Scan code verification report

Mechanical Test Report

Report No.: AH2021-QSJ-00595.

Inspection name: Disposable circumcision stapler

Inspection purpose: Commissioned inspection

Anhui Food (Tangerine) Gutuo Citation and Test Research

Explain

I. It is invalid to alter, add, delete or fail to affix the special seal for inspection report of our Institute on the first page of the inside page and the seam.

2. It is invalid to duplicate the inspection report without affixing the special seal for inspection report of our hospital.

III. The data and conclusions issued in this inspection report are the inspection results of the inspected items of the supplied samples.

IV. If there is any objection to this inspection report, please submit it in writing within the time limit specified in the relevant national documents from the date of receipt of the report, and it will not be accepted if it is overdue (unless otherwise specified).

V. Without the written consent of our hospital, this inspection report shall not be publicized by advertising, otherwise the consequences will be borne by ourselves.

Contact information

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Food Inspection Office Address: No.13, Yan'an Road,

Hefei City Tel: 0551-63356518

Re-examination and complaint telephone: 0551-63710067 website:**www.ahifdc.org.cn**

Inspection Report of Anhui Institute for Food and Drug Inspection Home

Report No.: AH2021-QSJ-00595.

Sample name: Disposable circumcision stapler — Sample No. I AH2021-QSJ-00595.

Sample delivery () Sampling ( )

Business Client: Mark 1 Yi Lian Changzhou Haida Medical Equipment Co., Ltd. Inspection Category: Commissioned inspection

Address of the entrusting party 1 Sanhekou Industrial Concentration Zone, Zhenglu Town, Tianning District, Changzhou City

Item number I is 20210120. /Batch number

Manufacturer: Changzhou Haida Medical Equipment Co., Ltd.

Sample sheet No. II

Inspected unit: Changzhou Haida Medical Equipment Co., Ltd.

Production date I 2021.07.20

Sampling unit:/

Number of samples I 30

Sampling basis/

Date of sampling/

Inspection locationAnhui Institute of Food and Drug Inspection

Date of sample receipt I 2021/09/14

Date of inspection **2021/09/14~2021/12/15**

Inspection items **2. 1-2.8**

Inspection basis: Technical requirements for disposable circumcision stapler of Changzhou Haida Medical Equipment Co., Ltd.

Inspection conclusion: Ji Changzhou Haida Medical Equipment Co., Ltd. "Disposable Prepuce Heart Deflection" 刀割吻合器"产品...

...章或检验单位公章)

2021/12/15

Rema: The technical requirements of this product do not involve/partially involve national standards and industry standards, and cannot be directly used as the basis for qualification recognition and licensing, but the laboratory has the corresponding inspection capacity for the inspection items involved in the report. In the report, "--" means not applicable, and "I" "means blank.

Core: Ding Wei Lord Inspection: For Bao Zhao

Title: Authorized Signatory

Anhui Institute of Food and Drug Inspection
Inspection report

Serial number	Inspection items		Standard terms	Standard requirements		Inspection results	Single conclusion
1	Appearance		2.1.1	The stapler shall be smooth in appearance, clear in outline, and free of defects such as burrs, sharp edges, scratches, and cracks.		Meet the requirements	
			2.1.2	The surface of the anastomotic nail shall be smooth and free of defects such as burrs and dents.		Meet the requirements	
			2 1.3	The surface of the stapler band shall be smooth and free of defects such as burrs and sharp edges.		Meet the requirements	
			2.1.4	Surface roughness of the exposed metal nail seat of the stapler: Ra O8μm		Meet the requirements	
2	Auxiliary piece Zi Yan Performance	Turbidity and color	2.2 1	The test solution shall be colorless and transparent.		Meet the requirements	
		PH value	2.2.2	The difference between the pH values of the test solution and the blank control solution of the same batch shall not exceed 20		0.6	
		Total heavy metals ^Gu Yu "" Li	2.2.3	The total content of heavy metals in the test solution shall not exceed 5 μg/mL		Meet the requirements	
		Reducing substance	2.2.4	Potassium permanganate solution consumed by test solution and blank solution [C (KMn04) = 0.002mol/L] The difference between the volumes of the does not exceed 2.0 mL		0.2mL	
		Evaporation residue	2.2.5	The total amount of evaporation residue shall not exceed 2.0 mg. (50mL of test solution)		0.2mg	
3	Basic dimensions		2.3	Model and specification: HBQ-15	Height (CH): 3.0mm, tolerance: 0.5mm	2.9mm	
					D1 (outer diameter of ring knife): medium 15mm, Allowable soil 1.0mm	15.4mm	
					Auxiliary piece D3: 204 mm, tolerance: 2.0 pieces n	20.0mm~20.5mm	
					Number of nails (PCs): 11	11	
4	Hardness		2.4	The hardness of the ring knife of the stapler shall not be lower than 377HV0.2.		530HV0.2~537HV0.2	
5	Performance		2.5.1	The merging and unfolding of the stapler handle shall move smoothly without block.		Meet the requirements	
			2 5.2	When the glans base assembly is inserted into the stapler and connected with the hand wheel assembly, the hand wheel assembly shall rotate clockwise smoothly without blocking and can be connected with the nail seat assembly smoothly.		Meet the requirements	

