	0	0
3	160	206	0	0	0	0	0	0
4	279	296	0	0	0	0	0	0
5	1518	1476	0	10	2	4	2	5
6	921	874	0	7	3	7	1	3
Total (*T*), CFU	2975	2998	<1	17	5	11	3	8
Average (C), CFU	$3.0x10^3 = (P_A+P_B)/2$							
BFE ,%				99.4	99.8	99.6	99.9	99.7
Requirements	≥ 98							
Remarks	*P* is the value of corresponding corrected particle counts as specified by the manufacturer of the cascade impactor. *T* is the total of *P* value for the test specimen. *C* is the mean of the total of *P* value of the two positive controls.							

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Physical & Microbiological Test

Test Report No.: 721653518-9
Report Date: 20 April 2020

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 : Medical face masks
Specification : KZM-001
Lot Number : /
Sample Receiving Date : 2020-04-02

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)℃ 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 4.9cm², 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/cm²)	Average (Pa/cm²)	Requirements	Judgement
1#	61.7	55.3	< 60	Pass
2#	51.7			
3#	55.2			
4#	51.8			
5#	56.0			

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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	:	Medical face masks
Specification	:	KZM-001
Lot Number	:	/
Sample Receiving Date	:	2020-04-02

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 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.

Table 1 Target weight difference

Fluid Pressure (mmHg)	Weight difference for 1 s 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).

6.18 For 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.

6.20 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.

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Report Date: 20 April 2020

Results:

Specimen	Test Results*	Requirements	Judgement
1#	None Seen	Pass Pressure at 16.0 kPa (120mmHg)	Pass
2#	None Seen		Pass
3#	None Seen		Pass
4#	None Seen		Pass
5#	None Seen		Pass
6#	None Seen		Pass
7#	None Seen		Pass
8#	None Seen		Pass
9#	None Seen		Pass
10#	None Seen		Pass
11#	None Seen		Pass
12#	None Seen		Pass
13#	None Seen		Pass

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Physical & Microbiological Test

Test Report No.: 721653518-9
Report Date: 20 April 2020

Microbial Cleanliness Test

1. Purpose

The purpose of the test was to measure microbial cleanliness of mask.

2. Sample description was given by client

Sample description	:	Medical face masks
Specification	:	KZM-001
Lot Number	:	/
Sample Receiving Date	:	2020-04-02

3. Test Method

According to EN ISO 11737-1:2018 to determine the microbial cleanliness of mask material, and refer to the procedure as described in EN 14683:2019+AC:2019(E) Annex D

4. Apparatus and materials

4.1 Orbital shaker.
4.2 0.45 um filter.
4.3 Tryptic Soy Agar (TSA).
4.4 Sabouraud Dextrose Ager (SDA) with chloramphenicol.
4.5 Formula of Extraction Liquid: 1g/L peptone, 5g/L NaCl and 2g/L Tween 20.
4.6 Extraction apparatus.

5. Test specimen

5.1 As requested by client, take a total of 5 mask samples.
5.2 Mask samples for testing are provided in the original primary packaging.
5.3 Condition at (18 to 26)℃ and (45 to 65)% relative humidity during testing.

6. Procedure

6.1 Five test specimens are selected from the top, bottom and 3 randomly chosen marks.
6.2 The mask is aseptically removed from the packaging and placed in a sterile 500 mL bottle containing 300 mL of extraction liquid.
6.3 The bottle is laid down on an orbital shaker and shaken for 5 min at 250 rpm.
6.4 After extracting, 100mL of the extraction liquid is filtered through a 0.45 um 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 SDA for fungi enumeration.
6.5 The plates are incubated for 3 days at 30°C and 7 days at (20 to 25)°C for TSA and SDA plates respectively.
6.6 Calculate the colonies of each agar plate.

7. Calculation

For each test specimen calculate the microbial cleanliness as follows by counting the total colonies of the TSA and SDA plates.

