



证书编号: 04718Q10000538

医疗器械 质量管理体系认证证书

兹证明

北京谊安医疗系统股份有限公司

(统一社会信用代码: 91110106760939205G)

住所: 北京市丰台区科学城 11B2 号楼[园区] 邮编: 100070

生产地址: 北京市丰台区科学城 11B2 号楼[园区]

河北省三河市燕郊开发区潮白大街 10 号(仅供出口)

质量管理体系符合:

YY/T 0287-2017 idt ISO 13485:2016

体系覆盖:

呼吸机、急救呼吸机、麻醉机、MC 系列医用空气压缩机、输液泵、注射泵、医用分子筛制氧机、LED 手术无影灯、整体反射手术无影灯、电动手术台、OP 系列电动手术台、病人监护仪、医用升温毯的设计开发、生产和服务 LED 医用内窥镜冷光源的设计开发、生产 医用吊塔、吊桥 (医疗器械配套使用产品) 的设计开发、生产、安装和服务。

颁证日期: 2019 年 03 月 01 日

有效期至: 2022 年 02 月 28 日

总经理:

北京国医械华光认证有限公司





证书编号: 04718Q10472R0M

质量管理体系认证证书

兹证明

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河北省三河市燕郊开发区潮白大街 10 号(仅供出口)

质量管理体系符合:

GB/T 19001-2016 idt ISO 9001:2015

体系覆盖:

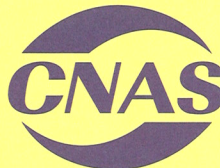
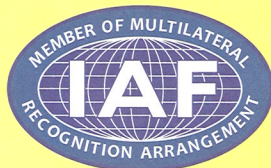
呼吸机、急救呼吸机、麻醉机、MC 系列医用空气压缩机、输液泵、注射泵、医用分子筛制氧机、LED 手术无影灯、整体反射手术无影灯、电动手术台、OP 系列电动手术台、病人监护仪、医用升温毯的设计开发、生产和服务 LED 医用内窥镜冷光源的设计开发、生产 医用吊塔、吊桥 (医疗器械配套使用产品) 的设计开发、生产、安装和服务。

颁证日期: 2018 年 10 月 25 日

有效期至: 2021 年 10 月 24 日

总经理:

北京国医械华光认证有限公司



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C047-M



Benannt durch/Designated by
 Zentralstelle der Länder
 für Gesundheitsschutz
 bei Arzneimitteln und
 Medizinprodukten
 www.zlg.de
 ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
 (Devices in Class IIa, IIb or III)

No. G1 065725 0019 Rev. 01

Facility(ies):

Beijing Aeonmed Co., Ltd.
 Room 405, Basement 1 to 4th Floor of 901 Unit, Building 9, No.26
 Outer Ring West Road, Fengtai District, 100070 Beijing,
 PEOPLE'S REPUBLIC OF CHINA

Beijing Aeonmed Co.,Ltd.
 No. 10 Chaobai Street, Yingbin Road West, Yanjiao Development
 Zone, 065201 Langfang City, Hebei Province, PEOPLE'S
 REPUBLIC OF CHINA

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 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT

Certificate Number CN19/41152

The management system of

Beijing Aeonmed Co., Ltd.

Room 405, Basement 1 to 4th Floor of 901 Unit, Building 9,
No.26 Outer Ring West Road, Fengtai District, Beijing, 100070, P.R. China

Dun & Bradstreet D-U-N-S identification number : 52-758-6284

has been audited against the criteria stated below and found to conform to those criteria for the scope
contained in this certificate



MDSAP (ISO 13485:2016)

Brazil:

RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 /RDC ANVISA n. 67/2009

United States:

21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D / 21 CFR 821

For the following activities and devices

See second page for the scope.

The certificate is valid from
Effective Date: 2019-12-12 until Expiry Date: 2022-12-11
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 2022-09-20
Issue 1. Certified since 2019-12-12

Authorised by J Hall
Business Manager



SGS United Kingdom Ltd
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SGS United Kingdom Ltd is an MDSAP authorized auditing organization

MDSAP M2

Page 1 of 2



Certificate Number CN19/41152, continued

The management system of

Beijing Aeonmed Co., Ltd.

