MDST

Mechanical Tests

Test Report

Report No.: G20160 058

Product name: HSN series **Disposable Linear Stapler And Reload Units**

Model: HSN-30H

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

Sample name	HSN Series Disposable Linear Stapler and **Reload Units**		
Specification and model	HSN-30H	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	20150916		
Inspection basis	**The Registered Product Standard Of HSN Series Disposable Linear Stapler and Reload Unit 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 items of the tested samples conform to the requirements of the registered product standard of HSN Series Disposable Linear Stapler and Components 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	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) Structure: It is mainly composed of a nail seat, a positioning pin, a suture assembly, a shell, a firing handle, a feeding handle, a reset button, a suture nail, etc. b) **Principle and purpose: 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

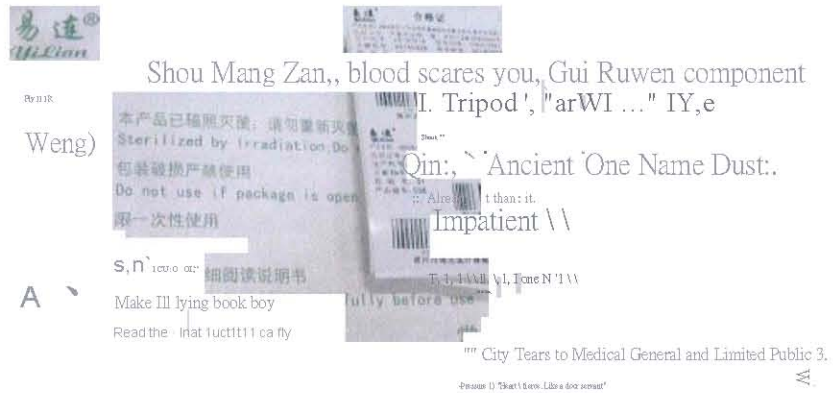
Serial number	Test items	Standard terms	Standard requirements	Measured results			Conclusion
1	Appearance	4. 1	The stapler and its components shall be smooth in appearance, clear in outline, and free of burrs, scratches, etc. Trapped	1	2	3	Qualified
				Conform	Conform	Conform	
			The handwriting and signs shall be clear, the labels shall be correct, and there shall be no dislocation, skew and other defects. I One!	1	2	3	Qualified
				Conform	Conform	Conform	
			The head of the suture nail shall be sharp, and the surface shall be free of burrs, dents and other defects.	1	2	3	Qualified
				Conform	Conform	Conform	
			Exposed metal surface roughness of stapler and components Ra≤0. 8 μ m	1	2	3	Qualified
				<0.8	<0.8	<0.8	
2	Size	4. 2	The basic dimensions of the stapler and its components shall be in accordance with Figure 1 and Table 1, L = (374 ± 5.0). mm	1	2	3	Qualified
				374. 0	374. 0	374. 0	
			H=(4. 5±0. 3) mm	1	2	3	Qualified
				4. 5	4. 5	4. 5	
			Staple diameter towel ϕ=(0. 28 ±0. 02) mm	1	2	3	Qualified
				0. 28	0. 28	0. 28	
			L1=(33. 8 ±1. 0) mm	1	2	3	Qualified
				33.8	33. 8	33. 8	
3	Performance	4. 3	The anastomat is accurate in positioning, flexible and reliable in movement and rotation, No blocking	1	2	3	Qualified
				Conform	Conform	Conform	
			The staples shall be stably installed in the assembly, and there shall be no Dropping phenomenon	1	2	3	Qualified
				Conform	Conform	Conform	
			The spring of the stapler shall be elastic	1	2	3	
			enough to recover quickly when the handle is loosened. Bit	Conform	Conform	Conform	Qualified
			The stapler should have good suture performance.	1	2	3	Qualified

