MDST

Mechanical Test

Test Report

Report No.: G20160067



Product Name : Disposable Wound Protector/Retractor

Model: HRA-220/230-220/250

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 Devices Original Noise Test 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

Report number： G20160067

Sample name	一次性使用切口牵开固定器 Disposable Wound Protector /Retractor		
Model No.	HRA-220/230-220/250	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	20Pieces	Sample production Date	/
Sample lot/number	20151207		
Inspection basis	Changzhou Haida Medical Equipment Co.,Ltd issued the registered Product standard of "Disposable Wound Protector /Retractor"		
Inspection items	4. 1-4. 5		
Date of inspection	From January 12, 2016 to March 4, 2016		
Inspection conclusion	The Tested items Of the samples Conform to the requirements of the product standard of the main volumee I of the Disposable Wound Protector /Retractor issued by Changzhou Haida Medical Equipment Co.,Ltd		

检验报告专用章

Approval: Audit: Audit:

Title: Engineer

Date： 2016. 03. 08 Date： 2016. 03. 07 Date： 2016. 03. 04

Inspection location	There are four photos in the barrel.			
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			
Declaration on Evaluating Measurement Uncertainty /information	/			
Opinions and interpretations	/			
Sample Pudijie	a) **Structural composition: mainly composed of outer ring, channel, insertion ring, etc** b) **Principle and purpose: Mainly suitable for small incision surgery and minimally invasive surgery to enlarge the incision, prevent incision damage, and reduce incision infection** c) Characteristic parameters: mainly including appearance, size, hardness, performance, corrosion resistance and packaging d) The sample is in good condition.			
Other instructions	/			

Test Result

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Serial number	Test items	Standard terms	Standard requirements				Decision theory
1	Appearance	4.1	The shape of the bindings was smooth, soft and acyclic.	1	2	3	Qualified
				Conform	Conform	Conform	
			Free of burr, flash, scratch and shrinkage	1	2	3	Qualified
				Conform	Conform	Conform	
			The retracting bindings of the cutting plant shall be intact, free of damage and impurities.	I	2	3	Qualified
				Conform	Conform	Conform	
2	Size	4.2	The basic dimensions of the incision retraction bindings shall be in accordance with Figure 1, Figure 2 and Table 1, Dl = (230 ±10.0) mm	1	2	3	Qualified
				230.0	230.0	230.0	
			D2= (220 ±10.0) mm	1	2	3	Qualified
				220.0	220.0	220.0	
			D:3 = (220^{+5}_{-20}) mm	I	2	3	Qualified
				220	220	220	
			L= (250^{+5}_{-20}) mm	1	2	3	Qualified
				250	250	250	
			DL = (6±1.0)	I	2	3	Qualified
				6.0	6.()	6.0	
			D2 = (6±1.0) mm	I	2	3	Qualified
				6.5	6.5	6.4	
			LI= $(12^{+2.5}_{-2.5})$ mm	1	2	3	Qualified
				14.0	I3.5	14.0	
3	Heat intensity	4.3.I	|, IRA type incision pulling bindings channel thermal intensity not less than 0.140N/n plate	0..567			Qualified
4	Performance	4.3	Each used connection of the incision retracting bindings can bear the traction force of more than flon, and does not fall off	I	2	3	Qualified
				Conform	Conform	Conform	
			Incision retraction of bindings of the stomach into the lesion, the lesion is not received outside.	I	2	3	Qualified

Summary of Test Results

检 测 结 果 汇 总

Report No.: G20160067

No.	Test items	Standard terms	Standard requirements	Actual Measurement Results 实测结果			Conclusion Judgment
			Under the action of a radial external force less than 20N, it can undergo elastic deformation and recover elastically after the external force is released	Conform	Conform	Conform	
			The channel of HRB Disposable Wound Protector/Subtractor should be able to smoothly curl or stretch with the elastic deformation or natural recovery of the inserted ring and outer ring	/			Not Applicable
			The channel length of the HRA Disposable Wound Protector/Retractor should be adjustable according to surgical needs, and it should curl and shrink or stretch and elongate with the manual flipping of the outer ring	1	2	3	Qualified
				Conform	Conform	Conform	
5	**Sterile**	4.4	Disposable Wound Protector should be sterilized through the established cobalt-60 irradiation sterilization process, and the product should be sterile	Conform			Qualified
6	Packing	4.5.1	Disposable Wound Protector /Translator sterile packaging should be intact and free of foreign substances	1	2	3	Qualified
				Conform	Conform	Conform	
			Unopened or incompletely sealed	1	2	3	Qualified
				Conform	Conform	Conform	
			No moisture, water or watermarks	1	2	3	Qualified
				Conform	Conform	Conform	
			The two contact surfaces to be torn shall be smooth and continuous without delamination or tearing	1	2	3	Qualified
				Conform	Conform	Conform	
7	Peel strength	4.5.2	The peel strength of the aseptic seal of the bindings should be 0.1N/mm ~ O.4.N/nnn	0.2			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

