20141003295

Mechanical Test Report

(2016) Clas ZC no.1142

Sample name
Product Name: Disposable Trocar

Specification and model
Specifications: HCCK-5-100

Inspection category
Test Category: Test

Entrusting unit
Entrusting Unit: 注册检

Changzhou Haida Medical Equipment Co., Ltd.

Jiangsu Institute for Medical Device Inspection
Jiangsu Province Institute for Medical Equipment Testing

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Sample name	Disposable Trocar Sample delivery (heart) Sampling 0	Sample number	SLZC1612431
Trademark	/	Specification and model	HCCK-5-100
Client	Changzhou Haida Medical Equipment Co., Ltd.	Inspection category	Registration inspection
The mailing address of the Client	Sanhekou Industrial Concentration Zone, Zhenglu Town, Tianning District, Changzhou City, Jiangsu Province	Product number/batch number	20161101
Mark the production unit	Changzhou Haida Medical Equipment Co., Ltd.	Sample sheet number	/
Inspected unit	Changzhou Haida Medical Equipment Co., Ltd.	Date of manufacture	/
Sampling unit	/	Number of samples	25
Sampling location	/	Sampling basis	/
Date of sampling	/	Inspection location	The laboratory of this laboratory
Date of sample receipt	December 5, 2016	Date of inspection	December 28, 2016-February 9, 2017
Inspection items	Part of the project		
Inspection basis	Technical Requirements for Products of Changzhou Haida Medical Instruments Co., Ltd. "Disposable Laparoscopic Puncture Device"		
Inspection conclusion	The requirements specified in the Instrument. Official seal of the inspection unit) February/3		
Remark	1) The "— —" in the report indicates that this item is not applicable, and the "/" in the report indicates that the heart means that the biology is stricter than "LP17" table. 2) The "W" "in the report header indicates physics," 1-I "indicates chemistry, and" S "" Indicate electrical safety "E" means electromagnetic compatibility, "BW" means packaging material physics, "BH" means packaging material chemistry, and "Z" means photo.		

Approved by: Xi Qian

Xuan Che Position: 4 Li Li ik

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Sequential plant JI,	Inspection items	Terms	Request	Inspection results 1#~5#	Single conclusion	Remark
I	Appearance	2.1.1	The surface of the puncture outfit shall be flat and smooth, free of burrs and edges, and free of pores, cracks and furrows that can be identified by naked eyes.	Meet the requirements	Conform	/
2	Roughness	2.1.2	Surface roughness of puncture rod assembly Ra 0.8 un。	<0.8μm	[illegible]	/
3	Size	2.2	L2: 184mm± 5.0mm	183.5mm ~184.0mm	Conform	/
			LI: I 00mm soil 2.0mm	101.5mm ~102.0mm	Conform	/
			Casing inner diameter: cJ) 5.8 mm	5.87mm~5.90mm	[illegible]	/
4	Flexibility	2.3.1	The vent valve and choke valve of the puncture outfit shall be opened and closed flexibly, and shall not be blocked or jammed.	Meet the requirements	[illegible]	/
5	Fit performance	2.3.2	The fit between the cannula of the puncture outfit and the puncture should be good, and there should be no clamping stagnation when moving.	Meet the requirements	Conform	/
6		2.3.3	The maximum fit clearance between the cannula of the puncture outfit and the puncture rod is not more than 0.3mm.	0.02mm~0.04mm	Conform	/
7		2.3.4	When the cannula of the puncture device is matched with the puncture cone, the puncture head must be completely released.	Meet the requirements	[illegible]	/
8	Tightness and gas barrier	2.4.1	The vent valve of the puncture outfit shall be well sealed, and there shall be no obvious leakage when the air pressure is 4kPa.	Meet the requirements	Conform	/
9		2.4.2	The choke valve of the puncture outfit shall have good choking performance. When the air pressure is 4kPa, the number of bubbles emitted shall be 20.	0 ~]	[illegible]	/
10	Packaging performance	2.5.1	The koji-free package shall be intact and free of foreign substances; No opening or incomplete sealing; No moisture, moisture, or watermarks.	Meet the requirements	Conform	/

Sampling plan: n = S [Ac = O, Re=l]

Preface , '	Inspection items	Terms	Request	Inspection results	Single conclusion	Remark
11	Packaging performance	2.5.2	The peel strength of the seal of the puncture outfit is O.IN/mm~0.5 N/111111。 The two contact surfaces to be torn shall be smooth, continuous and uniform, without delamination or tearing.	0.22N/mm ~0.27N/mm Meet the requirements	Conform	/

Inspection: Five leaves Audit: Cen Xuan

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Preface	Inspection items	Terms	Request	Inspection results	Single conclusion	Remark
Benevolent Beggar I	Residual residue of epoxy ethyl Kang	2.6.2	The residual olives in epoxy B shall not be more than 10 μgig.	＜0.1 μ g/g	Paying ': A port	/

检 验： 审 核：

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Serial number	Inspection items	Terms	Technical requirements	Inspection results	Single conclusion	Remark
1	Sterile	2.6.1	The final package of the puncture outfit shall be sterilized by ethylene oxide.	Aseptic growth	Ren Liu Pian R4 mooh	/
The following is blank						

检 验：

审 核：

Photo Page of Inspection Report of Jiangsu Institute for Medical Device Inspection

Photos and captions



Product name: Disposable Trocar

outfit Model and specification: HCCl-5-100

Production batch number: 2016 1101 20161103

Company Name: Changzhou Haida Medical Equipment Co., Ltd.

Address: Sanhekou Industrial Zone, Zhenglu Town, Tianning District, Changzhou City

Sample description

Model, specification or other description

The product model and specification is HCCK-5-100.