



PA 700B Medical Ventilator



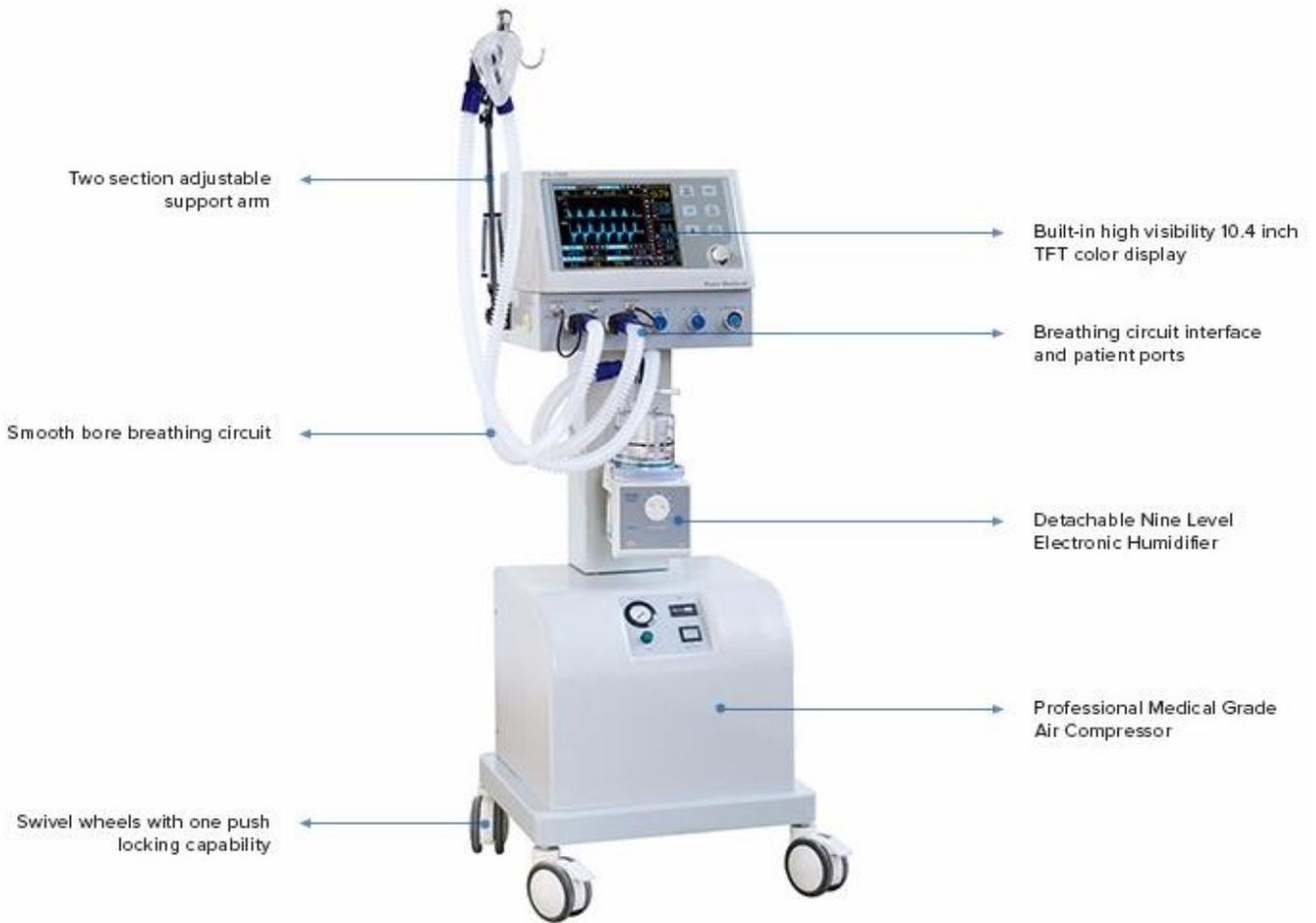
PUAO MEDICAL

Anesthesia Machine
Patient Monitor
Ventilator

Overview

Quick Details

Brand Name:	PUAO	Model Number:	PA-700B with air compressor
Place of Origin:	Jiangsu, China	Instrument classifi...	Class III
Ventilation Mode:	A/C, IPPV, SIPPV, IMV, SIMV, Standby, SPONT MANUAL	Respiratory Rate:	1-99bpm
I:E:	4:1-1:4	Display:	10.4 inch high visibility color TFT display
Tidal Volume:	Adjustable range: 50-1500ml, Display range: 0-2000ml	PEEP:	0-20cmH2O
SIMV Rate:	1-20bpm	Adjustable Oxygen ...	1. 21-100% 2. With air compressor
Inspiratory Pressur...	-10-10cmH2O	nspiratory Plateau:	Adjustable from 0-50% of inspiratory time
Type:	Anesthesia Equipments & Accessories		



PA 700B DESIGN FEATURES

Annotated Features Diagram For PA 700B Advanced Medical Ventilators



PA 700B ACCESSORIES

Featured Accessories For PA 700B Medical ICU Ventilators



Air Compressor



PSH-1 Humidifier



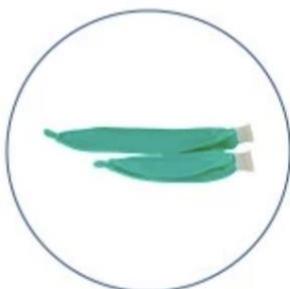
Breathing Circuit
Tubes



Disposable Breathing
Circuit Tubes



Breathing Mask



Breathing Bag



Color Coded Gas
Connecting Tubes



Oxygen Regulator



Infrared Sensor



Two Section Support
Arm



Battery



Power Cord

PA-700B Ventilator Technical Parameters

Features

- General-purpose, multi-mode, multi-function, pneumatic and electronically controlled ventilator, which can be used for clinical respiratory first aid and respiratory therapy.
- It has various breathing modes such as control, assist / control, command ventilation, manual, and breathing functions such as peep and sigh. It is a necessary breathing equipment for hospitals.
- Blister molding, modular, environmentally friendly rack, precise structure, exquisite model design.



Parameters

- Display Mode: 10.4-inch bright color LCD display, two real-time waveforms displayed on the same screen.
