



# Inspection Report

Report Number: W(X)-1842-2013

Commissioned by Zhuozhou Firm Shield Biotech Company

Sample name Disposable surgical face mask

Model

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FS 9501-L

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Inspection type

Registration inspection (√)

Registration supplementary inspection () \_\_\_\_\_

Other inspections () \_\_\_\_\_

**China Food and Drug Administration Beijing Medical Device Quality Supervision  
and Inspection Center**

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No .	Inspection item	Standard clause	Standard requirement	Inspection results	Conclusion of each item
1	Basic requirements of the mask	4.1	The mask should cover the wearer's mouth and nose; should have good facial tightness; there should be no holes, dirt on the surface, and there should be no exhalation valve.	Meet the requirements	Qualified
2	Nose clip	4.2.1	The mask should be equipped with nose clip.	Meet the requirements	Qualified
		4.2.2	The nose clip should be adjustable.	Meet the requirements	Qualified
3	Attachment straps	4.3.1	The attachment straps should be easy to adjust.	Meet the requirements	Qualified
		4.3.2	There should be sufficient strength to fix the position of the mask. The breaking strength of the connection point between each attachment strap and the mask body should not be less than 10N.	> 10N	Qualified
4	Filtration efficiency	4.4	At a gas flow rate of 85L/min, the filtering efficiency of the mask on non-oily particles should meet the following requirements:  Level: 1, Filtration efficiency: $\geq 95\%$	Minimum value before temperature pretreatment: 97.6%	Qualified
				Minimum value after temperature pretreatment: 97.3%	Qualified
5	Airflow resistance	4.5	At a gas flow rate of 85L/min, the suction mutual resistance of the mask must not exceed	Maximum value before temperature	Qualified

			343.2Pa (35mmH <sub>2</sub> O).	pretreatment: 207.0Pa	
				Maximum value after temperature pretreatment: 189.8Pa	Qualified

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6	Synthetic blood penetration	4.6	2mL of synthetic blood was sprayed to the mask at a pressure of 10.7kPa (80mmHg), and the inside of the mask should not be penetrated.	Not penetrated	Qualified	
7	Surface moisture resistance	4.7	The level of water on the outer surface of the product should not be lower than the Level 3 in GB / T4745-1997.	Level 3	Qualified	
8	Microbial index	4.8.1	The microbiological index of the product shall meet the requirements of GB 15979-2002.			
			Total bacterial colonies, cfu/g	≤200 cfu/g	< 20cfu/g	Qualified
			Coliform	Must not be checked out	Not be checked out	Qualified
			Pseudomonas aeruginosa	Must not be checked out	Not be checked out	Qualified
			Staphylococcus aureus	Must not be checked out	Not be checked out	Qualified
			Hemolytic streptococcus	Must not be checked out	Not be checked out	Qualified
			Total number of fungal colonies, cfu/g	≤100 cfu/g	20cfu/g	Qualified
9	Flame retardant performance	4.10	Product materials should be made of non-combustible materials. Afterflame time should not exceed 5s.	Before temperature pretreatment: 0s	Qualified	
				After temperature pretreatment: 0s	Qualified	
10	Skin irritation	4.11	The mask material's primary stimulus score should not exceed 1.	Very slight	Qualified	

11	Tightness	4.12	The product design should provide good tightness, and the overall fit factor of the mask should not be less than 100.	Meet the requirements	Qualified
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