

Test Report

Number: GZHT02297731

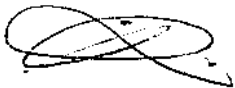
Report Ref:	GZHT02297731		
Date received:	Jun 01, 2020	Date Issued:	Jun 10, 2020

Company Name:	TAIZHOU KANGJIAN MEDICAL EQUIPMENT CO.,LTD		
Address:	THE MACHINE ELECTRICITY ZONE YUHUAN COUNTY TAIZHOU ZHEJIANG 317600 CHINA		
Contact Name:	邱跃文		

The Following Sample Was Submitted And Identified By/On Behalf Of The Applicant As:	
End Uses	: Non-Sterile Medical Face Mask
Ratings	: Type I
Sample Name	: Disposable Medical Mask
Size	: 17.5*9.5cm
Colour	: Blue
Standard	: EN 14683:2019+AC:2019; EN 14362-1: 2012; EN ISO 14184-1:2011
Manufacturer	: TAIZHOU KANGJIAN MEDICAL EQUIPMENT CO.,LTD.
Date received/ Test Started	: Jun 01, 2020
Ref	: 65% Non-Woven Fabric 35% Melt-Blown Fabric 浙械注准 20202141267

Test was conducted on specific items, at our client's request.

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch



Lin Lin
General Manager

WEN / abbyqzeng



Page 1 Of 7

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

深圳天祥质量技术服务有限公司广州分公司

Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801,
No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China

中国广州经济技术开发区科学城彩频路7号之二第1-8层02房、01房、101、

E201、E301、E401、E501、E601、E701、E801

Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663

Room 03F, Hengyun Building, 235 Kaifa Ave., Guangzhou

Economic & Technological Development District, Guangzhou, China

中国广州经济技术开发区开发大道235号恒运大厦3楼

Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730



Original Sample Photo



Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

Lin Lin
General Manager

WEN / abbyqzeng



Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

深圳天祥质量技术服务有限公司广州分公司

Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801,
No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China

中国广州经济技术开发区科学城彩频路7号之二第1-8层02房、01房、101、

E201、E301、E401、E501、E601、E701、E801

Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663

3/F Hengyun Building, 235 Kaifa Ave., Guangzhou

Economic & Technological Development District, Guangzhou, China

中国广州经济技术开发区开发大道235号恒运大厦3楼

Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730



Test Report

Number: GZHT02297731

Summary of testing:

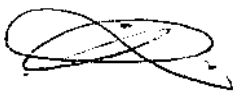
With reference to following standard:
• EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods Type I

Materials Used in The Submitted Sample Were Found To Comply With The Type I Requirements of EN 14683:2019+AC:2019 with respect to Microbial Cleanliness, Bacterial Filtration Efficiency and Differential Pressure tests.

The sample pass in client’s requirement with reference to Formaldehyde Content Requirement in Annex XVII Item 72 of REACH Regulation (EC) 1907/2006 and Its Amendment (EU) 2018/1513.

Tested components of the sample pass Azocolourants Content Requirement in Annex XVII Item 43 of the REACH Regulation (EC) No. 1907/2006 & Its Amendments

Prepared And Checked By:
For Intertek Testing Services Shenzhen Ltd. Guangzhou Branch



Lin Lin
General Manager



WEN / abbyqzeng

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

深圳天祥质量技术服务有限公司广州分公司

Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801,
No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China

中国广州经济技术开发区科学城彩频路7号之二第1-8层02房、01房、101、

E201、E301、E401、E501、E601、E701、E801

Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663

Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801,
Hengyun Building, 235 Kaifa Ave., Guangzhou

Economic & Technological Development District, Guangzhou, China

中国广州经济技术开发区开发大道235号恒运大厦3楼

Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730



Test Report

Number: GZHT02297731

Tests Conducted (As Requested By The Applicant)

1 Formaldehyde Content:

With Reference to EN ISO 14184-1: 2011, Followed by UV-Visible Spectrophotometer (UV-Vis).

<u>Result (mg/kg)</u>	<u>Requirement (mg/kg)</u>
17	75

2 Microbial Cleanliness

As Per EN 14683:2019+AC:2019 Medical face masks-Requirements and test methods Annex D.

<u>Test Item</u>	<u>Result (cfu/g)</u>					<u>Limit (cfu/g)</u>
	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	
Microbial cleanliness	<1#	<1#	<1#	<1#	<1#	Type I: ≤30

Remark:

cfu = colony forming unit

≤ = Not more than

= No colony was detected at the extraction liquid of the samples.

WEN / abbyqzeng



Test Report

Number: GZHT02297731

Tests Conducted (As Requested By The Applicant)

- 3 Bacterial Filtration Efficiency (BFE)
As Per EN 14683:2019+AC:2019 Medical face masks – Requirements And Test Methods Annex B.

