MDST

Mechanical Test

Test Report

Report No.: G20160064

Product name: Disposable Endo Cutter Stapler and Reload Units

Model: HENDO-L HENDO-45-3.5A

Inspected unit: Changzhou Haida Medical Instrument 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.: G20160064

Sample name	Disposable Endo Cutter Stapler and Reload Units		
Specification and model	HENDO-L HENDO-45-3.5A	Inspection category	Commissioned inspection
Client/unit Name	Changzhou Haida Medical Equipment Co., Ltd.		
Name of inspected unit	Changzhou Haida Medical Equipment Co., Ltd.		
manufacturer	Changzhou Haida Medical Equipment Co., Ltd.		
Sampling method	Send samples	Sampling location	/
Sampling date	/	抽样基数	/
Sampling personnel	/	样品接受日期	2016-1-12
Number of samples	20 Pieces	样品生产日期 Sample Produce Date	/
Sample lot/number	20151023		
Inspection basis	The Registered Product standard of "Disposable Endo Cutter Stapler and Reload Units" Issued By Changzhou Haida Medical Devices 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 07, 2016		
Inspection conclusion	The Tested Items Of the tested Samples Meet the requirements of the Product standard of "Disposable Endo Cutter Stapler and Reload Units" Issued by Changzhou Haida Medical Devices Co.,Ltd.		

CHANGZHOU HAIDA MEDICAL EQUIPMENT CO.,LTD 常州市海达医疗器械有限公司 3204210055628

国家食品药品监督管理局杭州医疗器械质量监督检验中心 检验专用章

检验报告专用章

Approval : Auditor: Main Auditors:

Title: Chief Engineer

Date: 2016. 03. 11 Date: 2016. 03. 10 Date: 2016. 03. 10

Inspection report

Inspection location	Center		There are six photographs in this report.	
Subcontract inspection item door	/			
Subcontract testing laboratory	Name	/	Zip code	/
	Address	/	Tun dialect	/
	Name	/	Zip code	/
	Address	/	Tun dialect	/
Client/f (1 digit	Tun dialect	13813660565	Zip code	213115
	Address	Zheng Luzhao [Sanhekou Industrial Zone, Tianning District, Changzhou City		
Inspection method used	■ Standard Method ☐ Customized Method ☐ The methods provided by this laboratory ☐ Other Method			
Assessing the addressing information to determine the information Degrees of Luming	/			
Opinions and interpretations	/			
Sample description	a) The structure comprises a main lock chamber sleeve, an outer sleeve, an adjusting knob, an upper adjusting shell, a lower adjusting shell, a lock pin, a push block, a fixed handle, a firing handle, a nail chamber, a bracket, a nail resisting seat, a nail resisting seat cover, a pressure plate cover, a safety plate, a suture nail and the like. b) Principle and purpose: Mainly suitable for tissue resection, transection, and anastomosis in abdominal surgery, gynecology, pediatrics, and open endoscopic thoracic surgery c) Main characteristic parameters: appearance, size, hardness, performance, corrosion resistance, packaging performance, peel strength, sterility, etc. d) Sample status: intact			
Other instructions	/			

Summary of test results

Preface Number	Test items	Standard terms	Standard requirements	Measured results			Judgment conclusion
1	Appearance	1.1	The stapler and its components shall be smooth in appearance and free of sharp edges, burrs and Crack	1	2	3	Qualified
				Conform	Conform	Conform	
			The stapler and component shell shall be firmly bonded without cracks and obvious deposits.	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	I4hominohn:, 6.	^ 1 inch ·/I, · I today	
			The surface roughness of the outer surface of the stapler shall be Ra O. 8 μm	1	2	3	Qualified
				:S;0. 8	O. 8	::S0. 8	
			The outer surface of the stapler assembly is golden and rough. Ra O. 8 μ m	1	2	3	Qualified
				O. 8	O. 8	<O.8	
2	Size	4.2	The basic dimensions of the stapler and its components shall be in accordance with Figure 1 and Table 1 and Table 2. L = (377 ± 5) mm	1	2	3	Qualified
				377	377	377	
			The component L1 = (45 Soil 2) mm	1	2	3	Qualified
				45	45	45	
			Nail Shang (3.5 Soil (0.3) mm	)	2	3	Qualified
				3.5	3.5	3.5	
3	Hardness	4.3	The hardness of the cutting edge of the cutter shall not be less than 377llVO.2.	1	2	3	Qualified
				546	528	549	
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	
			The assembly shall be firm after being installed into the stapler, and the suture nail shall not be used. Fall off	1	2	3	Qualified
				Conform	Conform	Conform	
			The spring of the stapler shall be elastic enough to recover quickly when the handle is loosened.	1	2	3	Qualified

Summary of test

Preface Number	Test items	Standard terms	Standard requirements	Measured results			Judgment conclusion
			Bit	Conform	Conform	Conform	
			The components of the stapler should have good suturing and cutting performance. After anastomosis, the staples should be in the shape of "B" "" and arranged in six rows, and the cutter should not be rolled. Blade, broken blade	1	2	3	Qualified
				Conform	Conform	Conform	
			The components of the stapler shall only have good cutting performance, and the cutting knife shall not be coiled. Blade, broken blade	1	2	3	Qualified
				Conform	Conform	Conform	
			Anastomosis II of stapler and components after anastomosis shall be able to withstand no less than 3.6 kPa. The pressure of	I	2	3	Qualified
				Conform	Conform	Conform	
			The anastomotic stoma after anastomosis of the stapler and components shall be free of leakage. Water and tearing phenomena	1	2	3	Qualified
				Conform	Conform	Conform	
5	Packaging performance	4.6	The stapler and its components shall be well packed and free of foreign substances.	1	2	3	Qualified
				Conform	Conform	Conform	
			Stapler and component package shall not be unsealed Or the seal is incomplete	I	2	3	Qualified
				Conform	Conform	Conform	
			Stapler and component packaging shall be free of moisture, moisture, or water Seal	1	2	3	Qualified
				Conform	Conform	Conform	
			The stripping degree of the closure of the stapler shall be 0.1 0. 5 CN/ In the range of dish (n)	1	2	3	Qualified
				0.3	0.3	0.3	
			Component seal stripping force should be in 0. 0. 5 CN/ Mm)	]	2	3	Qualified
				0.3	0.2	0.2	
			The two contact surfaces of the stapler and the component seal II that are torn shall be smooth, continuous and uniform without delamination or tearing.	1	2	3	Qualified
				Conform	Conform	Conform	

Summary of test

No.	Detection item	Standard terms	Standard requirements	Measured results			Judgment conclusion
6	Sterile	4.7	The stapler is finally packaged and then irradiated by y rays. Sterile after irradiation	Conform			Qualified
			After final packaging, the assembly shall be free of X ray irradiation.	Conform			Qualified
7	Corrosion resistance	4.8	The corrosion resistance of the cutter shall conform to 5.4 in YY/T0119. Level B provisions	1	2	3	Qualified
				Conform	Conform	Conform	
			The corrosion resistance of the nail seat shall conform to YY/T0149 5.1. Level B provisions	1	2	3	Qualified
				Conform	Conform	Conform	

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Photo 6 第6幅