- Air source requirements: medical oxygen source and compressed air source of 280 ~ 600 kPa.
- Ventilation mode: SIMPPV, IPPV, SIMV, IMV, Manual and other modes.
- Tidal volume: 50 ~ 1500mL adjustable, step size: 10mL, display range: 0 ~ 2000mL, resolution: 10mL.
- Compliance: Real-time display.
- Minute ventilation: ≥ 18 L / Min.

- Oxygen concentration of output gas: 21% ~ 100% adjustable.
- Pressure limit: 1.0 kPa ~ 6.0 kPa.
- Respiratory frequency: 1 bpm ~ 99 bpm.
- Intermittent command frequency: 1 bpm ~ 20 bpm.
- Breathing ratio: 4: 1,3: 1,2: 1,1: 1,1: 1.5,1: 2.0,1: 2.5,1: 3.0,1: 4.0.
- Maximum safe pressure: ≤ 6.0 kPa.
- Trigger mode: pressure trigger.
- Control method: pressure control.
- Inspiratory triggering pressure: -1.0 kPa ~ 1.0 kPa adjustable, step value 0.1 kPa.
- Positive end-expiratory pressure: 0 kPa ~ 1.0 kPa.
- Sigh: Adjustable 1 ~ 8 times per 100 breathing cycles, with ventilation not less than 1.5 times the tidal volume.
- Inhalation platform time: 0 ~ 50% adjustable, step size is 5%.
- Controlled breathing and assisted breathing switching time: 6 seconds.
- Waveform display: pt, ft.
- Knob and shuttle parameter settings are fast and convenient.
- Using dual infrared, rotary, high-precision pressure sensors and flow sensors.
- Monitoring parameters: tidal volume, frequency, airway pressure, inspiratory ratio, inspiratory oxygen concentration, inspiratory and expiratory status, inspiratory trigger status, etc.
- Alarm function: with audible and visual alarm, ventilation limit alarm, tidal volume limit alarm, airway pressure limit alarm, low oxygen supply alarm, power failure alarm, etc.
- Tidal volume alarm setting: The upper limit alarm setting range is 10 ~ 2000mL, and the lower limit alarm setting range is 0 ~ 1800mL.
- Airway pressure alarm: Upper airway pressure alarm range: 0.1 ~ 6kPa, lower airway

pressure alarm range: 0 ~ 5kPa.

