

Finished product inspection report

Serial number: JR/QP-12-F05 A/0

Product name	Self sealing pouch	Production order	W07AMT2301	
Model number	/	Specifications	57*130mm	
Lot number	/	Temperature and	28.5°C/55 RH%	
Lot qty	280000	Sampling	80	
Date of	2023.6.27	Date of report	2023.6.30	
Inspection	SIP-19 《Standard for inspection of single-use sterilized bags》			
Inspection item	Inspection Standard	Test results	Conclusion	
Visual inspection	1 The sterilizing bag shall not have any oil or foreign matter which obviously affects the appearance or cleanliness.	It fits the bill	Qualified	
	2 hold the flat sterilizing bag with both hands to seal the edge without obvious wave phenomenon.	It fits the bill		
	3 printing should not have the Burr, the air print affects the recognition effect.	It fits the bill		
	4 Printing surface should not be stained or dragged when making bags.	It fits the bill		
	5 Packing method and marking shall be in accordance with factory standard and customer requirements.	It fits the bill		
	6 The quantity (volume/box) shall be in accordance with the packing indication and customer requirements.	It fits the bill		
	7 The indicator color shall conform to the color card before and after sterilization.	It fits the bill		
Inspection of specifications	The surface, dimension, structure and material of the disinfection bag should be consistent with that indicated on the surface, the length and width error is ± 2 mm, the sealing width and the thumb opening error is ± 1 mm	Bag Length	129-131mm	Qualified
		Bag Width	56-58mm	
		Sealing width	9-11mm	
		Thumb opening	14-16mm	
	Printing surface weight error $\pm 5\%$	60g Arjo paper	58-61g/m ²	
	Weight/thickness error $\pm 5\%$	5.2s high temperature film e	0.051-0.053mm	
	The printed area of the sterilization indication is ≥ 100 mm ²		It fits the bill	
Seal Strength Test	The sample is cut 15mm in width and pulled apart at a speed of 200mm/min	Before sterilization ≥ 2.1 N/15mm	2.5-3.3N/15mm	Qualified
		After sterilization ≥ 1.5 N/15mm	1.8-2.3N/15mm	Qualified
Sealing edge leakage test	A syringe (which can be made of plastic or glass) is used to absorb an appropriate amount of aqueous solution of dye and inject it into the disinfection bag. After the injection of Dye, the depth of the water solution on the sealing edge of the disinfection bag should be greater than 5 mm, the Dye is evenly distributed on one side of the sterilizing bag and left to rest for 5-20 seconds. If there is any leakage of 1/2 width of the sealing specification, it is regarded as unqualified		It fits the bill	Qualified

Tearing test	<p>测 Pull back the fastening point of the bottom seal, slowly and carefully open the sterilizing bag with both hands, apply force to two layers of material and tear apart the two sides. On the sealing edge, can not produce more than 10 mm of paper fracture</p>	It fits the bill	Qualified
Tolerance test for disinfection	<p>The sterile bag is divided into two parts. One part is tested and the other part is sealed with gauze or the corresponding product. After sterilization, the bag should not be broken at any sealing place. And printing can not produce halo-dye or decolorization, composite film melt crack and so on, to observe the composite film can not have two layers of peeling off the film</p>	It fits the bill	Qualified
<p>CONCLUSION: This product is tested according to SIP-19 《Standard for inspection of single-use sterilized bags》, and the test results of this batch of products are qualified.</p> <p style="text-align: right;"> 天长市嘉瑞医用材料有限公司 TIANCHANG JIARUI PACKAGING MATERIAL CO., LTD. Date: 2023. 6. 30 </p>			

Test:FEI. WANG

Recheck: YUANFANG. TAO

Permission granted: WEN. CHENG