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Physical & Microbiological Test

Test Report No.: 721653518-9
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Results*:

Specimen	Colonies of the TSA Plate	Colonies of the SDA Plate	Microbial Cleanliness, (CFU/g)	Requirements	Judgement
1#	6	4	10	According to EN ISO 11737-1:2018 the microbial cleanliness of the mask shall be ≤30 CFU/g tested.	Pass
2#	5	4	9		
3#	12	6	18		
4#	8	5	13		
5#	10	7	17		

Note:

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

2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

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Biocompatibility Test

STC ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L3428

Test Report

Date: 2020-05-20
No. : DY20040115

TEST FACILITY

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CONFIDENTIAL

STUDY TITLE

Guinea Pig Maximization Sensitization Test

TEST ARTICLE NAME

Medical face masks

TEST ARTICLE IDENTIFICATION

CP-MD-2081

CSD NO.: CL20200400172

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Biocompatibility Test

STC

Test Report

Date: 2020-05-20
No. : DY20040115

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Biocompatibility Test

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Test Report

Date: 2020-05-20 **Page 3 of 21**
No. : DY20040115

Summary

The test article, Medical face masks, was evaluated for the potential to cause delayed dermal contact sensitization in a guinea pig maximization test. This study was conducted based on the requirements of ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. The test articles were extracted in 0.9% sodium chloride injection and soybean oil. Each extract was intradermally injected and occlusively patched to ten test guinea pigs (per extract). Following a recovery period, the test and control animals received a challenge patch of the appropriate test article extract, the vehicle control. All sites were scored for dermal reactions at 24 and 48 hours after patch removal.

The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test.

Authorized Signatory Approval: Tang
Jonathan Tang

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Test Report

1. Introduction

1.1 Purpose

The purpose of this study was to evaluate the potential of the test articles to cause delayed dermal contact sensitization in the guinea pig maximization test.

1.2 Testing Guidelines

This study was conducted based on the requirements of the International Organization for Standardization ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

1.3 Dates

Test Article Received:	2020.04.02
Treatment Started:	2020.04.18
Observations Concluded:	2020.05.16

2. Identification of Test and Control Articles

The test articles provided by the sponsor were identified and handled as described below:

Table 1: Test Article

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Test Report

Name:	Medical face masks
Size:	N.A.
CAS:	N.A.
Model:	KZM-001
Lot:	200327
Initial State:	Not Sterilized
Strength, Purity and Composition:	N.A.
Color:	N.A
Physical Description of the Test Article:	Solid
Manufacture date:	N.A.
Expiration Date:	N.A.

Table 2: Negative Control Article

Name:	0.9% Sodium chloride injection (SC) Soybean oil (SO)
Purity, Composition, And Other Characteristics:	SC: Composition: 0.9% NaCl ± 5.0% of label claim, balance is water; sodium chloride CAS No.: 7647-14-5/water CAS No.: 7732-18-5 SO: Composition: CAS No.: 8001-22-7

Table 3: Ancillary Material

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Test Report

Name:	Freund's Complete Adjuvant (FCA) was mixed 50:50 (v/v) with the appropriate vehicle and used at Induction I. A 10% (w/w) sodium lauryl sulfate (SLS) suspension in petrolatum was used prior to Induction II. These materials were provided by the test facility.

Table 4: Reagents

Name	Brand	Lot
SC	YUYUAN/GUANGDONGKELUN	H19111807/G19112004B
SO	TIANYUSHAN	220200401/20200302-3/20191202
Freund's Adjuvant, Complete	SIGMA	SLBR3877V

3. Test System

3.1 Test System and Justification of Test System

Species: Guinea pig (Cavia porcellus)
Strain: Hartley
Source: Guangzhou baiyun district longgui xingke animal farm （广州市白云区龙归兴科动物养殖场）
Sex: Male
Age: Young adult
Acclimation Period: Minimum 5 days
Number of Animals: 30

3.2 Justification of Test System

The albino guinea pig (animal) has been used historically for sensitization studies (Magnusson and Kligman, 1970). The guinea pig is believed to be the most sensitive animal model for this type of study. This study was referred to the quarterly positive control test report number DCA20190004, which confirmed guinea pig strain sensitivity to known sensitizer 1-chloro-2, 4-dinitrobenzene (DNCB) in the STC.

