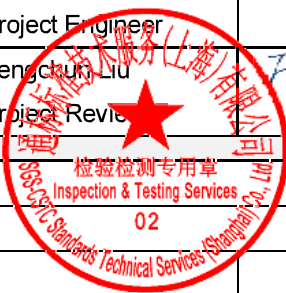


IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No. :	SHES190501629601
Date of issue :	2020-06-02
Total number of pages..... :	118 pages
Testing Laboratory :	SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.
Address..... :	No. 588 West Jindu Rd, Xinqiao Town, Songjiang District 201612 Shanghai CHINA
Applicant's name..... :	Nanjing Pua Medical Equipment Co., Ltd.
Address..... :	No. 9, Gaoke 1st Road, National Hi-Tech Zone, Nanjing, Jiangsu, China
Test specification:	
Standard..... :	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure..... :	Type test
Non-standard test method..... :	N/A
Test Report Form No. :	IEC60601_1K
Test Report Form Originator	UL(US)
Master TRF..... :	2015-11
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General disclaimer:	
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Test item description	Medical Ventilator
Trade Mark	/
Manufacturer	Nanjing Pua Medical Equipment Co., Ltd. No. 9, Gaoke 1st Road, National Hi-Tech Zone, Nanjing, Jiangsu, China
Model/Type reference	PA-500, PA-700B, PA-900B
Ratings	For PA-500 Input: 100-240 VAC, 50/60 Hz, 45VA For PA-700B & PA-900B Input: 100-240 VAC, 50/60 Hz, 80VA

	Internally battery: Two rechargeable sealed lead acid battery modules, 11.1VDC, 6.6Ah
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Testing procedure and testing location:	
<input checked="" type="checkbox"/>	Testing Laboratory: SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.
Testing location/ address : No. 588 West Jindu Rd, Xinqiao Town, Songjiang District 201612 Shanghai CHINA	
<input type="checkbox"/>	Associated Testing Laboratory:
Testing location/ address :	
Tested by (name, function, signature) : Cherry Wu <i>Cherry Wu</i> Project Engineer	
Approved by (name, function, signature) .. : Fengchun Liu <i>Fengchun Liu</i> Project Review	
	
<input type="checkbox"/>	Testing procedure: CTF Stage 1:
Testing location/ address :	
Tested by (name, function, signature) :	
Approved by (name, function, signature) .. :	
<input type="checkbox"/>	Testing procedure: CTF Stage 2:
Testing location/ address :	
Tested by (name, function, signature) :	
Witnessed by (name, function, signature) .. :	
Approved by (name, function, signature) .. :	
<input type="checkbox"/>	Testing procedure: CTF Stage 3:
<input type="checkbox"/>	Testing procedure: CTF Stage 4:
Testing location/ address :	
Tested by (name, function, signature) :	
Witnessed by (name, function, signature) .. :	
Approved by (name, function, signature) .. :	
Supervised by (name, function, signature) :	

List of Attachments (including a total number of pages in each attachment):	
<p>IEC 60601-1-8:2006+A1:2012 test report, 23 pages ISO 80601-2-12:2011 test report, 48 pages Attachment 1: Technical documentations, 10 pages Attachment 2: Photo documentations, 11 pages</p>	
Summary of testing	
<p>All tests have been passed with positive results. The submitted sample complied with applicable requirements specified in this standard.</p>	
Tests performed (name of test and test clause):	Testing location:
<p>All applicable test items as described in this report were carried out:</p> <ul style="list-style-type: none"> - 4.11 Power input - 5.7 Humidity preconditioning treatment - 5.9.2 Determination of accessible parts - 7.1.2 Legibility of markings - 7.1.3 Durability of markings - 8.4.3 Voltage or charge limitation - 8.6.4a Earthing and potential equalization test - 8.7 Leakage currents and patient auxiliary currents - 8.8.3 Dielectric strength - 8.8.4 Ball pressure test - 8.9.4 Creepage distances and air clearances - 9.4.2 Stability and transportability - 9.4.3 Instability from unwanted lateral movement - 9.6.2.1 Audible acoustic energy measurement - 9.8.2 Tensile safety factor - 11.1 Excessive temperature in ME equipment - 11.6 Overflow, spillage, leakage, cleaning, sterilization and disinfection - 11.8 Interruption of power supply - 13 Hazardous situations and fault conditions - 15.3 Enclosure mechanical strength 	<p>SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. No. 588 West Jindu Rd, Xinqiao Town, Songjiang District 201612 Shanghai CHINA</p>
Summary of compliance with National Differences	
<p>The product fulfils the requirements of EN 60601-1:2006/A1:2013</p>	