MDST

Mechanical Tests

Test Report

Report No.: G20160 058



Product name: **Disposable Hemorrhoids Stapler**

Specification and model: HYG-34

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 Number: G20160059

Sample name	**HYG Disposable Hemorrhoids Stapler**		
Specification and model	HYG-34	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	H sample location	/
Date of sampling	/	Sampling basis	/
Sampler	/	Date of sample acceptance	2016-1-12
Number of samples	20 pieces	Sample production date	/
Sample lot/number	20150708		
Inspection basis	**The Registered Product standard of HYG Series Disposable Hemorrhoids Stapler issued by Changzhou Haida Medical Equipment Co.,Ltd**		
Inspection items	4.1; 4.2; 4.3; 4.4; 4.5 ; 4.6 ; 4.7		
Date of inspection	January 12, 2016 ~ March 3, 2016		
Inspection conclusion	**The Tested Items Of the tested samples meet the requirements of the registered product standard of HYG Series Disposable Hemorrhoids Stapler Issued by Changzhou Haida Medical Equipment Co.,Ltd**		

检验报告专用章

Approved Title: Chief Engineer Main inspection:

Date: 2016.03.09 Date: 2016.03.08 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) The structure is mainly composed of a nail-resisting seat, a cover nail, an anastomosis component, a movable handle, a safety block, a fixed handle, an adjusting nut, a cushion knife ring, a suture nail, an annular knife, an anoscope piece, an anal dilatation piece, a suture and ligation piece, b) **Principle and purpose: Mainly suitable for repairing rectal mucosal prolapse or hemorrhoidal tissue nailing in the anal canal.** 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 shape of the stapler and the surface of the accessories shall be smooth, clear and free of burrs. Scratch and other defects	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.	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	
			The outer surface of the circular cannula of the stapler shall be free from brightness, Ra≤0.8 μm	1	2	3	Qualified
				≤0.8	≤0.8	≤0.8	
2	Size	4.2	The basic dimensions of the stapler shall be in accordance with Figure 1, Figure 2 and Table 1, Table 2, L = (395 ± 5.0) lnn	1	2	3	Qualified
				395.0	395.0	395.0	
			D = (34 ± 1.0) mm	1	2	3	Qualified
				34.0	34.0	34.0	
			D1=(24.2 Soil (0.5) mm	1	2	3	Qualified
				24.2	24.2	24.2	
			Screw diameter Small = (0.28 ± 0.02) mm	1	2	3	Qualified
				0.28	0.28	0.28	
			H = (3.8 ± 0.3) mm	1	2	3	Qualified
				3.8	3.8	3.8	
			D2 = (73 ± 2.0) mm	1	2	3	Qualified
				73.2	73.0	73.2	
			D3 = (48 ± 2.0) mm	1	2	3	Qualified
				48.5	48.6	48.0	
			D4 = (135 ± 2.0) lnn1	1	2	3	Qualified
				135.0	135.0	135.0	
			L1 = (129 ± 2.0) mm	1	2	3	Qualified
				129.5	129.0	129.5	

Serial number	Test items	Standard terms	Standard requirements	Measured results			Judgment conclusion
			H2 = (47 ± 2.0) mm	1	2	3	Qualified
				47.0	47.0	47.0	
			H3 = (78 ± 2.0) mm	1	2	3	Qualified
				79.0	79.0	79.0	
			H4 = (108 + 2.0) mm	1	2	3	Qualified
				108.0	108.0	108.0	
3	Hardness	4.3	The hardness of the ring knife shall not be less than 377HV0.2	1	2	3	Qualified
				450	443	448	
4	Performance	4.4	Staples shall be installed in the assembly in a fixed manner, and shall not be found after swinging. Dropping phenomenon	1	2	3	Qualified
				Conform	Conform	Conform	
			The safety device of the stapler shall be opened and closed flexibly, and shall be safe and effective in use.	1	2	3	Qualified
				Conform			
			The return spring of the stapler shall be elastic enough to release the handle quickly. Quick reset	1	2	3	Qualified
				Conform	Conform	Conform	
			The stapler should have good anastomosis performance and be sutured after anastomosis. "B" shape	1	2	3	Qualified
				Conform	Conform	Conform	
			The stapler should have good cutting performance. Yes, the cutting knife shall not have rolled edge or broken edge. Blade	1	2	3	
				Conform	Conform	Conform	Qualified
			After anastomosis, the anastomotic stoma shall be able to bear no less than 3.6KPa. The pressure of	1	2	3	Qualified
				Conform	Conform	Conform	
			The anastomotic stoma after anastomosis shall be free of water leakage and tearing.	1	2	3	Qualified
				Conform	Conform	Conform	
			Permanent deformation and fracture will not occur when a force of 50N is applied to any point of the dilator. Crack, not obviously willing to collapse	1	2	3	Qualified
				Conform	Conform	Conform	