- Oxygen concentration alarm: The upper limit alarm range is 22 ~ 100%, and the lower limit alarm range is 21 ~ 80%.
- Choking alarm: 15s.
- Power failure alarm: The alarm sounds immediately after the AC and DC power supply fails.
- Alarm time: The cause of the alarm is not cleared, the alarm signal is uninterrupted, and the alarm time is > 120s.
- Alarm silence time: Activate the alarm silence function, the sound signal elimination time is ≤120s.
- The intelligent alarm system is arranged according to high and medium priorities.
- High priority: airway pressure exceeds the limit, continuous pressure is too high, suffocation alarm, intubation fall off, air source pressure.
- Medium priority: tidal volume, minute ventilation is too low, frequency.
- AC power: After the power supply fails, the DC power supply continues for not less than 30 minutes.
- The whole machine has passed CE certification.
- It has the function of power-on self-inspection to ensure that the machine can provide high-quality services to medical staff without illness.



Notified Body No 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.
Zlín, Czech Republic – www.itczlin.cz

EC CERTIFICATE

No. 10 0491 QS/NB

issued in compliance with the Council Directive 93/42/EEC as amended, which is implemented by the Czech Government Order No. 336/2004 (Collection of Laws), certifies that the medical devices of Class IIb:

Ventilator

models: PA-500, PA-700B, PA-900B

manufactured by company

Nanjing Pua Medical Equipment Co., Ltd.
No.12 Dongmen, Caoyinguan, Pukou district, NanJing, China

are manufactured under conditions fulfilling the quality system requirements of Annex II, Section 3.2. of the Directive 93/42/EEC, as amended.

The Notified Body No. 1023 has performed an audit of the above products quality system covering the design, manufacture and final inspection of the certified products. The quality system has been assessed, approved and is subject to continuous surveillance according to Annex II, Sections 3.3. and 5. of the Directive 93/42/EEC. The detailed description of the system parts, requirements and measures applied by the manufacturer are presented in the Final Report No. 803600877/2010, which is enclosed to this Certificate.

This Certificate is issued under the following conditions:

1. *It applies only to the quality system maintained in the manufacture of above referenced models of medical devices and it does not substitute the design or type-examination procedures, if requested.*
2. *The Certificate remains valid until the manufacturing conditions or the quality system are changed but until the 6th June 2015 at the latest.*
3. *The Certificate validity is conditioned by positive results of surveillance audits.*
4. *After fulfilling the relevant EU legislation, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking followed by the number of the Notified Body according to this example:*

CE 1023

Issued in Zlín, on 7th June 2010



RNDr. Radomir Čevelík

Representative of the Notified Body No. 1023

SGS

Certificate CN19/42094

The management system of
**Nanjing Pua Medical Equipment
Co., Ltd.**

No. 9, Gaoke First Road, National New & High Technology Industrial
Development Zone, Nanjing, Jiangsu, 210032, P.R. China

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

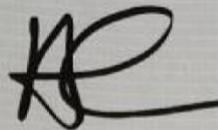
For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 1 August 2019 until 16 July 2022
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 3 April 2022
Issue 2. Certified since 17 July 2019

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by



SGS United Kingdom Ltd
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HC SGS 13485 2016 0118 M2

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Nanjing Puao Medical Equipment Co., Ltd.