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4. Animal Management

4.1 Husbandry, Housing and Environment

Conditions conformed to STC Standard Operating Procedures. Animals were housed in groups in stainless steel or plastic suspended cages identified by a card indicating the animal numbers, test code, sex, animal code and date dosed.

The animal housing room is conventional system lab. The lab animal use permit No. SYXK(粤)2019-0159. The animal housing room temperature and relative humidity were monitored daily. The temperature for the room was set to 19-26℃ and the relative humidity was set to 40-70%. There were no significant temperature or relative humidity excursions that adversely affected the health of the animals.

The light cycle was controlled (12 hours light, 12 hours dark).

4.2 Food, Water and Contaminants

Food: Laboratory animal formula feed (Guinea pig), Shenyang Maohua biotechnology co. LTD（沈阳茂华生物科技有限公司）, was provided daily.

Water: The water quality met the "Sanitary standard for drinking water" (GB5749-2006)

Food and water were sterile. No contaminants present in the feed and water impacted the results of this study.

4.3 Personnel

Associates involved in this study were appropriately qualified and trained.

4.4 Veterinary Care

Standard veterinary medical care was provided in this study.

4.5 IACUC

This procedure has been approved by the STC Institutional Animal Care and Use Committee (IACUC), and is reviewed at least annually by the same committee.

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4.6 Selection

Only healthy, previously unused animals were selected.

5. Method

5.1 Test and Control Article Preparation

The test articles were measured and calculated. The test article extracts and the vehicle control (extraction vehicle without the test article) were prepared fresh for each phase of testing and subjected to the extraction conditions as described in Table 5. The extracts were continuously agitated during extraction.

Table 5: Extraction

Vehicle: SC

Testing Phase	Treatment Group	Extraction Ratio	Article Amount	Volume of Vehicle	Extraction Condition
Induction I	Test	3 cm²:1 mL	363.4 cm²	121.1 mL	50±2°C for 72±2 h
	Control	N. A	N. A	20mL	
Induction II	Test	3 cm²:1 mL	363.4 cm²	121.1 mL	
	Control	N. A	N. A	20mL	
Challenge	Test	3 cm²:1 mL	363.4 cm²	121.1 mL	
	Control	N. A	N. A	20mL	

Vehicle: SO

Testing Phase	Treatment Group	Extraction Ratio	Article Amount	Volume of Vehicle	Extraction Condition
Induction I	Test	3 cm²:1 mL	363.4 cm²	121.1 mL	50±2°C for 72±2 h
	Control	N. A	N. A	20mL	
Induction II	Test	3 cm²:1 mL	363.4 cm²	121.1 mL	
	Control	N. A	N. A	20mL	
Challenge	Test	3 cm²:1 mL	363.4 cm²	121.1 mL	
	Control	N. A	N. A	20mL	

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The following table contain a description of the test and control article extracts before and after extraction and prior to dosing.

Table 6: Condition of Extracts

Vehicle: SC

Treatment group	Time Observed	Extract	Condition of Extracts		
			Color	Clarity	Particulates
Test	Before Extraction	Induction I	Colorless	Clear	None
		Induction I I	Colorless	Clear	None
		Challenge	Colorless	Clear	None
	After Extraction	Induction I	Colorless	Clear	None
		Induction I I	Colorless	Clear	None
		Challenge	Colorless	Clear	None
	Prior to Use	Induction I	Colorless	Clear	None
		Induction I I	Colorless	Clear	None
		Challenge	Colorless	Clear	None
Control	Before Extraction	Induction I	Colorless	Clear	None
		Induction I I	Colorless	Clear	None
		Challenge	Colorless	Clear	None
	After Extraction	Induction I	Colorless	Clear	None
		Induction I I	Colorless	Clear	None
		Challenge	Colorless	Clear	None
	Prior to Use	Induction I	Colorless	Clear	None
		Induction I I	Colorless	Clear	None
		Challenge	Colorless	Clear	None