Summary of test results

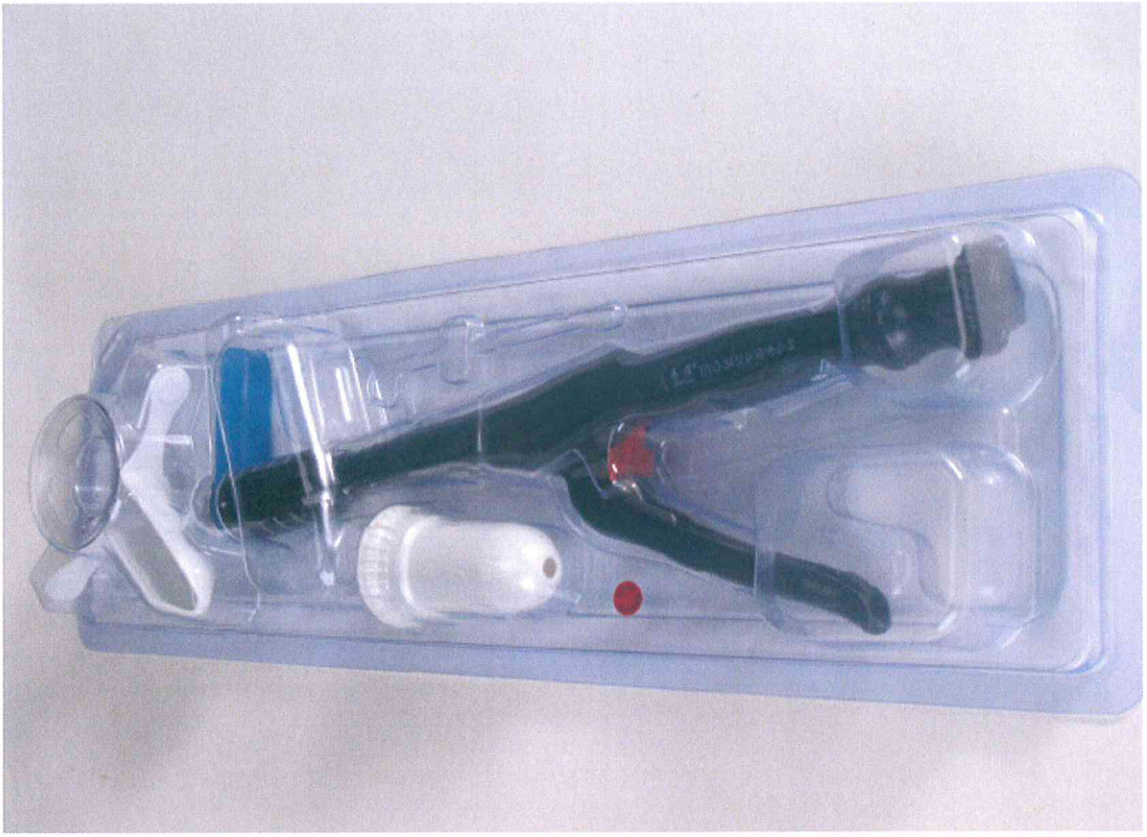
Serial number	Test items	Standard terms	Standard requirements	Measured results			Judgment conclusion
5	Corrosion resistance	4. 5	The corrosion resistance of the ring knife shall conform to 5.4 in YY/T0149. Level B provisions	1	2	3	Qualified
				Conform	Conform	Conform	
			The corrosion resistance of the nail seat shall conform to 5.4 in YY/T0149. Level B provisions	1	2	3	Qualified
				Conform	Conform	Conform	
6	Packaging performance	4. 6. 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 should be free of moisture, moisture, or watermarks	1	2	3	Qualified
				Conform	Conform	Conform	
7	Peel strength	4. 6. 2	The stripping strength of the seal shall be 0. 1~0. 5 (N/mm)	0. 3			Qualified
			The two contact surfaces from which the seal is torn shall be smooth and continuous without delamination or tearing	Conform			Qualified
8	Sterile	4. 7	The stapler is sterilized after being irradiated by γ rays after being finally packaged.	K4 inch I, mouth: A			Qualified

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