2012000743S

Mechanical Tests

Test Report

Report No.: G201600[illegible]

Product name: **Disposable Skin Stapler**

Model: HPF-35A

Inspected unit: **Changzhou Haida Medical Equipment Co.,Ltd**

Inspection type: entrusted inspection

State Food and Drug Administration

Hangzhou Medical Device Quality Supervision and Inspection Center

HANGZHOU CENTER OF MEDICAL DEVICE SUPERVISION AND TESTING, CFDA

State Food and Drug Administration Hangzhou Medical Device Quality Supervision and Inspection Center

Inspection report

Report No.: G20160061

Sample name	**Disposable Skin Stapler and Remover**		
Specification and model	HPF-35A	Inspection category	Commissioned inspection
Client/unit	Changzhou Haida Medical Equipment Co., Ltd.		
Name of the inspected unit	Changzhou Haida Medical Equipment Co., Ltd.		
Name of manufacturing unit	Changzhou Haida Medical Equipment Co., Ltd.		
Sampling method	Send the sample	Sampling location	/
Date of sampling	/	Sampling basis	/
Sample in	/	Date of sample acceptance	2016-1-12
Number of samples	30 pieces	Sample production date	/
Sample lot/number	**20150814**		
Inspection basis	**The Registered Product Standard Of HPF Disposable Skin Stapler and Remover Issued By Changzhou Haida Medical Equipment Co.,Ltd**		
Inspection items	2.1; 2.2; 2.3; 2.4; 2.5; 2.6; 2.7		
Date of inspection	January 12, 2016 ~ March 8, 2016		
Inspection conclusion	The tested items of the tested samples meet the requirements of the registered product standard of the Disposable Skin Stapler issued by Changzhou Haida Medical Equipment Co., Ltd. 检验报告专用章		

Approve position: Engineer Date: 2016. 03. 11

Review Date: 2016.03.08

Main inspection Date: 2016.03.08

Inspection report

Inspection location	Center			There are six photographs in this report.
Subcontract inspection items	/			
Subcontract testing laboratory	Name	/	Zip code	/
	Address	/	Phone	/
	Name	/	Zip code	/
	Address	/	Phone	/
Client/unit information	Phone	13813660565	Zip code	213115
	Address	Sanhekou Industrial Concentration Zone, Zhenglu Town, Tianning District, Changzhou City		
Inspection method used	■ Standard Method □ Customized Method □ The methods provided by this laboratory □ Other Method			
Assess measurement uncertainty. Declaration/information of degree	/			
Opinions and interpretations	/			
Sample description	a) The utility model is mainly composed of a pushing piece, a shell, a handle, a suture nail, etc. b) **Principle and purpose: Mainly suitable for suturing the surface skin of wounds and surgical incisions** c) **Main characteristic parameters: mainly including appearance, size, hardness, performance, corrosion resistance, packaging performance, sterility, etc.** d) **Sample status: intact**			
Other instructions	/			

