2011100649S

Mechanical Tests

Test Report

(2014) ZC Class 1650

Product Name **Disposable Purse String Stapler**

Specifications HYB-45

Test Category **Registration inspection**

Entrusting Unit **Changzhou Haida Medical Equipment Co.,Ltd**

CHANGZHOU HAIDA MEDICAL EQUIPMENT CO.,LTD 常州市海达医疗器械有限公司 3204210055629

Jiangsu Province Institute for Medical Equipment Testing

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Inspection Report Home

Report Number: 2014ZC1650

Sampler Name	Disposable Purse String Stapler Send samples	Sampler Number	2014ZC1650
Trademark	/	Model No: HYB-45	
Client	Changzhou Haida Medical Equipment Co.,Ltd	Inspection Category	Registration Inspection
Address	Sanhekou Industrial Park Changzhou, Jiangsu ,P.R.China	Lot Number	20140107
Manufacturer	Changzhou Haida Medical Equipment Co.,Ltd	Sampling Form Number	
Inspection Factory	Changzhou Haida Medical Equipment Co.,Ltd	Produce Date	
Name	/	Quantity Of Sampler	48 Pcs
Address	/	Sampling Base	
Date	/	Inspection location	Our laboratory
Received Sample date	2014.2.27	Inspection date	2014-2.27-2014.04.8
Inspection items	Whole project		
Inspection Basis	Changzhou Haid Medical Equipment Co.ltd Company's <Disposable Purse String Stapler> Standard		
Inspection Conclusion	The sampled product meets Changzhou Haid Medical Equipment Co.,Ltd company's <Disposable Purse String Stapler> standard requirements		
Notes			

Approve:

Position

Inspection Report Of Jiangsu Institute For Medical Device Inspection

Test Group	Sampling Plan	Inspection items	Standard terms	Standard requirements	Inspection results	Unqualified	Unqualified	Conclusion
B Class 1 Group	3 (0,1)	Stability	4.3.1	The sewing and installation of components should be stable inside, and there should be no detachment after swinging	Meet the requirements	O	O	Conform
		Matching performance	4.3.2	The stapler should have good anastomosis performance, and after anastomosis, it should be sewn into a "⌓" shape, allowing the purse string to automatically wrap around the tissue	Meet the requirements	O		
		Packaging appearance	4.5.1	The sterile packaging should be intact, free of foreign substances, and not opened or sealed incompletely. No moisture, water or watermarks	Meet the requirements	O		
C Class 1 Group	3 (1,2)	Size	4.2	L: 311 mm ± 2 mm	311.8-312.4mm	O	O	Conform
				L1: 47 mm ± 1 mm	46.1-46.5mm	O		
				L2: 745mm ± 5mm	743.6-747.6mm	O		
				H: 2.6mm ± 0.2mm	2.64-2.67mm	O		
				Φ: 0.350mm~0.399mm	0.361-0.366mm	O		
				Stapping quantity (Pcs) 18	18 PCS	O		
C Class II Group	3 (1,2)	Shape	4.1.1	The appearance of the stapler is smooth, with clear contours and no defects such as burrs, flying edges, scratches, shrinkage, etc	Meet the requirements	O	O	Conform
		Mark	4.1.2	The handwriting and markings are clear, the labels are correct, and there should be no defects such as misalignment or skewness	Meet the requirements	O		
		Stitching	4.1.3	The sewing head should be sharp, and the surface should not have defects such as dents, scratches, etc	Meet the requirements	O		

Inspection Report

Report Number:2014ZC1650

Test Group	Inspection items	Standard Terms	Standard Requirements	Inspection Results	Conclusion
Class A I Group	Peel strength of packaging sealing	4.5.2	The sealing peel strength should be within the range of 0.1-0.5 (N/mm)	0.24N/mm~ 0.26N/mm	Conform

Pull inspection:

Reviewed by:-Jie Gao

Inspection Report Of Jiangsu Institute For Medical Device

Inspection Report

Test Group	Inspection items	Standard Terms	Standard Requirements	Inspection Results	Conclusion
Class A I Group	Sterile	4.4	After the final packaging of the Disposable Purse String stapler, it is sterile after being irradiated with X-rays	Sterile growth	Conform

Pull inspection:

Reviewed by:-Jie Gao

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Report Number: 2014ZC1650

Photos and captions



description

Number, specification or other description

Product Model No: HYB-45