Anhui Institute of Food and Drug Inspection
Inspection report

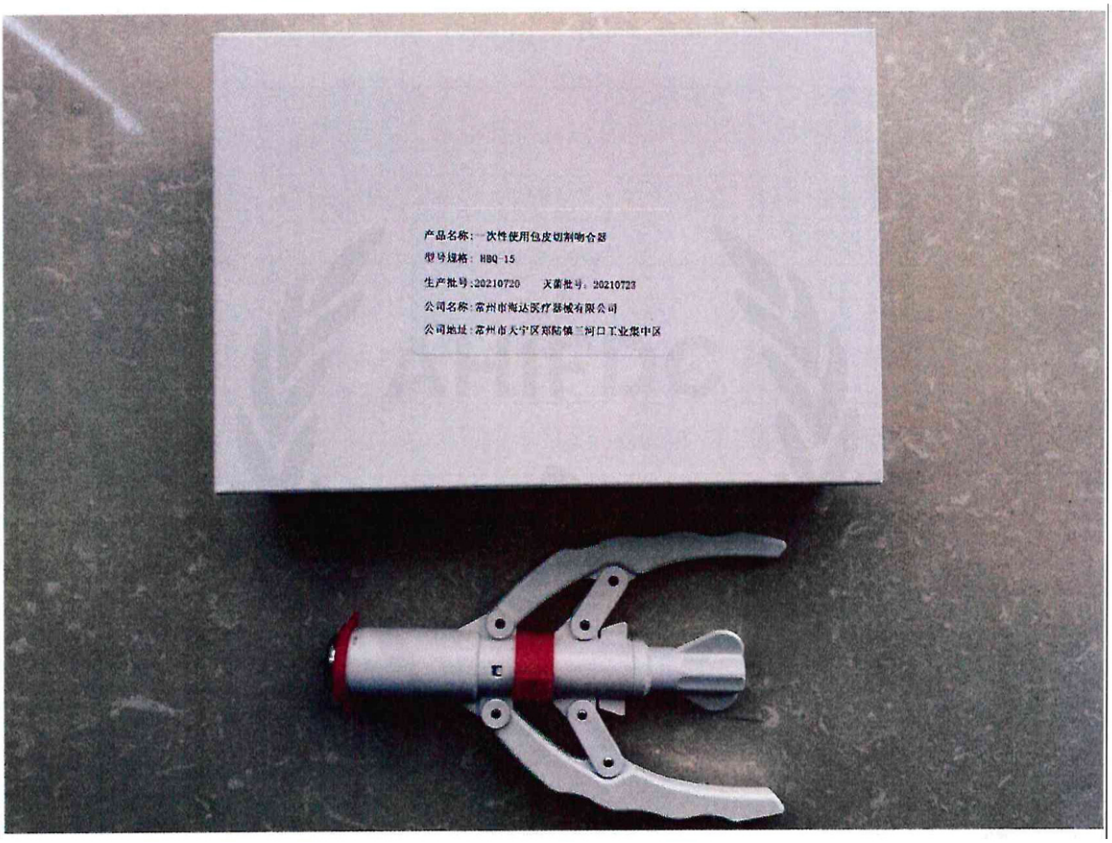
Preface	Inspection items	Standard terms	Standard requirements	Inspection results	Single conclusion
A deficit		2.5.3	The safety ring of the stapler shall be clamped into the outer sleeve groove with proper tightness without falling off.	Meet the requirements	1 Six-inch Place Shake
5	Performance	2.5.4	The stapler should have good suturing and cutting performance, and be stapled after anastomosis. "⊂⊃" shape, the ring knife shall not have a rolling blade or a chipping blade, and the cut edge shall be neat.	Meet the requirements	P Six-inch K magnet
		2.5.5	No burrs The binding head of the anastomat accessory can smoothly pass through the binding hole and can be locked without falling off.	Meet the requirements	Pa Liu Zuo Kou fa
		2.5.6	After the stapler was sutured, the two ends of the formed staple were subjected to 3 N tension and maintained for 3 s without distortion.	Meet the requirements	1 Six inches, six people
6	Corrosion resistance	26	The ring knife, suture nail and nail seat shall have good corrosion resistance, and the surface condition after the test shall conform to YY/T0149-2006 "Test Method for Corrosivity of Stainless Steel Medical Devices, Class 5.4b	Annular knife: Grade a suture nail: Grade a nail seat: Grade a meets the requirements	One meaning six inch tablet
		2.7.1	The stapler and accessories shall be aseptically packaged in good condition, and there shall be no passage or perforation in the adhesive sealing area.		Six inches, six tablets
7	Packaging performance	2.7.2	The peel strength of the blister seal of the stapler and accessories is 0.1 ~ 0.5 (N/mm). The two contact surfaces to be torn shall be smooth and continuous without delamination or tearing	0.3N/mm Meet the requirements	Six inches six today.
8	Sterile and epoxy B burning residue	2.8 1 2.8.2	The final package of the stapler shall be sterile after ethylene oxide burn sterilization. After the final package of the stapler is sterilized by epoxy ethane, the residual amount of epoxy ethane shall not exceed 10 μg/G.	Meet the requirements 5 μ g/g	4 Six-inch tablet, 4 mouth Six 1 inch tablet mouth 4

