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中国认可  
国际互认  
检测  
TESTING  
CNA<sup>C</sup> 2954

## Final Report

Report Number: SDWH-M20200531- (E)

# Skin Sensitization Test of DISPOSABLE MEDICAL FACE MASK

According to GB/T 16886.10-2017  
Conduct a Pig Maximization Test  
0.9% Sodium Chloride Injection Extract

Sponsor: XIANTAO HONGWEI NON-WOVEN FABRIC  
PRODUCTS CO., LTD

Address: Taizihu Industrial Park, Xiantao, Hubei, China



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Report No. W20030609-1

1) Formaldehyde content : GB/T 2912.1-2009

Details	Result	Standard's Requirement
Formaldehyde content, mg/kg	Not detected	
<i>Note:</i> The detection limit is 20mg/kg.		

2) pH value : GB/T 7573-2009, extraction medium: KCL

Details	Result	Standard's Requirement
pH value	6.1	4.0~8.5

3) Filter efficiency : GB/T 32610-2016, testing air flow volume: 85L/min

Details	Result	Standard's Requirement
Filter efficiency (saline medium, NaCl particles):		
Method: preprocessing:		
	①99.1	Saline medium: ≥95 (Level II)
	②99.1	
	③99.0	
	④99.0	
	⑤99.1	



Report No. W20030609-1  
(电子版)

## TEST REPORT

Applicant : MGROUP PTE.LTD.(新加坡)

Attention : -

The following sample(s) was/were submitted and identified on behalf of the client as:

### Sample Description

Sample Name : Disposable Face Mask ( )  
Sample Quantity : 50 Pieces  
Color : -  
Fiber Content : -  
Ref. No. : -  
Brand : Mico  
Product Class : -  
Safety Type : -  
Manufacturer : -

Receipt Date of Sample(s) : Received on 2020-09-02

Date of testing : From 2020-09-02 to 2020-09-03

Date of revision : Revised on 2020-09-08

Ref. standard : GB/T 32610-2016 Technical specification of daily protective mask

Test Result (s) : For further detail please refer to the following page(s).

Note : 1. English edition for Report No. W20030609.

Only some of the items in the standard GB/T 32610-2016 were tested according to the requirements of the client.



Signed for and on behalf of

胡景松

## Summary

### 1 Test Article

Test Article Name	DISPOSABLE MEDICAL FACE MASK
Manufacturer	XIANTAO HONGWEI NON-WOVEN FABRIC PRODUCTS CO., LTD
Address	Taizihu Industrial Park, Xiantao, Hubei, China
Model	ELASTIC FACE MASK
Lot/Batch	200616

### 2 Main Reference

GB/T 16886.10-2017 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization

### 3 Test Method

Potential skin sensitization of test article was evaluated using guinea pig maximization test in accordance with GB/T 16886.10-2017 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.

Study protocol number: SDWH-PROTOCOL-M202005314-2Amv01.

### 4 Conclusion

Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pigs. The positive rate of sensitization was 0%. No evidence of skin sensitization in guinea pigs was found.

# Test Report

(Electronic version)

No: 20R002627

**Results:**

Sample	T	BFE (%)	Requirement (%)	Classification	Result
1	22	98.84	≥98 EN 14683:2019+AC:2019	Type II R	Pass
2	37	98.05			
3	32	98.31			
4	19	99.00			
5	23	98.78			

**Remarks:**

For each test specimen calculate the bacterial filtration efficiency B, as a percentage, using the following formula:

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

where

B is bacterial filtration efficiency (BFE), %;

C is positive control average;

T is the total plate count for the test specimen.



# Test Report

(Electronic version)

Verification Website: [www.gtgc.net.cn](http://www.gtgc.net.cn)

Verification Code: POMT-3749-5

No: 20R002627

Issue Date: 2020-05-20

Applicant: XIANTAO HONGWEI NON-WOVEN FABRIC PRODUCTS CO.,LTD  
Address: TAIZIHU INDUSTRIAL PARK, XIANTAO CITY, HUBEI, CHINA

Information confirmed by applicant:

Disposable medical face mask

Quantity: 60 pieces

Type: Face mask with elastic for adult: 17.5\*9.5cm

Classification: Type II R

Standard Adopted:

EN 14683:2019+AC:2019 &lt;Medical face masks-Requirements and test methods&gt;

Date Received/Date Test Started: 2020-05-20

Conclusion:

Bacterial filtration efficiency (BFE)	M
Microbial cleanliness	M
Differential pressure	M
Splash resistance pressure	M

Note: "M"-Meet the standard's requirement "F"-Fail to meet the standard's requirement "--"-No comment

Remark:

All the tested items are tested under standard condition (except for indication).

Copies of the report are valid only if stamped.

The experiment was carried out at No.1, Zhujiang Road, Panyu District, Guangzhou, Guangdong, P.R.China.

Approved By:

ZiShan Guo

ZiShan Guo Senior Engineer



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