MDST

Mechanical Tests

Test Report

Report No.: G20160 057



Product name: HS series **Disposable Linear Stapler and Reload Units**

Model: HS-60

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 Linear Stapler and Reload Units**		
Specification and model	HS-60	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	20151020		
Inspection basis	**The Registered Product Standard Of HS Series Disposable Linear Stapler and Reload Units Issued By Changzhou Haida Medical Equipment Co.,Ltd**		
Inspection items	4.1; 4.2; 4.3; 4.4; 4.5; 4.6		
Date of inspection	January 12, 2016 ~ March 3, 2016		
Inspection conclusion	**The Tested Item Of the tested Samples Conform to the requirements Of the registered Product standard of HS Series Disposable Linear Stapler and Reload Units Issued by Changzhou Haida Medical Equipment Co.,Ltd**		

检验报告专用章

Approve position: Engineer — Date: 2016.03.09

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	Sanhemen 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 seat, a nail bin, a positioning pin, a shell, a movable handle, a safety button, an indicator window, a fixed handle, an adjusting screw, a suture nail, etc. b) **Principle and Application: Mainly suitable for sealing residual ends and interfaces in gastrointestinal surgeries such as gastric and intestinal procedures** 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.:: G20160057

No.	Test Items	Standard Terms	Standard Requirements	Measured Results			Judgment Conclusion
1	Appearance	4. 1	The shape of the stapler is smooth Smooth, clear outline Clear, burr-free, Scratch and other defects	1	2	3	Qualified
				Conform	Conform	Conform	
			Clear handwriting and mark Clear, the label is correct Indeed, there must be no mistake Position, skew and other defects	1	2	3	Qualified
				Conform	Conform	Conform	
			The head of that staple should Sharp, the surface is not There must be burrs and dents. Marks and other defects	1	2	3	Qualified
				Conform	Conform	Conform	
			Exposed gold of suturing instrument It belongs to surface roughness Ra≤0. 8 μm	1	2	3	Qualified
				≤0. 8	≤0. 8	≤0. 8	
2	Size	4. 2	The basics of the stapler Dimensions shall be in accordance with Figure 1 And Table 1, L=(308±5. 0) mm	1	2	3	Qualified
				308. 0	308. 0	308. 0	
			H=(4. 2±0. 3) mm	1	2	3	Qualified
				4. 2	4. 2	4. 2	
			Screw diameter Φ=(0. 28 ±0. 02) mm	1	2	3	Qualified
				0. 28	0. 28	0. 28	
			L1=(64±1. 0) mm	1	2	3	Qualified
				64. 0	64. 0	64. 0	
3	Performance	4. 3	The stapler is positioned accurately Yes, move, turn Flexible and reliable, No blocking	1	2	3	Qualified
				Conform	Conform	Conform	
			Staples are loaded into the group The inside of the part shall be stable. Not allowed swinging Dropping phenomenon	1	2	3	Qualified
				Conform	Conform	Conform	
			The spring of the stapler There should be enough ammunition. Sex, when let go of the hand When the handle can be quickly recovered.	1	2	3	Qualified
				Conform	Conform	Conform	
			The stapler shall have Good stitching Yes, after suturing Stitch into "B," Glyph, and in 2 rows The lines are interlaced	1	2	3	Qualified

Summary of test results

Serial number	Test items	Standard terms	Standard requirements	Measured results			Judgement
			Aligned	Conform	Conform	Conform	
			After suturing by the suturing device, the suturing mouth should be able to bear a lot. 3.6 kPa pressure	1	2	3	Qualified
				Conform	Conform	Conform	
			There shall be no water or tearing at the suture opening after suturing with the suturing device.	1	2	3	Qualified
				Conform	Conform	Conform	
4	Packaging performance	4.4.1	The aseptic package shall be intact and free of foreign substances	1	2	3	Qualified
				Conform	Conform	Conform	
			The aseptic package shall not be opened or sealed. Complete	1	2	3	Qualified
				Conform	Conform	Conform	
			Sterile packaging shall be free of moisture, moisture or Watermark	1	2	3	Qualified
				Conform	Conform	Conform	
5		4.4.2	Sealing stripping strength shall be 0. 0. 5 (N/mm)	0. 3			Qualified
	Packaging performance 2		The two contact surfaces from which the seal is torn shall be smooth and continuous without delamination or tearing	Conform			Qualified
6	Corrosion resistance	4.5	The nail seat shall have good corrosion resistance. Can	1	2	3	Qualified
				Conform	Conform	Conform	
7	Sterile	4.6	After the final packaging of the stapler and components, they should be sterile after being irradiated with X-rays	Conform			Qualified

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Photo 1 第1幅

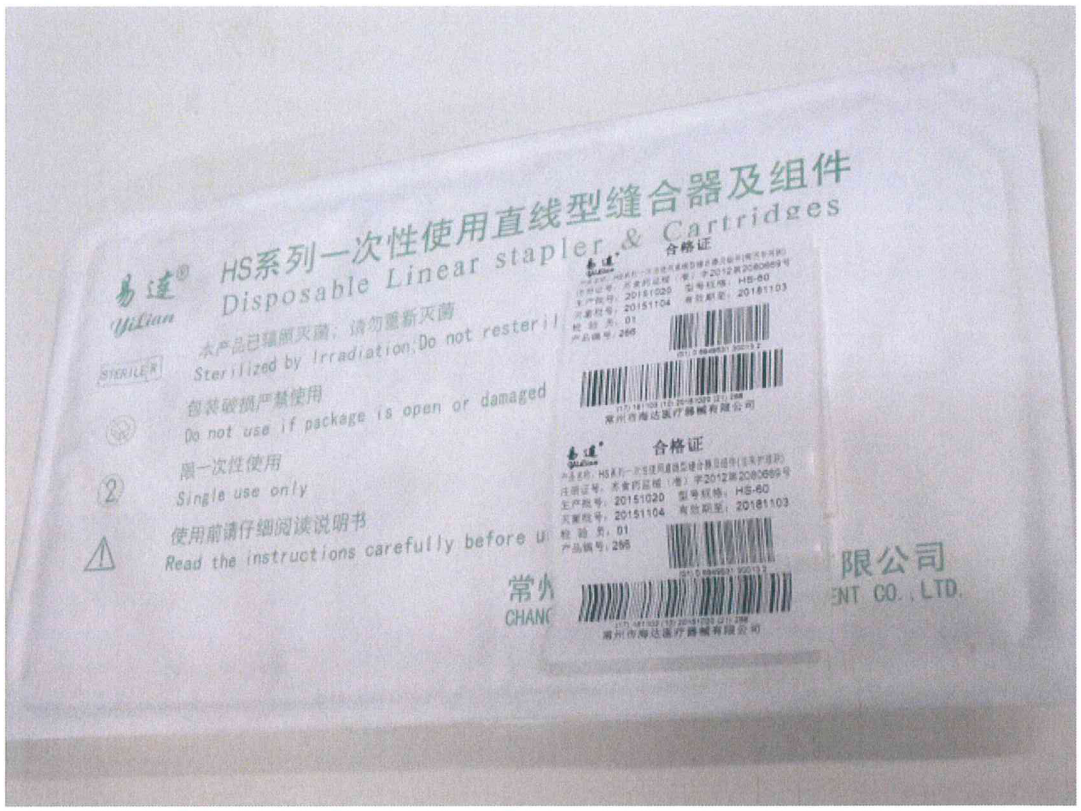


Photo 2 第2幅



照片粘贴处 The photo is pasted

Photo 3 第3幅



Photo 4 第4幅