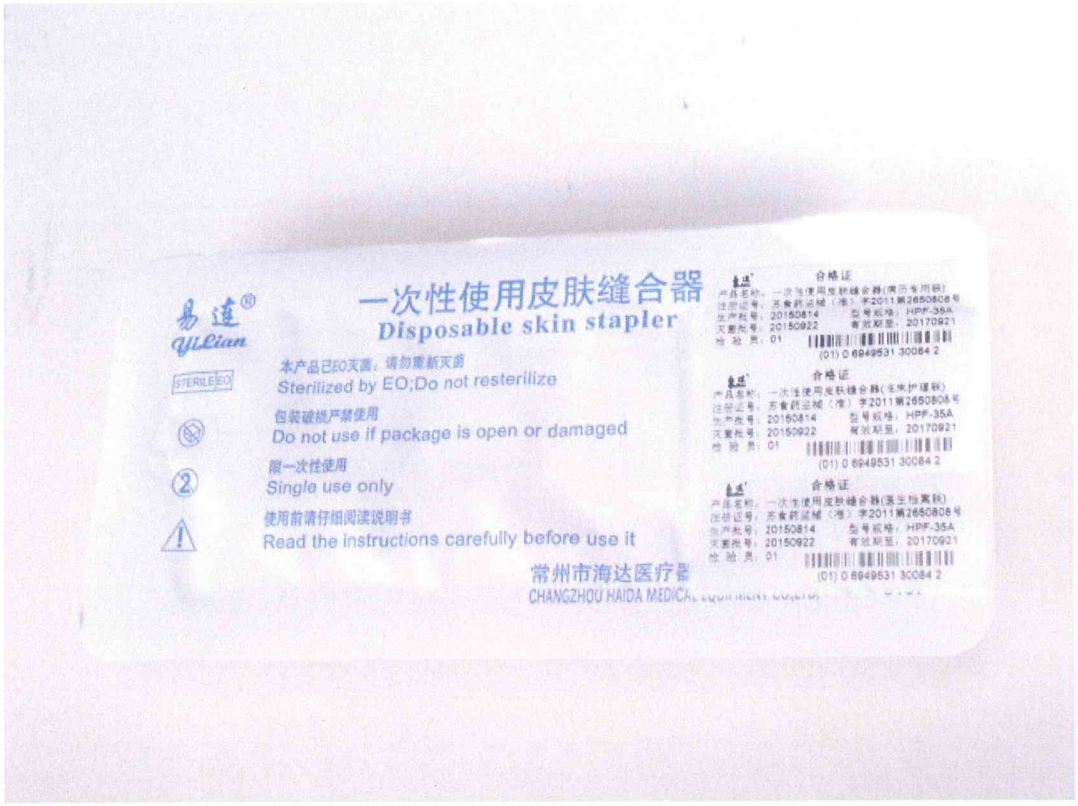
Summary of test results

No.	Test items	Standard terms	Standard requirements	Measured results	Judgment conclusion
1	Appearance	2.1	The stapler and nail remover shall be smooth in appearance, clear in outline, and free of defects such as burrs, sharp edges, scratches and cracks.	Conform	Qualified
			The writing and marks on the surface of the suturing device shall be clear and free of such defects as dislocation and deflection	Conform	Qualified
			The binding of the stapler shell shall be firm and free of cracks and obvious deposits.	Conform	Qualified
			The head of the suture nail shall be sharp, and the surface of the suture nail shall be smooth, free of burrs, depressions and other defects.	Conform	Qualified
			Surface roughness of the exposed metal of the stapler: Ra≤0.8um	≤0.8	Qualified
2	Basic dimensions	2.2	The basic dimensions of the stapler and its accessories are specified in Fig. 1, Fig. 2 and Table 1. The staple diameter is φ0.6mm±0.2mm	0.6	Qualified
			Width before staple formation (L) （13.5±0.5） mm	13.5	Qualified
			Width after staple forming (L1) （7.3±0.5） mm	7.2	Qualified
			The type and basic dimensions of the stapler are shown in Figure 1 and Table 1. Number of staples (35 + 3) PCs.	38	Qualified
			Type of stapler is HPF-35A	Conform	Qualified
3	Hardness	2.3	The hardness of the stapling plate of the stapler shall not be less than 330HV0.2	342	Qualified
			The hardness of the staple base shall not be less than 330HV0.2	368	Qualified
4	Performance	2.4	When the stapler is in use, all moving components shall move smoothly without jamming, sticking or loosening.	Conform	Qualified
			The spring of the stapler shall be elastic enough to reset quickly when the handle is released.	Conform	Qualified
			The suturing device shall have good suturing performance. All the loaded suturing nails shall be able to be ejected smoothly and fired normally, without jamming, multiple strikes and strikes. After firing, there shall be two pieces that should be smoothly twisted and penetrated. 5mm thick fresh pork skin in a rectangular shape, not Shape Phenomenon	Conform	Qualified
			The staples formed by the stapler shall be able to be removed smoothly, and the surface of two pieces of fresh pigskin with a thickness of 5mm shall not be damaged.	Conform	Qualified
5	Corrosion resistance	2.5	The suture nail shall have good corrosion resistance, and its surface condition after the test shall conform to the provisions of Grade 5.4b in YY/T0149-2006.	Conform	Qualified
6	Packaging performance	2.6	The peel strength of the package seal of the suturing device is not less than 0.1N/mm-0.5N/mm	0.3	Qualified
			The peel strength of the package seal of the nail remover is not less than 0.1N/mm-0.5N/mm	0.3	Qualified