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Vehicle: SO

Treatment group	Time Observed	Extract	Condition of Extracts		
			Color	Clarity	Particulates
Test	Before Extraction	Induction I	Colorless	Oily	None
		Induction I I	Colorless	Oily	None
		Challenge	Colorless	Oily	None
	After Extraction	Induction I	Colorless	Oily	None
		Induction I I	Colorless	Oily	None
		Challenge	Colorless	Oily	None
	Prior to Use	Induction I	Colorless	Oily	None
		Induction I I	Colorless	Oily	None
		Challenge	Colorless	Oily	None
Control	Before Extraction	Induction I	Colorless	Oily	None
		Induction I I	Colorless	Oily	None
		Challenge	Colorless	Oily	None
	After Extraction	Induction I	Colorless	Oily	None
		Induction I I	Colorless	Oily	None
		Challenge	Colorless	Oily	None
	Prior to Use	Induction I	Colorless	Oily	None
		Induction I I	Colorless	Oily	None
		Challenge	Colorless	Oily	None

The test article extracted in SC and SO remained unchanged during the extraction process. The extracts were maintained at ambient temperature <24 hours before use for all phases. The extracts were not centrifuged, filtered, or otherwise altered prior to dosing.

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5.2 Test Procedure

5.2.1 Induction I

On the first day of treatment, the animals were weighed and arbitrarily assigned to a treatment group as shown below.

Table 7: Treatment Group Assignment

Vehicle	Treatment Group	Number of Animals
SC	Test	10
	Control	5
SO	Test	10
	Control	5

The fur over the dorsoscapular region was removed with an electric clipper. The test animals were injected with the test article extract and the control animals were injected with the vehicle control. Three rows of intradermal injections (two injections per row) were given to each animal within an approximate 2 cm x 4 cm boundary of the fur clipped area as illustrated below

Cranial

4cm

2cm

a a
b b
c c

Caudal

Control Animals:

a. 0.1 mL of 50:50 (v/v) mixture of FCA and the chosen vehicle

b. 0.1 mL of vehicle

c. 0.1 mL of a 1:1 mixture of the 50:50 (v/v) vehicle/FCA mixture and the vehicle

Test Animals:

a. 0.1 mL of 50:50 (v/v) mixture of FCA and the chosen vehicle

b. 0.1 mL of test extract

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c. 0.1 mL of a 1:1 mixture of the 50:50 (v/v) vehicle/FCA mixture and the test extract

5.2.2 Induction II

At 7±1 days after completion of the Induction I injection, the fur over the dorsoscapular region (same area as used during Induction I) of each animal was removed with an electric clipper. The area was treated with a 10% SLS suspension in petrolatum sufficient to coat the skin. The SLS suspension, applied to provoke a mild acute inflammation, was massaged into the skin over the injection site. The area was left uncovered.

At 24 hours (±2 hours) any remaining SLS residue was gently removed with a gauze pad. An approximate 2 cm x 4 cm section of gauze patch, saturated with 0.3 mL of freshly prepared test article extract, was then topically applied to the previously injected sites of the test animals. The control animals were similarly patched with the appropriate vehicle control. Each patch was secured with a nonreactive tape and the trunk of each animal was wrapped with an elastic bandage. At 48 hours, the bandages and patches were removed

5.2.3 Challenge

At 14±1 days after completion of Induction II, the fur was removed from the sides and flank areas with an electric clipper. Nonwoven cotton disks contained in a Hill Top Chamber® were saturated with 0.3 mL of the test article extract or vehicle control. The test extract was applied to the right flank of each animal and the control vehicle was applied to the left flank of each animal. The trunk of each animal was wrapped with an elastic bandage to maintain well-occluded sites. At 24 hours, the wraps and Hill Top Chambers were removed. Any residue remaining at the sites was removed.

5.2.4 Laboratory Observations

1. Animals were observed daily for general health.
2. Body weights were recorded at pretreatment.

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3. Observations for dermal reactions were conducted at 24 and 48 hours after challenge patch removal. Dermal reactions were scored in accordance with the criteria shown below:

Table 8: Test Scoring

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

6. Evaluation

The responses from the challenge phase were compared within the test animal group and between test and control conditions. In the final analysis of data, consideration was given to the overall pattern, intensity, duration and character of reactions of the test as compared to the control conditions. The control conditions are (1) the control vehicle on the test animals, (2) the test on the control animals, and (3) the control vehicle on the control animals. Statistical manipulation of data was not applicable to this study. Grades of 1 or greater observed in the test group generally indicated sensitization, provided that grades of less than 1 were observed on the control animals. If grades of 1 or greater were noted on control animals, then the reactions of test animals that exceeded the most severe control reaction were considered to be due to sensitization.

