



PT. CAHAYA MAS CEMERLANG
ENVIRONMENTAL CONTROL & MEDICAL GAS ENGINEERING AND CONTRACTOR

VENTILATOR ACM812A



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CERTIFICATE



EC CERTIFICATE

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| | |  TÜVRheinland® | |
| EC Certificate | | | |
| Directive 93/42/EEC Annex II, excluding Section 4 | | | |
| Full Quality Assurance System | | | |
| Medical Devices | | | |
| Registration No.: | | HD 60133038 0001 | |
| Report No.: | | 16806267 006 | |
| Manufacturer: | Beijing Aerospace Changfeng Co., Ltd. CASNUC Building, No. 51-A, Yongding Road, Haidian District 100039 Beijing China | | |
| Products: | Medical devices (see attachment for site and products included) Replaces Certificate, Registration no.: HD 60130281 0001 | | |
| Expiry Date: | 2023-07-11 | | |
| <p>The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.</p> | | | |
| Effective Date: | 2019-11-07 | Notified Body | |
| Date: | 2019-11-07 |  Jing Zhang | |
| TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg | | | |
| TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197. | | | |

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| | | TÜVRheinland | |
| <p align="center">EC Certificate Directive 93/42/EEC Annex II, excluding Section 4 Full Quality Assurance System Medical Devices</p> | | | |
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Doc.: 1/1, Rev.: 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60133038 0001
Report No.: 16806267 006


Manufacturer: Beijing Aerospace Changfeng Co., Ltd.
CASNUC Building, No. 51-A,
Yongding Road, Haidian District
100039 Beijing
China

Products: 

- Anaesthetic Units
- Anaesthetic Vaporizers
- Ventilators
- Medical Ultrasound Diagnostic Systems

Site included:

Beijing Aerospace Changfeng Co., Ltd.
No.52 Yongding Road, Haidian District,
Beijing, 100039, China

Notified Body

Jing Zheng

Date: 2019-11-07



ACM812A Ventilator

Feature :

- a. Suitable for adult and child
- b. For various treatment environments such as emergency room, operating theater, ambulance, patient transfer and first-aid
- c. Unique invasive and non-invasive ventilation modes to meet the different patients' needs
- d. Inspiration halt, convenient for sucking phlegm
- e. Oxygen mixing technique to adjust oxygen concentration and meet the oxygen therapy need
- f. Alarm and monitoring system which meet the international safety standard
- g. TFT screen, displaying various respiration parameters and waveforms
- h. With built-in battery and on-vehicle power connector for A/C and D/C power supply
- i. PEEP valve, humidifier, trolley, supporting arm and other accessories as optional

a) Specification :

b) Main parameters

- a) Applications : Adult, child
- b) Control mode : Pneumatic driven and electric controlled, timeVentilation modes switch, pressure limit, volume control, apnea ventilation
- c) Ventilation modes : A/C, SIMV, SPONT, SIGH, NIPPV, manual Respiratory rate 4bpm ~80bpm
- d) Respiratory rate : 4bpm ~80bpm
- e) Tidal volume : 0, 50ml ~1500ml
- f) I:E ratio : 1: 0.3, 1: 0.5, 1: 0.7, 1: 1, 1: 1.5, 1: 2, 1: 2.5, 1: 3, 1:3,5, 1;4
- g) Trigger sensitivity : -2kPa ~ 2kPa,continuously adjustable
- h) Oxygen concentration : 48-100%
- i) Display mode : LCD screen display
- j) Waveform : Airway pressure waveform display

c) Monitoring parameters

- a) Tidal volume : 0ml ~1500ml
Manual can also be monitored
- b) Minute volume : 0L/min ~99L/min
- c) Lower Airway : 0kPa ~2kPa
- d) Pressure Limit
- e) Insufficient Air Source
- d)

Alarm parameters

- a) Low battery alarm
- b) Power supply failure ≤ 45
- c) Silence for alarm ≤ 120





ACM812 Ventilator

Feature :

- a. Aerospace quality, professional technology, popular model
- b. Easy to take, dampproof, quakeproof and salt fog resistance
- c. Invasive, non-invasive and manual ventilation in one machine
- d. Volume regulation, pressure limit, time switch, demonstrating the strategy of lung protection
- e. Inspiration halt, convenient for sucking phlegm and avoiding cross infection
- f. Driven mode: pneumatically driven and electrically controlled
- g. Three kinds of power supply: A/C, D/C and on-vehicle power supply

Application: adult & child

Specification :

a. Main parameters

- Applications : Adult, child
- Control mode : Pneumatic driven and electric controlled, timeVentilation modes switch, pressure limit, volume control, apnea ventilation
- Ventilation modes : A/C, SIMV, SPONT, SIGH, NIPPV, manual
Respiratory rate 4bpm ~80bpm
- Respiratory rate : 4bpm~80bpm
- Tidal volume : 50ml~1500ml
- I:E ratio : 1: 0.3, 1: 0.5, 1: 0.7, 1: 1, 1: 1.5, 1: 2, 1: 2.5, 1: 3, 1:3,5, 1;4
- Trigger sensitivity : -2kPa~2kPa,continuously adjustable
- Oxygen concentration : 48-100%
- Display mode : LCD screen display
- Waveform : Airway pressure waveform display

b. Monitoring parameters

- Inhaled Tidal volume
- Minute volume

- Peak airway pressure
- AC/DC indication
- Uper & Lower Airway
- Pressure Limit
- Insufficient Air Source
- Could monitor all parameters and waveforms in manual mode

c. Alarm parameters

- Low battery alarm
- Power supply failure
- Silence for alarm
- Power supply : AC220V± 10%, 50Hz± 1Hz, 12V on-vehicle power supply
- Built-in battery: provide a more than 2-hour power supply when power off
- Gas pressure: 0.25~0.6Mpa. Cylinder gas supply can work continuously for ≥30min.

Ventilator compliance: ≤40 x 10-ml/pa





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