Summary of test results

Serial number	Test items	Standard terms	Standard requirements	Measured results	Judgment conclusion
			After stripping, the two contact surfaces shall be smooth, continuous and uniform without delamination or tearing.	Conform	Qualified
7	Sterile	2. 7	The suturing device shall be sterile after being sterilized by epoxy ethylene after final packaging.	Conform	Qualified
			The nail remover shall be sterile after the final packaging and ethylene oxide sterilization.	Conform	Qualified
8	Ethylene oxide residue	2. 7	The residual amount of ethylene oxide in the suturing device shall not be greater than 10ug/g	7	Qualified
			The residual amount of epoxy ethylene oxide in the nail remover shall not exceed 10ug/g	<0. 1	Qualified

This page is empty below

The photo is pasted	
Photo 1 第1幅	
Photo 2 第2幅	

The photo is pasted

Photo 3 第3幅



Photo 4 第4幅



The photo is pasted

Photo 5
第5幅

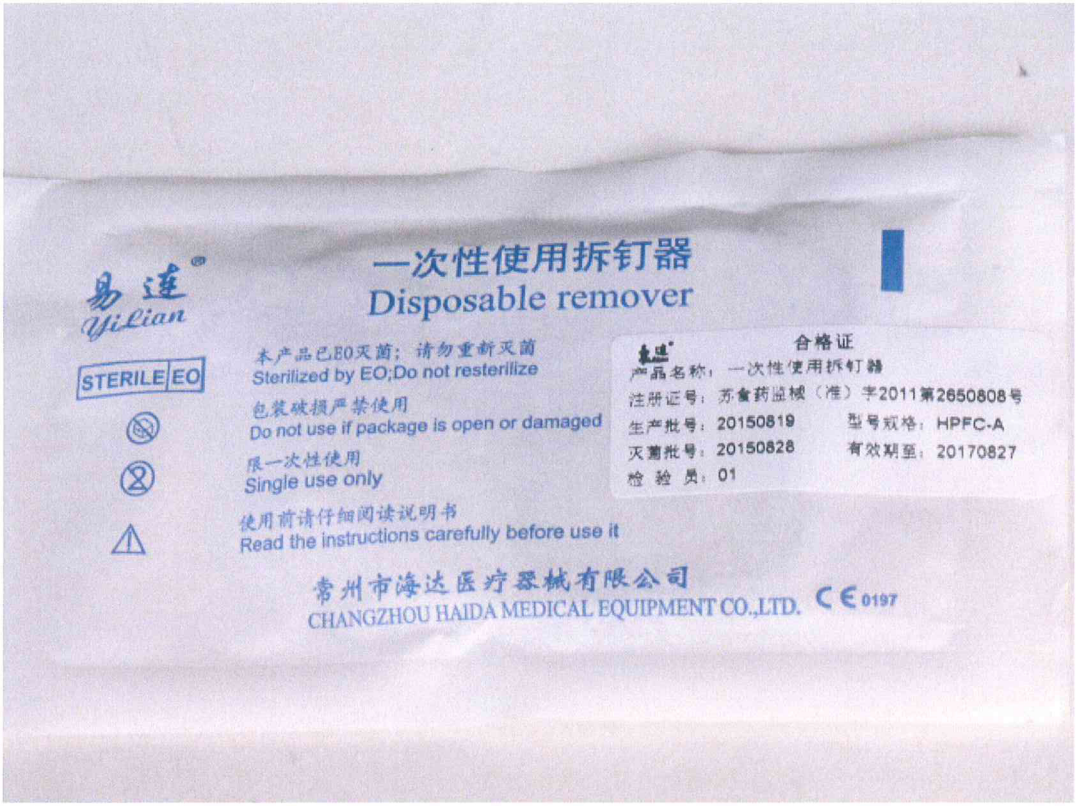


Photo 6
第6幅

