MDST

Mechanical Test

Test Report

Report No.: G20160055



Product Name: Disposable Circular Stapler

Model: HC-26

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.: G20160055

Sample name	HC Disposable Circular Stapler		
Specification and model	HC-26		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	Sampling method of Changzhou		
Haida Medical Equipment Co., Ltd.	Send the sample		
	Sampling location		/
Sampling date and person	/	Draw the auspicious base number	/
	/	Date of sample acceptance	20)6-1-12
Number of samples:	20 pieces	Sample production date	/
Sample lot/number	20151104		

Inspection basis: The registered product of HC series disposable tubular digestive tract stapler issued by Changzhou Xiangda Medical Devices Co., Ltd.

Inspect the dam mouth: 4.1 ; 4.2 ; 1. 3 ; 4.11 ; 4.5 ; 4.6; 4.7;

Date of inspection: January 12, 2016 ~ March 3, 2016

The test items of the sample are in line with the requirements of the registered product standard of HC Series Tubular Gastrointestinal Stapler issued by Changzhou Haida Medical Equipment Co., Ltd.

Inspection conclusion

质量监督检验中心 检验专用章

检验报告专用章

批准：		审核：		主检：	
职务：	总工程师				
日期：	2016. 03. 09	日期：	2016. 03. 08	日期：	2016. 03. 08

Inspection Report

Inspection location	Center of Inspection		I There are four photographs in this report.	
Subcontract inspection item door				
Subcontract testing laboratory	Name	/	Zip code	/
	Address	/	Phone	/
	Name	/	Zip code	/
	I is also the address	/	Tun dialect	/
Client/unit information	Phone	138]3660565	Zip code	213115
	Ground. Twenty	Zheng Luzhao [Sanhekou Industrial Zone, Tianning District, Changzhou City		
Inspection method used	■ Standard Method ☐ Customized Method ☐ The methods provided by this laboratory ☐ Other Method			
Assess uncertainty/ Declaration/information of degree	/			
Provoke and explain	/			
Sample description	a) Structure: It is mainly composed of a nail-resisting seat, a cover nail plate, an anastomotic cutting component I, a movable handle, a safety button, a fixed handle, an adjustable nut, a cushion knife circle, a suture nail, a ring, etc. b) Principle and purpose: Suitable for end-to-end anastomosis and end-to-end anastomosis of digestive tract tissues such as esophagus, stomach, colon, rectum, etc c) Main characteristic parameters: appearance, size, hardness, performance, corrosion resistance, packaging performance, peel strength, sterility, etc. d) Sample status: intact			
Other instructions	/			

Test results

Report No.: G20160055

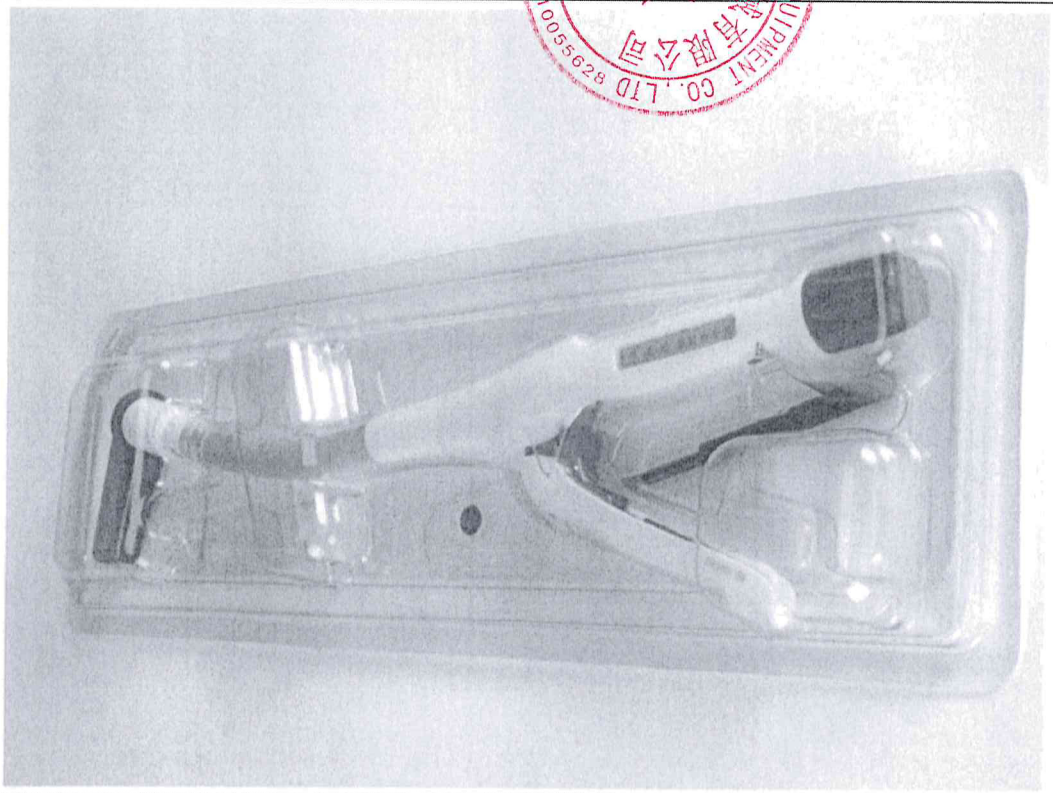
Number	Test items		Standard requirements	实测结果			判定结论
1	Appearance	4.1	The stapler has smooth appearance and flexible contour. Il analysis, no burr, scratch and other defects	1	2	3	Q ualified
				Conform	Conform	Conform	
			The handwriting and marks shall be clear and clear, and XE shall be correct, and 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, scratches and other defects.	1	2	3	Qualified
				Conform	Conform	Conform	
			The outer surface of the circular sleeve of the stapler should have no brightness and its surface roughness Ra≤0.8μm	1	2	3	Qualified
				≤0.8	≤0.8	≤0.8	
2	Size	4.2	The basic dimensions of the stapler should comply with the provisions of Figure 1, Figure 2, and Table 1 L=（450±5.0）mm	1	2	3	Qualified
				450.0	450.0	450.0	
			D=（26±1.0）mm	1	2	3	Qualified
				26.0	26.0	26.0	
			D1=（16±0.5）mm	1	2	3	Qualified
				16.0	16.0	16.0	
			H=(5.0±0.3) mm	1	2	3	Qualified
				5.0	5.0	5.0	
			Sewing Diameter Φ0.28mm±0.02mm	1	2	3	Qualified
				0.28	0.28	0.28	
			Anal Endoscope D2=（73±2.0）mm	/			Not Applicable
			Anal Endoscope H2=（46±2.0）mm	/			Not Applicable
			Anal Expansion Piece D3=（48±2.0）mm	/			Not Applicable
			Anal Expansion Piece H3=（79±2.0）mm	/			Not Applicable

