

Shenzhen Jolly Technology CO.,LTD

Testing report

Sample Name : Disposable AED pad

Sample No. : JY - 20240125J 01 sample batch number : 20240112501

Production unit: Shenzhen Jolly Technology Co.,Ltd

Requesting unit: Shenzhen Jolly Technology Co.,Ltd
- Development Department

Testing purpose: Verify sample performance meets requirements

Sample delivery time: 2024-01-18

Completion time: 2024-01-25

Test results				
serial number	Test items	judgement standard	quantity	determination
1	structure appearance	The appearance is good, and there is no looseness in the electrode connection;	2PCS	PASS
2	dielectric strength	No breakdown or arc flash	2PCS	PASS
3	Contact resistance	The impedance of the 10Hz signal should not exceed 3kΩ, 30kH2 The impedance should be less than 10Ω;	2PCS	PASS
4	defibrillation test	The temperature rise does not exceed 15°C	2PCS	PASS
5	Stay sticky	Fitting time>30s	2PCS	PASS
6	Defibrillation electrodes and cables	The fixed end of the cable is not loose or damaged, and each conductor The wire should not have 10% of the total core wires broken;	2PCS	PASS

Chief Inspector: 

批准:

1.Appearance and structure inspection

1.1 Testing equipment	Visually	
1.2 Detection environment	Laboratory temperature: 26.8 °C, humidity: 43%	
1.3 Testing standards	The appearance is good, and there is no loose connection between the electrode pads and cables;	
1.4 Detection methods	In normal temperature environment, visually inspect the appearance and structure of the product . The product should meet the requirements.	
1.5 Number of tests	2PCS	
1.6 Test data		
serial number	Test Results	determination
1#	Appearance is good, cable connections are not loose	PASS
2#	Appearance is good, cable connections are not loose	PASS
1.7 Test conclusion: The appearance and structure are good and the test is qualified.		
1.8 Test pictures		
Sample Pictures		





2. Dielectric strength

2.1 Testing equipment	Pressure tester				
2.2 Detection environment	Laboratory temperature: 26.8 °C, humidity: 43%				
2.3 Testing standards	No breakdown or arc flash				
2.4 Detection methods	Use a metal foil about 100mm long to wrap the cable sheath, use a tester to apply a test voltage between the core wire and the metal foil, increase the voltage to DC5000V at a constant speed within 10 seconds, and then maintain the test. 1min. During the test, monitor the leakage current between the core wire and the metal coating. If it is <0.25mA, the insulation is confirmed. Impedance exceeds 500MΩ				
2.5 Number of tests	2PCS				
2.6 Test data					
serial number	Test voltage(V)	Test time(s)	Leakage current (mA)	Test Results	determination
1#	DC5000	60	0.0	No breakdown or arc flash	PASS
2#	DC5000	60	0.0	No breakdown or arc flash	PASS
2.7 Test conclusion: There was no arc flash breakdown during the test, the leakage current was 0.0 mA , and the test was qualified;					
2.8 Test pictures					
Picture after test					



3. Contact resistance

3.1 Testing equipment	Electrode electrical performance tester, impedance tester			
3.2 Detection environment	Laboratory temperature: 26.8 °C, humidity: 43%			
3.3 Testing standards	No breakdown or arc flash			
3.4 Detection methods	Connect the electrodes in a glue-to-glue manner. When a current of no more than 100μA peak-to-peak flows, the impedance corresponding to the 10Hz signal should not exceed 3kΩ, and the impedance corresponding to 30kHz should be less than 10Ω. Repeat the test at 30kHz			
3.5 Number of tests	2PCS			
3.6 Test data				
serial number	10 Hz AC impedance (Ω)	30 kHz AC impedance (Ω)	Test Results	determination
1#	4	0.59	Impedance is within standard range	PASS
2#	5	0.73	Impedance is within standard range	PASS
3.7 Test conclusion: The AC impedance of 10 Hz and 30 kHz is within the standard range, and the test is qualified;				
3.8 Test pictures				

10 Hz AC impedance test pictures	30 kHz AC impedance test pictures
 <p>A photograph of a white medical device with a digital display showing '0004'. It is connected to two electrode pads with a human diagram on them. The device has a handwritten number '138' on its side.</p>	 <p>A photograph of a grey medical device with multiple digital displays showing '585', '186', and '700 有点用'. It is connected to two electrode pads with a human diagram on them.</p>

