MDST

Mechanical Test

Test Report

Report Number : G20160060

Product Name: **HQ Series Disposable Linear Cutter Stapler and Reload Units**

Model: HQ-80M

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 Dial Craftsman Sales Summer Inspection Center

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 报 告

Inspection

Report No.: G20160060

Sampler Name	HQ系列一次性使用直线型切割吻合器及组件 HQ Series Disposable Linear Cutter Stapler and Reload Units		
Model No.	HQ-80M	检验类别 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 Place	/
Sampling date	/	Sampling Base	/
Sampling personnel	/	Sample Acceptance Date	2016-1-12
Number of samples	20件	Sample production Date	/
Sample lot/number	20151105		
Inspection basis	The Registered Product Standard Of HQ series Disposable Linear Cutter Stapler and Reload Units (YZB/ S 0649-2012) issued By Changzhou Haida Medical Devices 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 HQ Series Disposable Linear Cutter Stapler and Reload Units (YZB/S 0649-2012) issued by Changzhou Haid Medical Devices Co.,Ltd 检验报告专用章		

Approval: Title: Engineer Date: 2016. 03. 16

Audit: Date: 2016. 03. 14

Audit: Date: 2016. 03. 14

Inspection
检 验 报 告

Report No.: G20160060

Inspection location	Center			There are 4 photos in the report
Subcontract inspection items	/			
Subcontract testing laboratory	Name	/	Zip code	/
	Address	/	Phone	/
	Name	/	Zip code	/
	Address	/	Phone	/
Entrusted/company information	Phone	13813660565	Zip code	213115
	Address	Zheng Luzhao [Sanhekou Industrial Zone, Tianning District, Changzhou City		
Inspection method	■ Standard Method ☐ Customized Method ☐ The methods provided by this laboratory ☐ Other Method			
Declaration on Evaluating Measurement Uncertainty /information	/			
Opinions and interpretations	/			
Sample description	a) Structural composition: mainly composed of oil sewing handle, shell, nail seat, booking bracket, booking, sewing, etc b) Principle and application: It is mainly applicable to the separation of tissues in the operation of intestinal tract, uterus, adnexa and lung lobe. c) Characteristic parameters: mainly including appearance, size, hardness, performance, corrosion resistance and packaging d) Condition: intact.			
Other instructions	/			

No.	Test items	Standard terms	Standard requirements				Conclusion Judgment
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.	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 external gold bending surface of the stapler shall be bright, and its surface roughness shall be Ra O. 8 μm	1	2	3	Qualified
				<0.8	<0.8	<0.8	
2	Size	4. 2	The basic dimensions of the stapler and its components shall conform to Figure 1 and Table 1, L = (280 Soil (4.O) mm	1	2	3	Qualified
				280.0	280. 0	280. 0	
			l-l = (3.8 ± 0.3) mm	1	2	3	Qualified
				3. 8	3. 8	3. 8	
			Screw diameter c])=(0.2 Soil (0.02) mm	1	2	3	Qualified
				0.20	0.20	0.20	
			L1 = (81 ± 1.0) mm	1	2	3	Qualified
				81. 0	81. 0	81. 0	
3	Hardness	4. 3.	The hardness of the cutting knife shall not be less than 377HV0.2	1	2	3	Qualified
				609	611	602	
4	Performance	4. 4.	Each moving part of the stapler can be pushed easily without jamming. Stuck and loose phenomenon	1	2	3	Qualified
				Conform	Conform	Conform	
			The staples shall be stably installed in the assembly, and shall not appear after swinging. Dropping phenomenon	1	2	3	
				Conform	Conform	Conform	Qualified
			The stapler and suture components shall have good anastomosis and cutting performance, and shall be stapled after suturing	1	2	3	Qualified

