CMA

2014100329$

Mechanical Test Report

(2016) QW No. 1026

Sample name
Product Name: Disposable Trocar

Specification and model
Specifications: HCCK-5-100

Inspection category
Test Category: 委托检验

Entrusting unit
Entrusting Unit: Changzhou Haida Medical Equipment Co., Ltd.

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

Inspection Report of Jiangsu Institute for Medical Device Inspection Home

Report No.: 2016 QW10268

Sample name	Disposable Trocar Sample delivery (✓) Sampling ()	Sample number	SLQW1612051
Trademark	/	Specification and model	I-ICCK-5-100
Client	Changzhou Haida Medical Equipment Co., Ltd.	Inspection category	Commissioned 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-March 20, 2017
Inspection items	2.7.1 Cytotoxicity, 2.7.2 Delayed hypersensitivity, 2.7.3 Intradermal irritation		
Inspection basis	Technical Requirements for Products of Changzhou Haida Medical Instruments Co., Ltd. "Disposable Trocar "		
Inspection conclusion	The requirements specified in the Instrument. （检验报告专用章或检验单位公章） 签发日期 2017 年 3 月 20 日		
Remark	L) ""- "in the report indicates that this item is not applicable, and"/ "in the report indicates that this item is blank. Dou 2) "W" in the report header indicates physics, "+ [" indicates chemistry, "S" indicates biology, and "D" "E" means electromagnetic compatibility, "BW" means packaging material physics, "BI-I" means packaging material chemistry, and "Z" means photo.		

Approved: 何云平

Title: 副所长

Jiangsu Institute for Medical Device Inspection

Inspection Report

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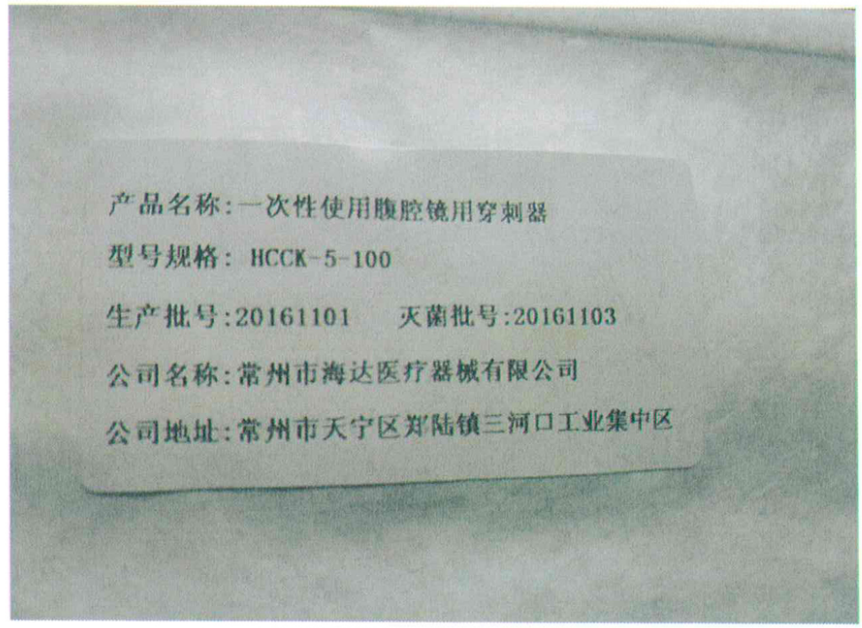
Preface	Inspection items	Terms	Request	Inspection results	Single conclusion	Remark
1	The cells are high	2.7.1	The cell height of the puncture outfit should be less than 1 grade.	MTT method: Grade 1	Conform	/
2	Delayed percussion hypersensitivity	2.7.2	Puncture device delayed onset just hypersensitivity (sensitization) should not be grade 1.	No delayed onset hypersensitivity	Conform	/
3	Intracutaneous stimulation	2.7.3	The puncture outfit shall be free of intradermal irritation.	No intradermal irritation	Conform	/
The following is blank						

Inspection: 金楼 Coin core: 王静贤

Photo page of inspection report

Photos and captions





Sample description

/

Model, specification or other description

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