

# Jiangsu Medical Device Inspection Institute

## Inspection report home page

Report number:2016ZC3167

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Sample name	Acupuncture needle		Sample number	2016ZC3167
	Sample delivery( )	Sampling( )		
Trademark	/		Model specification	0.25*40mm
Principal	Suzhou Hualun Medical Appliance Co.,Ltd		identify category	Registration inspection
Principal's mailing address	Shengtian Economic Zone,Huangqiao Town,xiangcheng District,Jiangsu,China.		Product number	160501
Label production unit	Suzhou Hualun Medical Appliance Co.,Ltd		Sample number	/
Unit under inspection	Suzhou Hualun Medical Appliance Co.,Ltd		Production Date	/
Sampling unit	/		Number of samples	1box
Sampling location	/		Sampling base	/
Sampling date	/		Inspection location	Our laboratory
Date Received	June 8, 2016		Inspection date	June 16 to July 25, 2016
Test items	Full project			
Basis of inspection	Product technical requirements of Suzhou Hualun Medical Appliance Co.,Ltd "Acupuncture needle"			
Test results	The sample to be inspected meets the requirements of the technical requirements of Suzhou Hualun Medical Products Co., Ltd.			
Remarks	<p>1) The "_____" in the report indicates that this item does not apply, and the "/" item in the report is blank.</p> <p>2) The "W" in the header of the report indicates physics, "H" for chemistry, "S" for creatures, and "Z" for photos.</p>			

Approve:

Position:

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Serial number	Technical terms	Test items	skills requirement	skills requirement	Single conclusion	Remark
				1#~5#		
1	2.2	basic size	D:0.25mm±0.015mm I:40mm±0.80mm L:75mm±1.50mm	0.247~0.249mm 39.71~39.84mm 73.98~74.70mm	conform	/
2	2.4	Needle hardness	≥460HV0.2kg	638HV0.2kg~ 662 HV0.2kg	conform	/
3	2.5	Tip sharpness	The tip of the needle should be round, unbiased, burr-free, hook and other shortcomings. After the tip of the needle is pressed by the top pressure of 0.4N and the hard block is pressed, the puncture force should be ≤0.7N.	0.481N~0.545N	conform	/
4	2.6	Needle toughness	The needle body of the acupuncture needle should have good toughness, and there should be no cracks, breaks and delamination after the winding test.	Meet the requirements	conform	/
5	2.7	Surface roughness	The surface of the needle body should be smooth, and there should be no obvious defects such as scars, traces and silk lines. The surface roughness Ra value is ≤0.63 μ m.	Meet the requirements < 0.63 u m	conform	/
6	2.8	Connection fastness	The connection between the needle body and the needle handle should be firm, and the pull test should be carried out under the force value of 9N. The axial displacement of the two should not exceed 3mm.	0~0.2mm	conform	/
7	2.9	Needle handle winding wire	The needle handle spiral ring should be evenly arranged without obvious separation	Meet the requirements	conform	/
8	2.10	Handle burr	The handle of the acupuncture needle must not have burrs.	Meet the requirements	conform	/
9	2.12	Curvature	The acupuncture needle should be straight and must not have obvious curvature.	Meet the requirements	conform	/
10	2.13	Handle color	The surface of the handle of the acupuncture needle should be uniform in color. If the handle is silver-plated, the coating should be silver-white and there should be no delamination.	Meet the requirements	conform	/
11	2.14	Corrosion resistance	The needle body should have good corrosion resistance.	Meet the requirements	conform	/

Examine \_\_\_\_\_

Review \_\_\_\_\_

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Page H1

Serial number	Test items	Terms	Requirement	test result	Single conclusion	Remark
1	Ethylene oxide residue	2.15	The residual amount of ethylene oxide should be no more than 10 µg/g.	5.9µg/g.	Conform	/

Examine\_\_\_\_\_

Review\_\_\_\_\_

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Page S1

Serial number	Test items	Terms	Requirement	test result	Single conclusion	Remark
1	Sterile	2.14	Sterilized acupuncture needles should be sterile	No bacteria	conform	/
Following blank						

Examine\_\_\_\_\_

Review\_\_\_\_\_



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## Inspection report photo page

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### Photos and descriptions



### Sample discription

Model specifications or other instructions

Product model specification is 0.25\*40mm