Summary of Test Results

检 测 结 果 汇 总

Report No.: G20160060

No.	Test items	Standard terms	Standard requirements	实测结果 Actual measurement results			Conclusion Judgment
			"B" and Two Rows and Four Rows are staggered with Each other on both sides of a straight Line	Conform	Conform	Conform	
			The cutting knife shall not have a curling edge or a chipping edge	1	2	3	Qualified
				Conform	Conform	Conform	
			The anastomotic stoma after anastomosis shall be able to bear a pressure not less than 3.6 KPa.	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	
5	Corrosion resistance	4. 5	The corrosion resistance of the cutter shall conform to 5.4 in YY/T0149.	1	2	3	Qualified
				Conform	Conform	Conform	
			The corrosion resistance of the nail seat shall conform to 5.4 in YY/T0149.	1	2	3	Qualified
				Conform	Conform	Conform	
6	Packaging performance	4. 6. 1	Sterile packaging of stapler and suture components shall be intact and free of foreign substances.	1	2	3	Qualified
				Conform	Conform	Conform	
			The sterile package of the stapler and suture components shall not be unsealed or the seal is incomplete.	1	2	3	Qualified
				Conform	Conform	Conform	
			Sterile packaging of the stapler and suture components shall be free of moisture, moisture, or watermarks	1	2	3	Qualified
				Conform	Conform	Conform	
7	Peel strength	4. 6. 2	The peeling strength of the sealing of the stapler and component packaging is 0.1-0.5 (N/mm)	0. 3			Qualified
			Package sealing of stapler and suture assembly Touch the surface to be torn, the light should be smooth, continuous and uniform, without split image layer or tear.	Conform			Qualified
8	Sterile	4. 7	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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照片粘贴处
Photo pasting location

Photo 1 第1幅

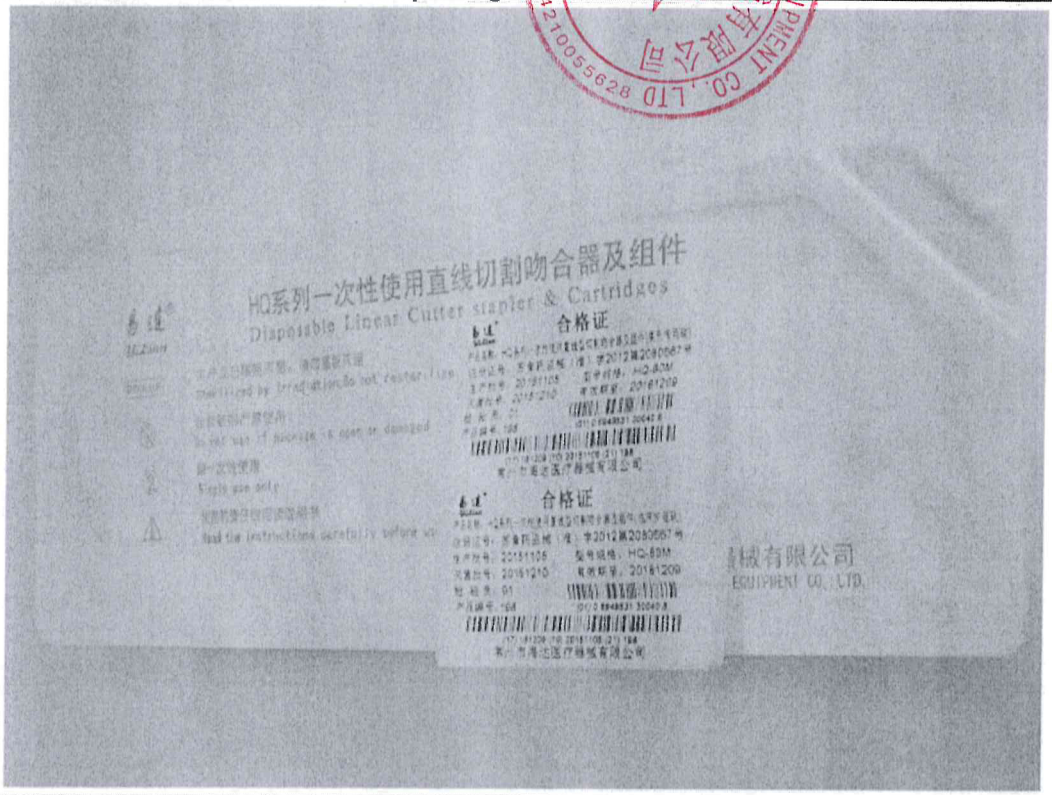


Photo 2 第2幅



照片粘贴处
Photo pasting location

Photo 3 第3幅



Photo 4 第4幅