Test Item	Results (%)					Performance Requirement for Medical Face Mask (%)
	Specimen (1)	Specimen (2)	Specimen (3)	Specimen (4)	Specimen (5)	
Bacterial Filtration Efficiency (BFE)	99.9	99.6	99.7	99.8	99.9	Type I: ≥95

Remarks:

1. Biological Aerosol: *Staphylococcus aureus* (ATCC 6538).
2. Testing side: Outside of the test specimen was facing towards the challenge aerosol.
3. Test area: 78 cm²
4. Flow rate: 28.3 L/min
5. The average plate count results of the positive controls: 2500 CFU
6. The average plate count results of the negative controls: < 1 CFU
7. CFU = Colony Forming Unit

WEN / abbyqzeng

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

深圳天祥质量技术服务有限公司广州分公司

Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China
 中国广州经济技术开发区科学城彩频路7号之二第1-8层02房、01房
 101、E201、E301、E401、E501、E601、E701、E801
 Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663

Hengyun Building, 235 Kaifa Ave., Guangzhou Economic & Technological Development District, Guangzhou, China
 中国广州经济技术开发区开发大道235号恒运大厦3楼
 Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730



Test Report

Number: GZHT02297731

Tests Conducted (As Requested By The Applicant)

- 4 Detection of Amines Derived from Azocolourants and Azodyes:
 By Gas Chromatographic - Mass Spectrometric (GC-MS) Analysis.
 Test Method: EN 14362-1: 2012

No.	Forbidden	Cas No.	Result (1+2+3)
1.	4-Aminodiphenyl	92-67-1	ND
2.	Benzidine	92-87-5	ND
3.	4-Chloro-o-Toluidine	95-69-2	ND
4.	2-Naphthylamine	91-59-8	ND
5.	o-Aminoazotoluene	97-56-3	ND
6.	2-Amino-4-Nitrotoluene	99-55-8	ND
7.	p-Chloroaniline	106-47-8	ND
8.	2,4-Diaminoanisole	615-05-4	ND
9.	4,4'-Diaminodiphenylmethane	101-77-9	ND
10.	3,3'-Dichlorobenzidine	91-94-1	ND
11.	3,3'-Dimethoxybenzidine	119-90-4	ND
12.	3,3'-Dimethylbenzidine	119-93-7	ND
13.	3,3'-Dimethyl-4,4'diaminodiphenylmethane	838-88-0	ND
14.	p-Cresidine	120-71-8	ND
15.	4,4'-Methylene-Bis(2-Chloroaniline)	101-14-4	ND
16.	4,4'-Oxydianiline	101-80-4	ND
17.	4,4'-Thiodianiline	139-65-1	ND
18.	o-Toluidine	95-53-4	ND
19.	2,4-Toluylenediamine	95-80-7	ND
20.	2,4,5-Trimethylaniline	137-17-7	ND
21.	o-Anisidine	90-04-0	ND
22.	4-Aminoazobenzene	60-09-3	ND

WEN / abbyqzeng

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

深圳天祥质量技术服务有限公司广州分公司

Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801, No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China
 Hengyun Building, 235 Kaifa Ave., Guangzhou Economic & Technological Development District, Guangzhou, China
 中国广州经济技术开发区科学城彩频路7号之二第1-8层02房、01房
 中国广州经济技术开发区开发大道235号恒运大厦3楼
 Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663
 Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730



Test Report

Number: GZHT02297731

Tests Conducted (As Requested By The Applicant)

Remark: ND = Not Detected
 Detection Limit = 5 ppm
 Requirement = 30 ppm (Max.)
 ppm = Parts Per Million = mg/kg

Tested Components:

- (1) Blue non-woven fabric (shell)
- (2) White non-woven fabric (lining)
- (3) White elastic band (strap)

- 5 Differential Pressure (EN 14683:2019+AC:2019 Annex C):
 Air flow: 8L/min, Test area diameter 25 mm, Test area: 4.9 cm².

<u>Tested Sample</u>	<u>Result (Pa/cm²)</u>	<u>Performance Requirement for Medical Face Mask (Pa/cm²)</u>
Specimen (1)	39.2	Type I: < 40
Specimen (2)	36.6	
Specimen (3)	36.8	
Specimen (4)	38.4	
Specimen (5)	38.1	
Average	37.8	

Remark : Test was conducted by external provider.

End of Report

This report is made solely on the basis of your instructions and/or information and materials supplied by you. It is not intended to be a recommendation for any particular course of action. Intertek does not accept a duty of care or any other responsibility to any person other than the Client in respect of this report and only accepts liability to the Client insofar as is expressly contained in the terms and conditions governing Intertek's provision of services to you. Intertek makes no warranties or representations either express or implied with respect to this report save as provided for in those terms and conditions. We have aimed to conduct the Review on a diligent and careful basis and we do not accept any liability to you for any loss arising out of or in connection with this report, in contract, tort, by statute or otherwise, except in the event of our gross negligence or wilful misconduct. No copy of the test report(except for full text copy) shall be made without the written approval by Intertek.

WEN / abbyqzeng

Page 7 Of 7

Intertek Testing Services Shenzhen Ltd. Guangzhou Branch

深圳天祥质量技术服务有限公司广州分公司

Room 02, 1-8/F & Room 01, E101/E201/E301/E401/E501/E601/E701/E801,
No.7-2, Caipin Road, Guangzhou Science City, GETDD, Guangzhou, China

中国广州经济技术开发区科学城彩频路7号之二第1-8层02房、01房

E201, E301, E401, E501, E601, E701, E801

Tel: +86 20 8213 9001 Fax: +86 20 8208 9909 Postcode: 510663

8/F Hengyun Building, 235 Kaifa Ave., Guangzhou

Economic & Technological Development District, Guangzhou, China

中国广州经济技术开发区开发大道235号恒运大厦3楼

Tel: +86 20 8396 6868 Fax: +86 20 8222 8169 Postcode: 510730