7. Results

7.1 Clinical Observations and Body Weight Data

All animals were clinically normal throughout the study. The clinical observations and individual body weights at pretreatment are presented in Appendix 1.

7.2 Dermal Observations

No evidence of sensitization of test extracts group was observed. Individual results of dermal scoring for the challenge phase are presented in Appendix 2.

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Moderate and intense dermal reactions of positive group were observed. Individual results of dermal scoring for the challenge phase are presented in Appendix 3.

8. Conclusion

The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig. The test article was not considered a sensitizer in the guinea pig maximization test. Results and conclusions apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility.

9. Records

All raw data pertaining to this study and a copy of the final report are retained in designated STC archive files in accordance with STC SOPs.

10. ISO Compliance

All procedures were complanced to ISO 17025.

11. References

International Organization for Standardization (ISO) 10993-1, Biological evaluation of medical devices -Part 1: Evaluation and testing within a risk management process (2018).
International Organization for Standardization (ISO) 10993-2, Biological evaluation of medical devices -Part 2: Animal welfare requirements (2006).
International Organization for Standardization (ISO) 10993-10, Biological evaluation of medical devices -Part 10: Tests for irritation and skin sensitization (2010).
International Organization for Standardization (ISO) 10993-12, Biological evaluation of medical devices -Part 12: Sample preparation and reference materials (2012).
International Organization for Standardization/International Electrotechnical Commission (ISO/IEC) 17025, General requirements for the competence of testing and calibration laboratories (2017).

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Appendix 1 - Clinical Observations and Individual Body Weight Data

SC group

Treatment Group	Animal number	Individual Observation	
		Pretreatment Body weight(g)	Clinical Observations
Test	1	458.8	Healthy
	2	406.5	Healthy
	3	360.8	Healthy
	4	322.7	Healthy
	5	357.0	Healthy
	6	375.8	Healthy
	7	356.8	Healthy
	8	376.4	Healthy
	9	416.2	Healthy
	10	402.8	Healthy
Control	1	402.3	Healthy
	2	372.5	Healthy
	3	342.6	Healthy
	4	397.6	Healthy
	5	367.6	Healthy

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SO group

Treatment Group	Animal number	Individual Observation	
		Pretreatment Body weight(g)	Clinical Observations
Test	1	359.2	Healthy
	2	354.7	Healthy
	3	355.8	Healthy
	4	423.6	Healthy
	5	492.7	Healthy
	6	387.5	Healthy
	7	390.2	Healthy
	8	483.2	Healthy
	9	345.1	Healthy
	10	369.5	Healthy
Control	1	394.5	Healthy
	2	389.0	Healthy
	3	329.6	Healthy
	4	340.5	Healthy
	5	400.3	Healthy

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Appendix 2 - Dermal Reactions Following Challenge Exposure

SC group

Treatment Group	Animal number	Dermal reaction			
		24 hour score		48 hour score	
		Control Site	Test Extract Site	Control Site	Test Extract Site
Test	1	0	0	0	0
	2	0	0	0	0
	3	0	0	0	0
	4	0	0	0	0
	5	0	0	0	0
	6	0	0	0	0
	7	0	0	0	0
	8	0	0	0	0
	9	0	0	0	0
	10	0	0	0	0
Control	1	0	0	0	0
	2	0	0	0	0
	3	0	0	0	0
	4	0	0	0	0
	5	0	0	0	0

