MDST

Mechanical Tests

Test Report

Report No.: G2016 0062



Product name: **Disposable Curved Cutter Stapler and Reload Unit**

Model: HHQ-45A

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.: G20160057

Sample name	**Disposable Curved Cutter Stapler and Reload Units**		
Specification and model	HHQ-45A	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	20 pieces	Sample production date	/
Sample lot/number	20150706		
Inspection basis	**The Registered Product Standard Of HHQ Series Disposable Curved Cutter Stapler and Reload Units Issued By Changzhou Haida Medical Equipment Co.,Ltd**		
Inspection items	4. 1, 4. 2, 4. 3, 4. 4, 4. 6, 4. 7, 4. 8		
Date of inspection	January 12, 2016 ~ March 7, 2016		
Inspection conclusion	**The Tested Item Of the tested Samples Conform to the requirements Of the registered Product standard of HHQ Series Disposable Curved Cutter Stapler and Reload Units 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 four 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	Sanhe 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) Structure: It is mainly composed of a nail support seat, a positioning pin, a knife cushion seat, a suture assembly, a pin pushing rod, a pin pushing rod button, a shell, a firing handle, a feeding handle, a reset button, a cutter, a suture nail, etc. b) **Principle and purpose: Mainly suitable for tissue transection and resection in gastrointestinal surgery** 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

Report No.: G20160062

No.	Test items	Standard terms	Standard requirements	Measured results			Judgment conclusion
1	Appearance	4.1	The anastomat has smooth appearance and no sharp edge, Burrs and cracks	1	2	3	Qualified
				Conform	Conform	Conform	
			The bonding of the stapler shell shall be firm and free of cracks and Obvious accumulation	1	2	3	Qualified
				Conform	Conform	Conform	
			The head of the suture nail shall be sharp, and the surface shall be free of dents and scratches. Injury and other defects	1	2	3	Qualified
				Conform	Conform	Conform	
			Exposed metal surface roughness of anastomat Ra≤0.8μm	1	2	3	Qualified
				≤0.8	≤0.8	≤0.8	
2	Size	4.2	The basic dimensions of the stapler shall be as specified in Figure 1 and Table 1, L=（438 ±3.0）mm	1	2	3	Qualified
				438.0	438.0	438.0	
			H=（4.5 ±0.3）mm	1	2	3	Qualified
				4.5	4.5	4.5	
3	Hardness	4.3	The cutting edge hardness of the cutting knife shall not be lower than 377HV0.2	1	2	3	Qualified
				420	410	408	
4	Performance	4.4	Each moving part of the stapler shall be able to be pushed easily, and shall not be stuck or loose. Elephant	1	2	3	Qualified
				Conform	Conform	Conform	
			After the staple cartridge assembly is installed into the stapler, it should be firm, and the suture nails should not be There should be shedding	1	2	3	Qualified
				Conform	Conform	Conform	
			The spring of the stapler shall be elastic enough to recover quickly when the handle is loosened. Bit	1	2	3	Qualified
				Conform	Conform	Conform	
			The stapler shall have good suturing and cutting performance. After anastomosis, the staples shall be in the shape of "" B "" and arranged in four rows of arcs, and the cutter shall not have curled or broken edges.	1	2	3	Qualified
				Conform	Conform	Conform	

Summary of test results

No.	Test items	Standard	Standard requirements	Measured results			Judgment conclusion
			After stapling, the anastomotic stoma should be able to withstand a lot of pressure. Pressure of 3.6 kPa Force, must not have Water and tearing phenomena	1	2	3	Qualified
				Conform	Conform	Conform	
5	Packaging performance	4.6	The stapler package shall be intact and free of foreign substances; No opening or incomplete seal	Conform			Qualified
			No moisture, moisture, or watermarks	Conform			Qualified
			Closure and stripping of stapler Swallow lT cloud yield should be in (0.1~0.5 (N/mm)	0.2			Qualified
			The two contact surfaces to be torn shall be smooth and continuous without delamination or tearing.	Conform			Qualified
6	Sterile	4.7	The stapler shall be sterile after y-ray irradiation after final packaging	Conform			Qualified
7	Corrosion resistance	4.8	The corrosion resistance of the cutter shall conform to 5.4 in YY/T0149. Level B provisions	1	2	3	Qualified
				Conform	Conform	Conform	
			The corrosion resistance of the nail seat shall conform to 5.4 in YY/T0149. Level B provisions	1	2	3	Qualified
				Conform	Conform	Conform	

