

# TEST REPORT

Report number: 2020YZW415

Name of Company: Xiantao Zhongtai Protective Equipment Co., Ltd.  
Sample: Medical Surgical Mask  
Model: Earloop mask 17.5x9.5cm (Standard)  
Test Category: Registration Test (-)  
Registration Supplementary Test (-)  
Others (✓) Registration Test for Emergency Purpose

**Hubei Medical Device Quality Supervision and Inspection Institute**

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7. The test result is only valid for the tested sample(s).

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Sample Name	Medical surgical mask			Sample Serial Number	2020YZW415
	Sample delivered by the client(√)	Random (/)	Sample collected onsite (/)		
Trademark	/			Model Specifications	Earloop mask 17.5x9.5cm (Standard)
Client	Xiantao Zhongtai Protective Equipment Co., Ltd.			Detection Category	Registration Test for Emergency Purpose
Client Address	Taizihu Industrial Park, Pengchang Town, Xiantao City			Product Number / Batch Number	ZT-200403-2
Production Company	Xiantao Zhongtai Protective Equipment Co., Ltd.			Sample Number	/
Inspected by	Xiantao Zhongtai Protective Equipment Co., Ltd.			Production Date	April 3, 2020
Sampling Unit	/			Number of Samples	80
Sampling Location	/			Sampling Base	/
Sampling Date	/			Inspection Location	laboratory
Sample Collection Date	April 7, 2020			Inspection Date	2020-04-07 ~ 2020-04-16
Test Standard	4.1 Appearance, 4.2 Structure and Size, 4.3 Nose Clip, 4.4 Head Band, 4.5 Synthetic Blood Penetration, 4.6.1 Bacterial Filtration Efficiency (BFE), 4.6.2 Particle Filtration Efficiency (PFE), 4.7 Pressure Difference ( $\Delta P$ ), 4.8 Flame Retardant Performance, 4.9.1 Microbiological Index				
Result Standard	YY 0469-2011 "Medical Surgical Masks"				
Test Conclusion	<p>Tested samples meet the requirements of YY 0469-2011 "Medical Surgical Masks".</p> <p style="text-align: center;">(Special seal for test report uses or the official seal of the institute)</p> <p style="text-align: right;">Issue Date: April 16, 2020</p>				
Remark	<p>1) "---" : not applicable;    "/" : blank.</p> <p>2) The enterprise entrusts the testing items in this report, and this report is expected to be used for the medical device emergency registration declaration of the product during the epidemic prevention and control.</p>				

Approved by: Ke Tang

Audited by: Mei Duolin

Tested by: Wang Chao

Title: Vice President

Reviewed by: Wu Huan

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No.	Test Item [Unit]	Standard & Terms	Requirements	Test Results	Conclusion	Remarks
1	Appearance	4.1	The appearance of the mask is neat and in good shape, with no damage or stains on the surface.	Meet the requirements	Qualified	
2	Structure and Size	4.2	The mask should cover the nose, mouth, and jaw.	Meet the requirements	Qualified	
			Structure and size should meet the standard design size and tolerance. (According to the size requirements on the product manual provided by the company) Length: 17.5cm ± 0.875cm Width: 9.5cm ± 0.475cm	Length: (17.517~17.563) cm Width: (9.427 ~ 9.458) cm		
3	Nose clip	4.3.1	The mask should be equipped with a nose clip, which is made of plastic material.	Meet the requirements	Qualified	
		4.3.2	The length of the nose clip should not be less than 8.0cm.	10.6 cm		
4	Head Band	4.4.1	The headband should be comfortable to wear and take off.	Meet the requirements	Qualified	
		4.4.2	The breaking strength of the headband should not be less than 10N.	Meet the requirements		
5	Synthetic Blood Penetration	4.5	There should be no penetration on the inner side of the mask after sprayed 2ml of synthetic blood on the outer side of the mask with a pressure of 16. 0KPa (120mmHg).	Meet the requirements	Qualified	
6	Bacterial Filtration Efficiency (BFE)	4.6.1	The bacterial filtration efficiency of the mask should not be less than 95%	99%~100%	Qualified	
7	Particle Filtration Efficiency (PFE)	4.6.2	The filtering efficiency of the mask on non-oily particles should not be less than 30%.	91%	Qualified	
8	Pressure Difference (ΔP) (Pa)	4.7	The air exchange pressure difference (ΔP) between the two sides of the mask should not exceed 49Pa.	34	Qualified	
9	Flame Retardant Performance (s)	14.8	The burning time of the mask should not longer than 5 seconds after pulled away from the flame.	0	Qualified	

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No.	Test Item [Unit]	Standard & Terms	Requirements		Test Results	Conclusion	Remarks
10	Microbiological Index	4.9.1	Non-sterile masks should meet the requirements of Table 1	Total bacterial colonies: $\leq 100\text{CFU/g}$ ;	<1 CFU/g	Qualified	
				Coliform bacteria: None;	None		
				Pseudomonas aeruginosa: None;	None		
				Staphylococcus aureus: None;	None		
				Hemolytic streptococci: None;	None		
				Fungus: None;	None		
		4.9.2		Masks marked "sterilized" or "sterile" on the packaging or illustrated should be sterilized	----		
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### Photos and Descriptions

#### Sample Photo