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SO group

Treatment Group	Animal number	Dermal reaction			
		24 hour score		48 hour score	
		Control Site	Test Extract Site	Control Site	Test Extract Site
Test	1	0	0	0	0
	2	0	0	0	0
	3	0	0	0	0
	4	0	0	0	0
	5	0	0	0	0
	6	0	0	0	0
	7	0	0	0	0
	8	0	0	0	0
	9	0	0	0	0
	10	0	0	0	0
Control	1	0	0	0	0
	2	0	0	0	0
	3	0	0	0	0
	4	0	0	0	0
	5	0	0	0	0

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Appendix3 - Periodic Positive Control Study for the Guinea Pig Maximization Test

What was tested:
1 -chloro-2, 4-dinitrobenzene (DNCB)

Dates:
Treatment Started: 2020.02.27
Observations Concluded: 2020.03.28

Purpose:
A periodic positive control study was conducted for the Guinea Pig Maximization Test to meet the following objectives: 1) confirm the methodology in ISO 10993-10:2010, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization, 2) substantiate the potential of DNCB to cause delayed dermal contact sensitization, 3) verify proper training of the technicians performing these studies, and 4) substantiate the susceptibility of the guinea pig strain to dermal contact sensitization.

Methods:
The test utilized young adult, male Hartley guinea pigs supplied by Guangzhou baiyun district longgui xingke animal farm (广州市白云区龙归兴科动物养殖场). The weight at study initiation ranged from 300 grams to 500 grams. A 0.1% (w/w) concentration of DNCB in ethanol was intradermally injected and occlusively patched to five test guinea pigs in an attempt to induce sensitization. The ethanol vehicle was similarly injected and occlusively patched to five control guinea pigs. Following a recovery period, the test and control animals received a challenge patch of 0.1% (w/w) DNCB in ethanol and ethanol alone. All sites were scored for dermal reactions at 24 and 48 hours after patch removal. The patch sites were graded using the scale:

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

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Results:
All of the ten animals demonstrated a positive sensitization response to the known sensitizer, DNCB. None of the control animals demonstrated a sensitization response. The results are shown below:

Treatment Group	Animal number	Dermal reaction				Results (+) or (-)
		24 hour score		48 hour score		
		Test	Control	Test	Control	
Test	1	3	0	3	0	+
	2	2	0	2	0	+
	3	2	0	2	0	+
	4	1	0	1	0	+
	5	2	0	2	0	+
Control	1	0	0	0	0	-
	2	0	0	0	0	-
	3	0	0	0	0	-
	4	0	0	0	0	-
	5	0	0	0	0	-

Conclusion:
The known sensitizer DNCB produced evidence of causing delayed dermal contact sensitization in the guinea pig. Therefore, the following objectives were met: 1) the methodology in ISO 10993-10:2010, Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Skin Sensitization was confirmed, 2) the potential for DNCB to cause delayed contact sensitization was substantiated, 3) proper training of the technicians performing this study design was verified and 4) the susceptibility of the guinea pig strain to sensitization was substantiated.

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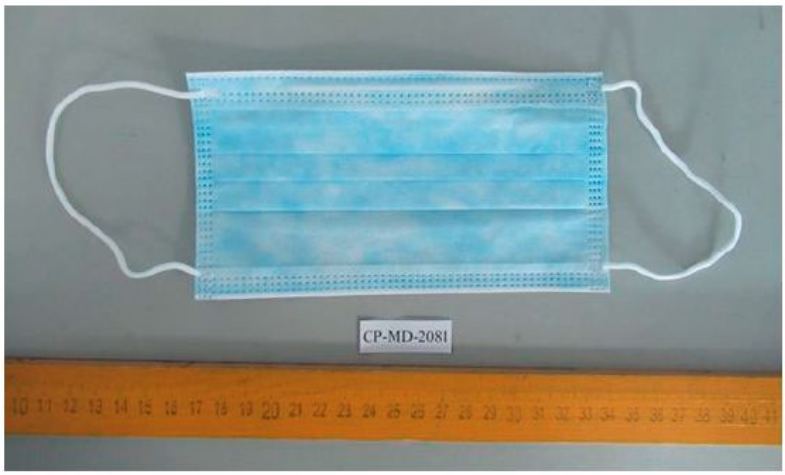
Appendix 4 – Photograph of Test Articles



***** END OF TEST REPORT *****

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