MDSAP (ISO 13485:2016)

Issue 1

Detailed scope

Design and Development, Production, Distribution, and Servicing of Anesthesia Workstation, Ventilators, Medical Air Compressors, Vaporizers, for the area of anesthesiology, intensive care, respiratory therapy. Contract manufacturing of Operating tables and contract manufacturing and installation of Surgical Lights, for use in the area of Operating Room, ICU

Facility Activities:

Design and Development of Anesthesia Workstation, Ventilators, Medical Air Compressors, Vaporizers, for the area of anesthesiology, intensive care, respiratory therapy.



Additional facilities

No.10 Chaobai Street, Yingbin Road West, Yanjiao Development Zone, Langfang City, Hebei Province, 065201, P.R. China

Dun & Bradstreet D-U-N-S identification number : 55-448-8089

Detailed scope

Production, Distribution, and Servicing of Anesthesia Workstation, Ventilators, Medical Air Compressors, Vaporizers, for the area of anesthesiology, intensive care, respiratory therapy.

Contract manufacturing of Operating tables and contract manufacturing and installation of Surgical Lights, for use in the area of Operating Room, ICU



中华人民共和国
PEOPLE' S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号: 京丰食药监械出20190784

Certificate NO.

产品名称: 呼吸机

Product(s): Ventilator

规格型号: VG70、VG60、VG50

Model: VG70、VG60、VG50

产品注册或备案凭证号: 国械注准20153540500

Registration certificate(s)

生产企业: 北京谊安医疗系统股份有限公司

Manufacturer: Beijing Aeonmed Co.,Ltd.

生产企业住所: 北京市丰台区外环西路26号院9号楼-1至4层901内4层405

Address of manufacturer: Room 405, Basement 1 to 4th Floor of 901 Unit, Building 9, No.26 Outer Ring West Road, Fengtai District, Beijing 100070, China

生产许可或备案凭证号: 京食药监械生产许20040070号

Manufacturing License(s)

兹证明上述产品已准许在中国生产和销售。

This is to certify that the above products have been registered to be manufactured and sold in China.

证明有效日期至: 2020-03-30

This certification valid until: 2020-03-30

备注:

Remark:



中华人民共和国医疗器械注册证

注册证编号： 国械注准20153540500

注册人名称	北京谊安医疗系统股份有限公司
注册人住所	北京市丰台区科学城11B2号楼[园区]
生产地址	北京市丰台区科学城11B2号楼[园区], 河北省三河市燕郊开发区潮白大街10号
代理人名称	/
代理人住所	/
产品名称	呼吸机
型号、规格	VG70、VG60、VG50
结构及组成	标配：呼吸机主机（包括显示屏、通气控制单元（即主机箱）、氧传感器和电池组成）；选配：小车。
适用范围	该产品可用于ICU病房的重症治疗及其他科室对呼吸病人的抢救与治疗, 以及医疗机构对患者进行呼吸支持用。该产品适用对象为婴幼儿、儿童和成人患者。
附件	注册产品标准
其他内容	/
备注	