4. Defibrillation test





4.1 Testing equipment	LIFEPAAK 20 defibrillator/monitor, FLUKE defibrillation pacing analyzer, AM 801					
4.2 Detection environment	Laboratory temperature: 26.8 °C, humidity: 43%					
4.3 Testing standards	After 15 consecutive 360J defibrillation energy discharges, the temperature rise does not exceed 15°C					
4.4 Detection methods	<p>1. Turn on the FLUKE defibrillation pacing analyzer and adjust it to the defibrillation mode.</p> <p>2. Attach the defibrillation electrode pads to the surface of the steel plate, and use a wire clip to connect the steel plate to the FLUKE defibrillation pacing analyzer. Connect, the electrode pad plug is connected to the LIFEPAAK 20 defibrillation/monitor interface.</p> <p>3. Turn on the LIFEPAAK 20 defibrillator/monitor, press the "Analyze" button in AED mode, and the defibrillator will automatically Automatically analyze whether defibrillation is progressing normally and operate according to the prompts.</p>					
4.5 Number of tests	2PCS					
4.6 Test data						
serial number	The first discharge energy (j)	The 15th discharge energy (j)	Initial temperature(°C)	Temperature after the 15th discharge (°C)	determination	

1#	354.4	352.6	27.0	27.2	PASS
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2#	356.6	353.1	27.0	27.2	PASS
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4.7 Test conclusion: After 15 times of discharge using 360J energy, the temperature rise is 0.2°C, and the test is qualified;

4.8 Test pictures

Test layout diagram	Initial temperature and first discharge energy test pictures
	
Temperature and 15th discharge energy test pictures after test	
	

5. Stay sticky

5.1 Testing equipment	Weights, stopwatch			
5.2 Detection environment	Laboratory temperature: 26.8 °C, humidity: 43%			
5.3 Testing standards	The time for the electrode pad to completely separate from the rigid plate should be >30s			
5.4 Detection methods	With the steel plate perpendicular to the ground, stick the electrode sheet on the steel plate, lift a weight of 1kg, and observe The time for the electrode piece to separate from the test plate			
5.5 Detection quantity	2PCS			
5.6 Test data				
serial number	Lifting weight (kg)	Test time(s)	Test Results	determination
1#	1	31	After lifting for 31 seconds, the sample did not detach.	PASS

2#	1	31	After lifting for 31 seconds, the sample did not detach.	PASS
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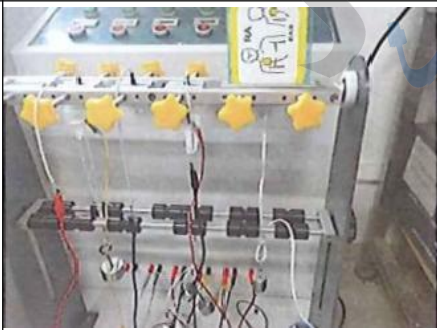

5.7 Test conclusion: After lifting a 1kg weight for 31 seconds, the electrode pad sticking position is not loose, and the test is qualified.

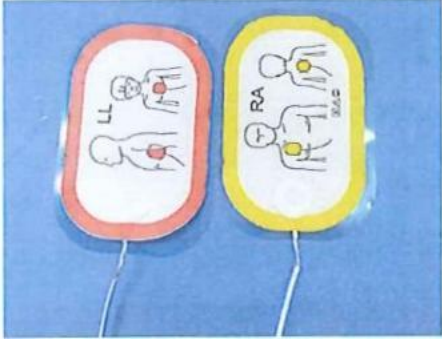
5.8 Test pictures

Pictures under test



6. Defibrillation electrodes and cables

6.1 Testing equipment	Bending testing machine			
6.2 Detection environment	Laboratory temperature: 26.8 °C, humidity: 43%			
6.3 Testing standards	There should be no looseness or damage at the fixed end of the cable. Each conductor should not have 10% of the total core wires broken.			
6.4 Detection methods	Use a bending testing machine to test, the bending angle is 2×45°, 30 times/min, hang a weight at least 300mm from the bending position, where the weight is the weight of the product (the product is about 62g, the lifting weight is 100g), number of bends is 100 times; during the test, after bending 50 times, rotate the cable 90°C at the same bending point, and then Bending 50 times;			
6.5 Number of tests	2PCS			
6.6 Test data				
serial number	Lifting weight (g)	Number of bends (s)	Test Results	determination
1#	100	100	Good structural appearance	PASS
2#	100	100	Good structural appearance	PASS
6.7 Test conclusion: After bending 100 times, the structural appearance is good, and the internal core copper wire has no breakage, and the test is qualified.				
6.8 Test pictures				
Pictures under test			Number of trials	
				
Disassembled view of bending position				



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