



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, Caoyingguan, 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 2020 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 2014



RNDr. Radomír Čevelík
Representative of the Notified Body No. 1023



REGISTRATION NO. 04716Q10000307

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

Nanjing Pua Medical Equipment Co., Ltd.

Registered Address: No. 9, Gaoke First Road, National New & High
Technology Industrial Development Zone, Nanjing, Jiangsu,
China Postcode: 210032

Manufacturing Address: No. 12, Caoyinguan, Dongmen, Pukou District,
Nanjing, China

Has been assessed and conformed to the following standard(s)
YY/T 0287-2003 idt ISO 13485:2003

The certificate is valid for the following scope:

The Design, Development,
Production and Service of
Anesthesia Unit, Ventilator.

Date of issue: August 26, 2016

Date of expiry: March 01, 2021

Director:

BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.

Note: The Certificate Information are available on the official website of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn) or the Website of CMD (www.cmdc.com.cn).
Add: 5th floor of Zhong Lan Building, No. 11188, An Ding Men Wai Dajie, Dong Cheng District, Beijing, 100011, CHINA TEL: 010-62351993