审批部门： 国家食品药品监督管理总局

批准日期： 二〇一五年三月三十一日
有效期至： 二〇二〇年三月三十日





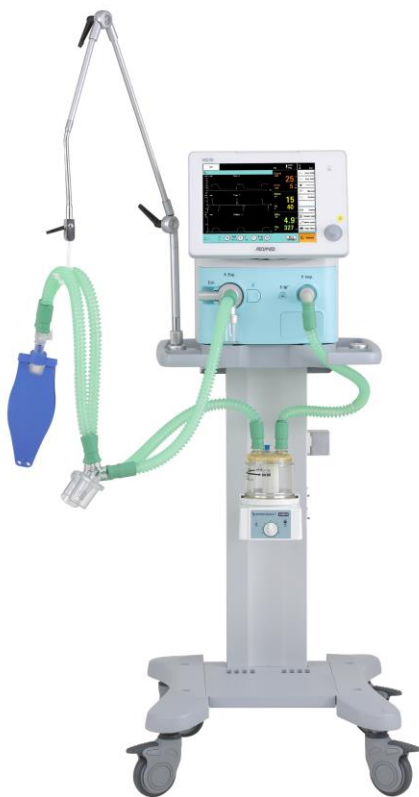
VG70

Ventilator

TECHNICAL
DATA

AEO MED
Reliable Quality Thoughtful Service

VG70 is a critical care ventilator suitable for intra-hospital transport and sub-acute care of infants, children and adults. VG70 combines the advantages of a flexible noninvasive ventilator with a full-featured invasive ventilator. It has comprehensive functionality and a user-friendly design. VG70's internal turbine provides needed air pressure with a low sound level and, along with its internal batteries, prepare it fully for mobile use.



Patient Type

Adult, Child (>3 Kg)

Ventilation Modes

VCV	SIMV(VCV)+PSV
PCV	SIMV(PCV)+PSV
PRVC	SIMV(PRVC)+PSV
SPONT/CPAP+PSV	BIVENT/APRV+PSV
NIV-T	NIV/CPAP
NIV-S/T	

Parameter Setting

Tidal volume (Vt)	50-2000 mL (Adult) 20-300 mL (Child)
Compliance compensation	ON/OFF
Pinsp	5-70 cmH ₂ O
Psupp	0-70 cmH ₂ O
CPAP in NIV	2-20 cmH ₂ O
PEEP	0-35 cmH ₂ O
PEEP in NIV	2-20 cmH ₂ O
Phigh	5-60 cmH ₂ O
Plow	0-35 cmH ₂ O
Psens	-20-0 cmH ₂ O
Vsens	0.5-20 L/min
Tube compensation (%)	0-100
ATC tube type	ET/TT
Esens	5-80 %
Inspiratory time (Ti)	0.2-9 s (Adult) 0.2-5 s (Child)
Backup ventilation Tinsp	0.2-9 s (Adult) 0.2-5 s (Child)
Pause time (Tpause)	0-4 s (Adult) 0-2.5 s (Child)
Rising time (Tslope)	0-2 s
Thigh	0.2-30 s
Tlow	0.2-30 s
Frequency (f)	1-80 bpm
NIV ventilation rate	4-20 bpm (Adult) 4-40 bpm (Child)
SIMV ventilation rate	1-40 bpm
I:E ratio	1:10-4:1
Nebulizer time	30 min or 45 min
O ₂ concentration	21-100 %

Enhancements

Apnea back-up ventilation	
Automatic tube compensation (ATC)	
HFT	Suction
Standby	Screen lock
Print screen	Alarm silence
Nebulization	Expiratory hold
Lung mechanics	Lung recruitment
Manual breath	Waveform freeze
Inspiratory hold	EtCO ₂ measurement
Non-invasive ventilation	Leakage compensation

Monitoring Data

Ppeak	Vti	Rexp	Tispont
Pplat	Vte	Cdyn	FiO ₂
PEEP	MVe	RSBI	FiCO ₂
Pmean	MVespont	Vdaw	EtCO ₂
Pmin	ftotal	I:E	Leak _{NIV}
fspont	WOB		

Lung Mechanics

Rinsp	PEEPi	Cstatic
Elastance	Tc	

Parameter Monitoring Range

VTi/VTe	0-4000 mL
MVi/MVe	0-60 L/min
FiO ₂	18-100 %
Paw	-20-80 cmH ₂ O

Alarm Setting

High Paw	5-80 cmH ₂ O
High MVe	1-60 L/min, OFF
Low MVe	OFF, 0.1-40 L/min
Apnea time	10-60 s, OFF
Frequency (f)	10-80 bpm, OFF
Low PEEP	OFF, 1-35 cmH ₂ O
High EtCO ₂	0.1-13.3 %
Low EtCO ₂	0.1-13.2 %, OFF