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Photo 1 第1幅

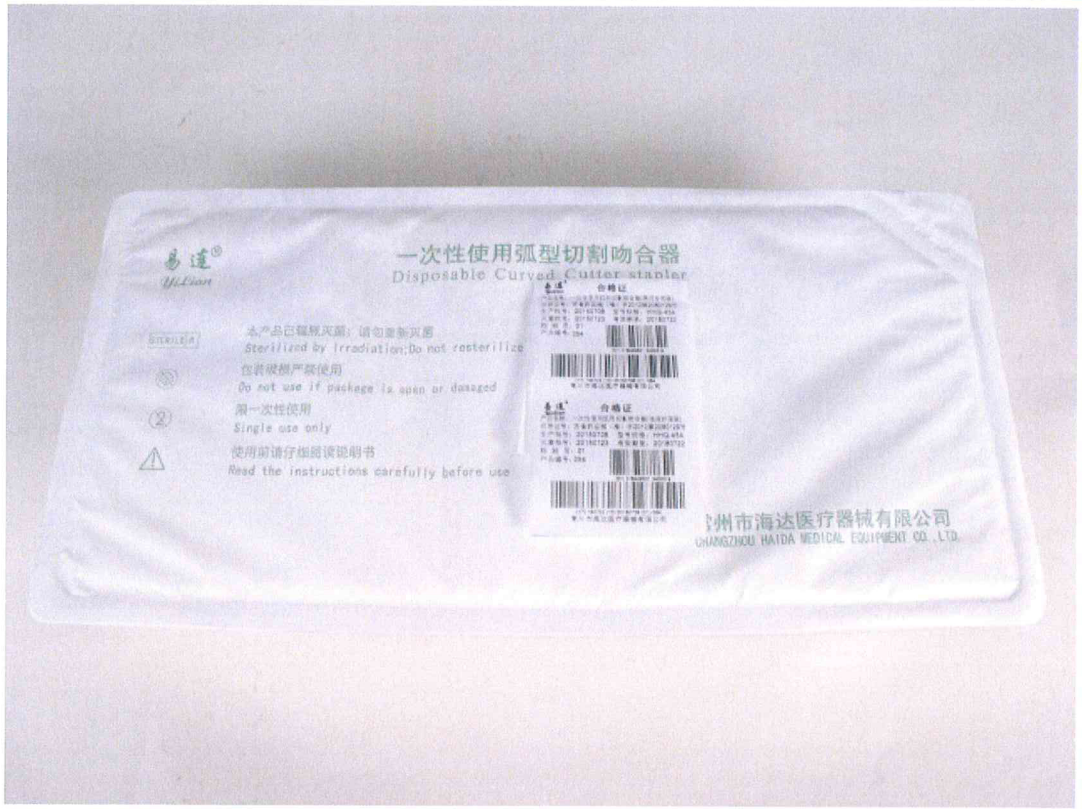


Photo 2 第2幅



照片粘贴处 The photo is pasted

Photo 3 第3幅

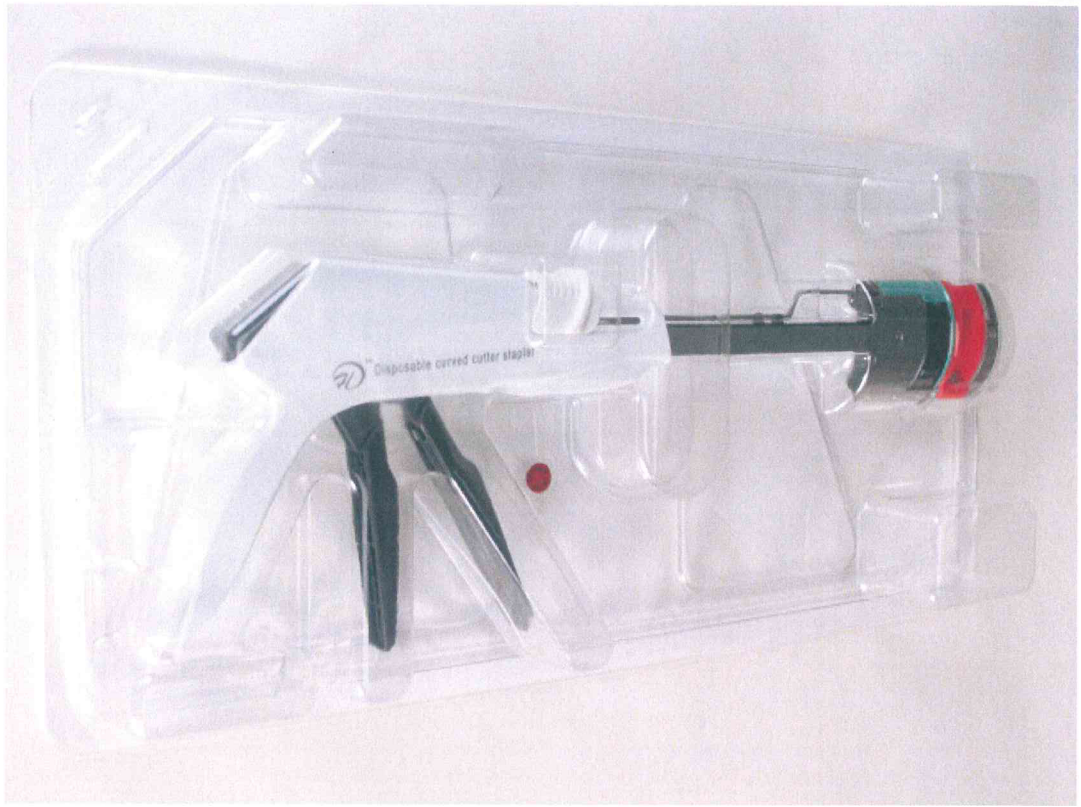


Photo 4 第4幅