ISO 13485:2016 EN ISO 13485:2016



Issue 2

Detailed scope

**Design and manufacture of Anesthesia machine,
Ventilator and Patient Monitor**

Additional facilities

No. 12, Caoyingguan, Dongmen, Pukou District,
Nanjing, Jiangsu, 210032, P.R. China



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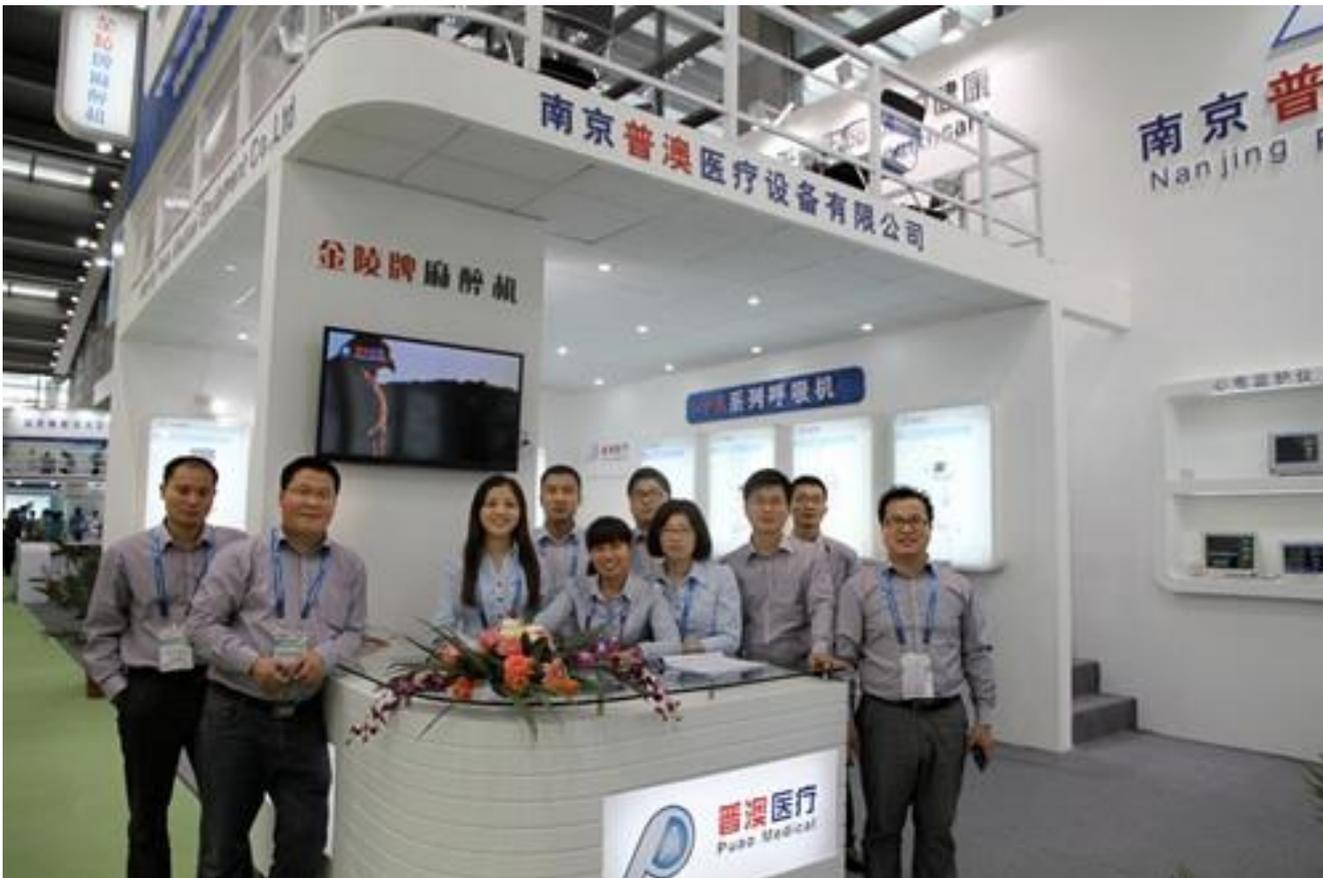
Nanjing Puaos Medical Equipment Co. Ltd.