Waveform Display

Flow-T	Paw-T	Volume-T	EtCO ₂ -T
V-F Loop	P-V Loop	F-P Loop	

Other Settings

Alarm volume	20, 40, 60, 80, 100 %
Trend	72 H
Log	3000 messages
Screen brightness	Day, Night

Language

Chinese	English	Other languages
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Environmental Requirements

Temperature	
Operating condition	5 °C-40°C
Storage condition	-20°C-60°C
Relative humidity	
Operating condition	5-95%
Storage condition	≤95 %
Barometric pressure	
Operating condition	70-106 kPa
Storage condition	70-106 kPa

Electrical

AC voltage	100-240 V, 50/60 Hz
DC voltage	12-24 V,
One battery run time	Minimum 2 hours
Two batteries run time	Minimum 4 hours

Gas Supply

Supply pressure (O ₂)	280-600 kPa (41-87 psi)
Connection standard	DISS, NIST
Low-flow oxygen inlet	≤600 kPa (pressure) ≤15 L/min (flow)

Physical Specifications

Dimension (main unit)	322*375*366 mm
Main unit weight	12.5 kg
Cart weight	25 kg
Screen size	12" color touch screen
Communication ports	Nurse call port Ethernet port RS-232 port CO ₂ port USB port VGA port

VG70 Ventilator Configuration List (European Std 112000079)				
Standard				
Part Number	Name	Description	Qty	
<input type="checkbox"/>	112000079	VG70 Ventilator	Include VG70 Ventilator Main Unit and Accessory	1
<input type="checkbox"/>	121000675	VG70 Ventilator Main Unit	Electronically driven and controlled, built-in flow and pressure sensor, built-in oxygen blender. Include Case	1
<input type="checkbox"/>	122009883	Accessory	European Standard	1
<input type="checkbox"/>	130013843	VG70 Ventilator User Manual	User manual	1
<input type="checkbox"/>	210002134	Power cable	European standard,5M	1
<input type="checkbox"/>	130000231	Diaphragm		2
<input type="checkbox"/>	130009651	Water Trap		1
<input type="checkbox"/>	130004094	Cover		1
<input type="checkbox"/>	130001347	One-way diaphragm		1
<input type="checkbox"/>	130015084	Tool to disassemble exhalation valve		1
<input type="checkbox"/>	130010423	Fan filter		1
<input checked="" type="checkbox"/>	130004358	Filter Core		1
<input type="checkbox"/>	130003930	Filter		1
<input type="checkbox"/>	230000728	Nebulizer		1
<input type="checkbox"/>	210003734	Internal battery RRC2024	Lithium Battery	1
<input type="checkbox"/>	210001975	Oxygen sensor		1
<input type="checkbox"/>	210003856	Fuse T3.15AH250V		2
<input type="checkbox"/>	230000934	Adult breathing circuit kit	Include : five Silicone threaded circuit Φ22、one Y-piece、two Water traps、one L-tie-in	1
<input type="checkbox"/>	230000951	800-21001Adult Test lung		1
<input type="checkbox"/>	230001094	Face Mask (L)	RAP-422 Adult ,English、 with head band、 NIV silic	1
<input type="checkbox"/>	230001187	Elbow(inner diameter 22mm)	Must choose when face mask is chosen	1
<input type="checkbox"/>	230000952	800-51900-11Bacterial filter	Reusable	2
<input type="checkbox"/>	122006184	Oxygen inlet filter		1
<input type="checkbox"/>	122000048	Oxygen pipe line	European Standard	1
<input checked="" type="checkbox"/>	240000474	VHB10A Humidifier	European Standard	1
<input checked="" type="checkbox"/>	122007662	Cart assembly (220V)	Include cart, power supply unit and etc. European standard.	1
<input type="checkbox"/>	240000030	Arm		1
The buyers: _____ The sellers: _____ Sold price: <u>88000CNY</u>				
Note: 1. When using this configuration list as annex of contract, it should be in duplicate, each of the parties holds one copy, the contract will come into effect upon signature. 2. Mark ✓ in check box in the front of selected part number, mark × in check box in front of non-selected part number, do not left check box blank. 3. When releasing a new version of the configuration list, this configuration list becomes void immediately.				