Note:/

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Anhui Institute of Food and Drug Inspection
Photo page of inspection report

Photos and captions



Sample description

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Model, specification or other description

HBQ-15

Anhui Institute of Food and Drug Inspection
Comments on pre-evaluation of technical requirements for medical devices

1. Integrity and applicability of performance indicators in product technical requirements; Whether the inspection method is operable and repeatable, and whether it is compatible with the inspection requirements.

1. The performance index has integrity and adaptability;
2. The inspection method is operable and repeatable;
3. The inspection method shall be compatible with the inspection requirements.

2. The integrity of the mandatory national standards and industry standards used, the suitability of the standards and products used, and the applicability of the provisions used in accordance with the current mandatory or recommended national standards and industry standards.

The GB/T6682-2008 Specification and Test Methods for Water Used in Analytical Laboratories and GB/14233. 1-2008 are cited in the technical requirements of the product

Test Methods for Infusion, Transfusion and Injection Devices for Medical Use-Part 1: Chemical Analysis Methods, GB/T 4340.1-2009 Metallic Materials-Vickers Hardness Test-Part 1: Test Methods, YY/T 0149-2006 Test Methods for Corrosion Resistance of Stainless Steel Medical Devices, YY0876-2013 Linear Cutting Stapler and Components, YY/T0245-2008 General Technical Conditions for Staplers:

1. The suitability of the standards used;
2. The terms used are applicable.

3. If the inspection content involves the quotation of the relevant contents of the Chinese Pharmacopoeia, the completeness, suitability and applicability of the quotation. The standard method of sterility test in Chinese Pharmacopoeia (Volume IV, 2020 Edition) is quoted, which is complete and applicable.

4. Other issues that need to be explained.

None

V. Comprehensive evaluation opinions:

After the pre-evaluation, there is no supplementary or improvement opinion on the technical requirements of the product.

According to the oral pre-evaluation, the product technical requirements need to be further supplemented and completed in the following aspects:

（印章）

年 月 日