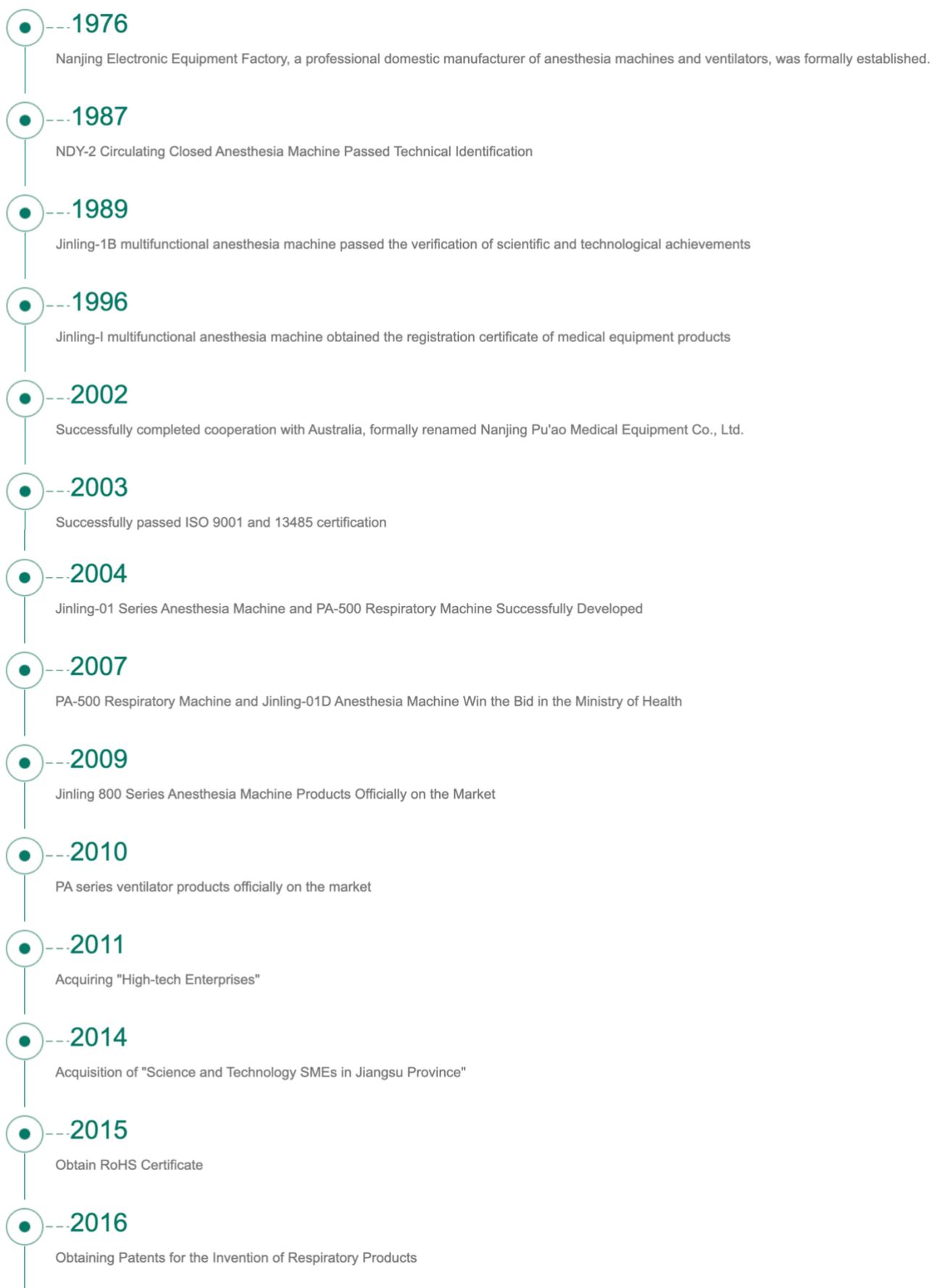
Nanjing Puaos Medical Equipment Co., Ltd, is a medical equipment manufacturer dedicated to the manufacturing, R & D, sales and servicing of anesthesia machines, ventilators and patient monitors. First established in the 1970s and formerly known as the government sponsored "Nanjing Jinling Anesthesia Machine Factory", Puaos Medical is the premier domestic manufacturer of anesthesia machines. Our "Jinling" series of anesthesia machines built with "safety, reliability, simplicity and effectiveness" in mind quickly established itself as a well-known and celebrated brand both domestically and abroad.