Summary of test results

Preface 号	Test items	Standard terms	Standard requirements	Measured results			Conclusion
			Stitching shall be in the shape of "B" and staggered in two rows of straight lines.	Conform	Conform	Conform	
			The anastomotic stoma sutured by the stapler shall be able to bear not less than 3. 6kPa	1	2	3	Qualified
				Conform	Conform	Conform	
			After suturing with a stapler, there should be no water leakageor tearing at the anastomotic site	1	2	3	Qualified
				Conform	Conform	Conform	
4	Packaging performance	4.1.1	The stapler and its components shall be aseptically packed in good condition 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 should be free of moisture, moisture, or watermarks	1	2	3	Qualified
				Conform	Conform	Conform	
5	Peel strength	4.4. 2	The seal peel strength of the stapler and components shall be shall be 0. 1~0. 5 (N/mrn)	0. 2			Qualified
			The two contact surfaces where the seal of the stapler and components is torn shall be smooth, continuous and uniform without delamination or tearing.	Conform			Qualified
6	Corrosion resistance	1. 5	The nail seat shall have good corrosion resistance.	1	2	3	Qualified
				Conform	Conform	Conform	
7	Sterile	4. 6	The stapler is sterilized after being irradiated by γ rays after being finally packaged.	Conform			Qualified

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". Certificate of conformity."

:::;; The registration certificate number of HSN Binglie disposable linear stapler and components (special monthly copy of medical records): SSYJX (Z) Zi 2012 No.2080544 Production batch number: 20150916 Model and specification: HSN-30H

Sterilization batch number: 20150928. Valid until: 20180927.

Inspector: 01

Where? Product number: 036

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Chang Wo Fu Yan Sui Wang and

Chu Dai Dai Zhi Xiao Si

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Photo 3

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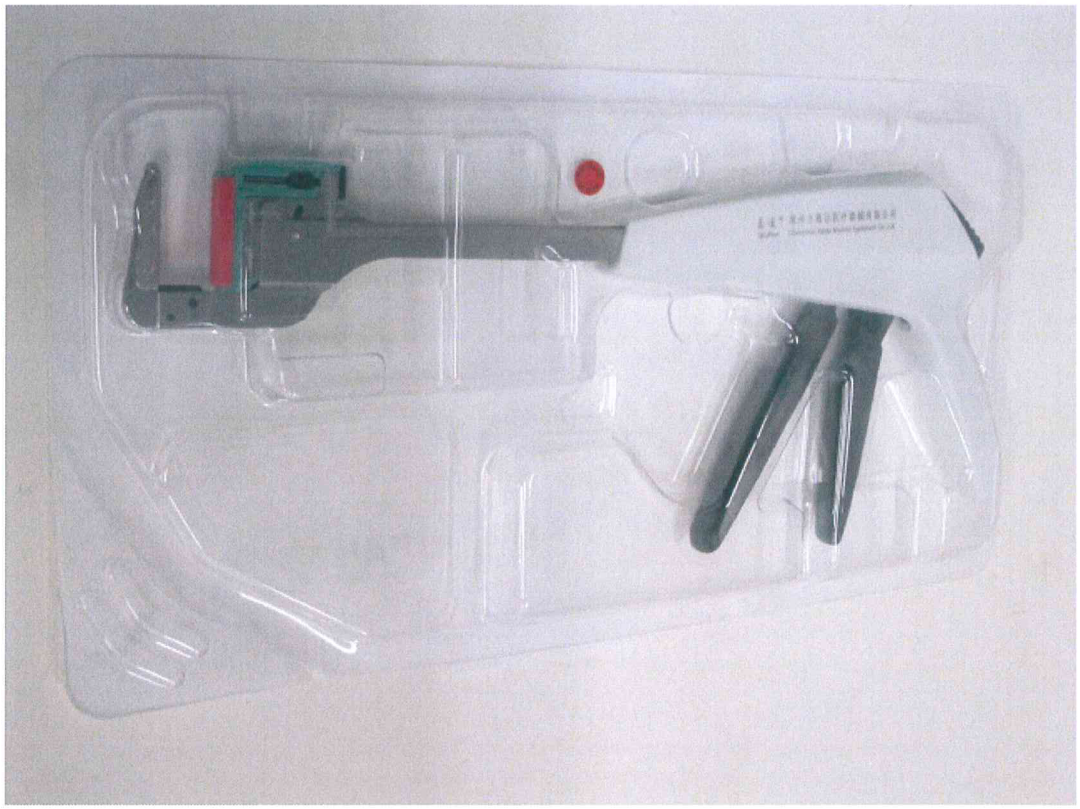


Photo 4

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