Preface F Beggar 1	Test items	Standard /Dong, J Dangshi\.	Standard requirements				Judgment conclusion
			Sewing only L pieces D4= (135 ±2.0) 1111 11				Not applicable
			Stitching piece H4= (108 ± 2.0) IIIII		/		Not applicable
			Crochet piece LI= C129 Soil 2.0) mm		/		Not applicable
			Connecting Rod L2= (158 Soil 2.0) mm	I	2	3	Discomfort ll
				158. 0	158. 0	158. 0	
3	Hardness	4. 3	The hardness of the ring knife shall not be lower than 377HVO.2.	1	2	3	Qualified
				458	456	450	
4	Performance	4. 4	Each moving part of the stapler shall be able to be pushed easily without jamming. Stay	I	2	3	Qualified
				In line with: in line	Conform	Conform	
			The installation of the suture nail into the assembly shall be fixed, and the Wei movement shall be deficient; f9; Have Dropping phenomenon	I	2	3	Qualified
				Payable: R. Today: J.	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	Conform	Conform	
			The return spring shall have sufficient elasticity when the handle is loosened It can be reset quickly	1	2	3	Qualified
				Conform	Conform	Conform	
			The stapler should have good anastomosis and cutting performance, and be stapled after anastomosis. 'B ") | Township, _ and Cutting knife is not allowed Roll blade, friend blade	1	2	3	Qualified
				Conform	Conform	/Fu, Gong: ^ Bai	
			After anastomosis, the anastomotic stoma shall be able to bear a force of not less than 3.6KPa:/Li without water and tearing.	1	2	3	Qualified
				Conform	Conform	Conform	

Preface	Test items	Standard terms	Standard requirements				Judgment conclusion
			Applying a force of 50N at any point on the anal expansion piece will not cause permanent deformation or fracture, and will not significantly collapse	/			Not applicable
(1)	Corrosion resistance	4.5	The corrosion resistance of the annular knife should comply with the provisions of YY/T0149, Grade 5.4b	1	2	3	Qualified
				Conform	Conform	Conform	
			The corrosion resistance of the reserved seat should comply with the provisions of YY/T0149, Grade 5.4b	1	2	3	Qualified
				Conform	Conform	Conform	
6	Packaging performance	4.6.1	The sterile packaging of the stapler should be intact and free of foreign substances	1	2	3	Qualified
				Conform	Conform	Conform	
			No opening or incomplete seal	1	2	3	Qualified
				Conform	Conform	Conform	
			No moisture, moisture, or watermarks	1	2	3	Qualified
				Conform	Conform	Conform	
7	Peel strength	4.6.2	The release strength of the stapler package seal is 0.5 (N/mm)	0.3			Qualified
			The two contact surfaces that have been torn apart should be smooth, continuous, and uniform, without delamination or tearing	Conform			Qualified
8	Wu Mo	4.7	The stapler is sterilized after being irradiated by Lu rays after being finally packaged.	Conform			Qualified

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Photo pasting location/贴处	
Photo 1	
Photo 2	

Photo pasting location	
Photo 3	
Photo 4	