Due to our status as a high-tech hardware and software enterprise known for its continuous and consistent innovation, Puaos Medical was granted with the establishment of a graduate work station at the Southeast University by the National Ministry of Education. Moreover as a result of our robust library of intellectual property rights and ever expanding mastery of core technologies, Puaos Medical products have passed numerous certifications such as the ISO 9001 & 13485 certification, the European quality system (CE) certification, the ROHS certification, software product certification and high and new technology certification.

Situated in Nanjing's National New & High Technology Industrial Development Zone with an area over 20,000 square meters in size, our workforce is comprised of some the country's best and brightest graduates, 60 percent of which hold senior engineering titles, postgraduate and doctoral degrees. Consequently Puaos Medical was able to perfect testing methodologies, develop dynamic hardware faculties, foster strong technical & economic strengths and boast an intensive sales network. Our companies major export market includes Russia, Africa, the Middle East, Latin America, Southeast Asia and many others. Furthermore our company has enjoyed tremendous successes in large scale overseas tenders, thereby becoming the qualified supplier of numerous government procurements.

In the face of fierce market competition, we at Puaos Medical adhere to an operational philosophy of "customer centric sustainable technological innovation as both the lifeblood and basis by which we expand", a quality philosophy of "ceaseless improvement in science and technology leads to a better tomorrow" and a service philosophy of "round-the-clock diligent customer service anytime anywhere". These philosophies serve as the guiding principles behind how Puaos Medical provides efficient and quality service to our numerous clients new or old, domestic and abroad.





中华人民共和国医疗器械注册证

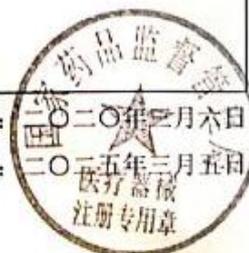
注册证编号：国械注准20143081900

注册人名称	南京普澳医疗设备有限公司
注册人住所	南京高新区高科一路9号
生产地址	南京市浦口区东门曹营关12号
代理人名称	/
代理人住所	/
产品名称	呼吸机
型号、规格	PA-700A、PA-700B、PA-900、PA-900A、PA-900B
结构及组成	产品由机架、控制系统、支臂组成。
适用范围	用于成人患者的呼吸管理
附件	产品技术要求
其他内容	/
备注	原注册证编号：国械注准20143541900

审批部门：国家药品监督管理局

批准日期：二〇一五年三月六日

有效期至：二〇二〇年三月五日



医疗器械生产产品登记表

企业名称	南京普澳医疗设备有限公司			
许可证编号	苏食药监械生产许20010074号			
许可证有效期限	2016-03-01 至 2021-02-28			
生产范围	II类:6821-9-无创监护仪器; III类:6854-2-呼吸设备, 6854-3-呼吸麻醉设备及附件。			
生产产品列表				
序号	产品名称	注册号	登载日期	备注
1	麻醉机	国食药监械(准)字 2012第3541497号	2016-03-01	
2	麻醉机	国食药监械(准)字 2013第3541468号	2016-03-01	
3	呼吸机	国食药监械(准)字 2014第3540786号	2016-03-01	
4	呼吸机	国械注准 20143541900	2016-03-01	
5	多参数监护仪	苏械注准 20152210574	2016-03-01	
发证部门(公章): 江苏省食品药品监督管理局 				

医疗器械生产许可证

许可证编号: 苏食药监械生产许20010074号

企业名称: 南京普澳医疗设备有限公司 生产地址: 南京市浦口区东门曹营关12号

法定代表人: 于欣 生产范围: 见医疗器械生产产品登记表

企业负责人: 高卫国

住 所: 南京高新区高科一路9号 发证部门: 江苏省食品药品监督管理局

有效期限: 至 2021 年 02 月 28 日 发证日期: 2016 年 03 月 01 日




编号 320100000201809250200



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营业执照

(副本)

统一社会信用代码 913201007512975706 (1/1)

名称 南京普澳医疗设备有限公司
 类型 有限责任公司(中外合资)
 住所 南京高新区高科一路9号
 法定代表人 于欣
 注册资本 859.3608万元人民币
 成立日期 2003年10月20日
 营业期限 2003年10月17日至*****
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