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

注：认证组织需通过年度监督审核后，此证书方为有效。 本证书信息可在国家认证认可监督管理委员会官方网站（www.cnca.gov.cn）或北京国医械华光认证有限公司网站（www.cmdc.com.cn）上查询。 地址：北京市东城区安定门外大街甲 88 号中联大厦第 5 层　邮编：100011　　电话：010-62351993

证书编号：04718Q10472R0M

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：

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：李朝晖

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

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
TÜV SÜD

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

TÜV SÜD 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

Manufacturer:
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

EC-Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

Product Category(ies):
Anaesthetic Workstation, Vaporizer, Ventilator, Medical Air Compressor, Infusion Pump, Ceiling Pendant, Multi-Parameter Patient Monitor, Videoscope System, Patient Warming System.

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: BJ19859044

Valid from: 2019-07-16
Valid until: 2022-05-03

Date, 2019-07-16

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT
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TÜV SÜD 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

.

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

A4 / 07.17

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

Jonathan M. Hall

SGS United Kingdom Ltd
202B Worle Parkway, Weston-super-Mare, BS22 6WA,UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS United Kingdom Ltd is an MDSAP authorized auditing organization

MDSAP M2

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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

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中华人民共和国医疗器械注册证

注册证编号： 国械注准20163540321

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	Shangrila510S、Shangrila515、Shangrila510
结构及组成	呼吸机由主机、呼吸阀、电源适配器组成。
适用范围	用于普通病房、急诊科、院外以及院内转运实现对病人的抢救与治疗。适用对象为成人患者和10 kg以上儿童患者。
附件	产品技术要求
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： 二〇一六年二月三日

有效期至： 二〇二一年二月二日

国家食品药品监督管理总局 医疗器械注册专用章

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20190787
Certificate NO.

产品名称 ：见附件
Product(s):见附件

规格型号：见附件
Model:见附件

产品注册或备案凭证号: 见附件
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： 2020-10-20
This certification valid until：2020-10-20

备注：
Remark：

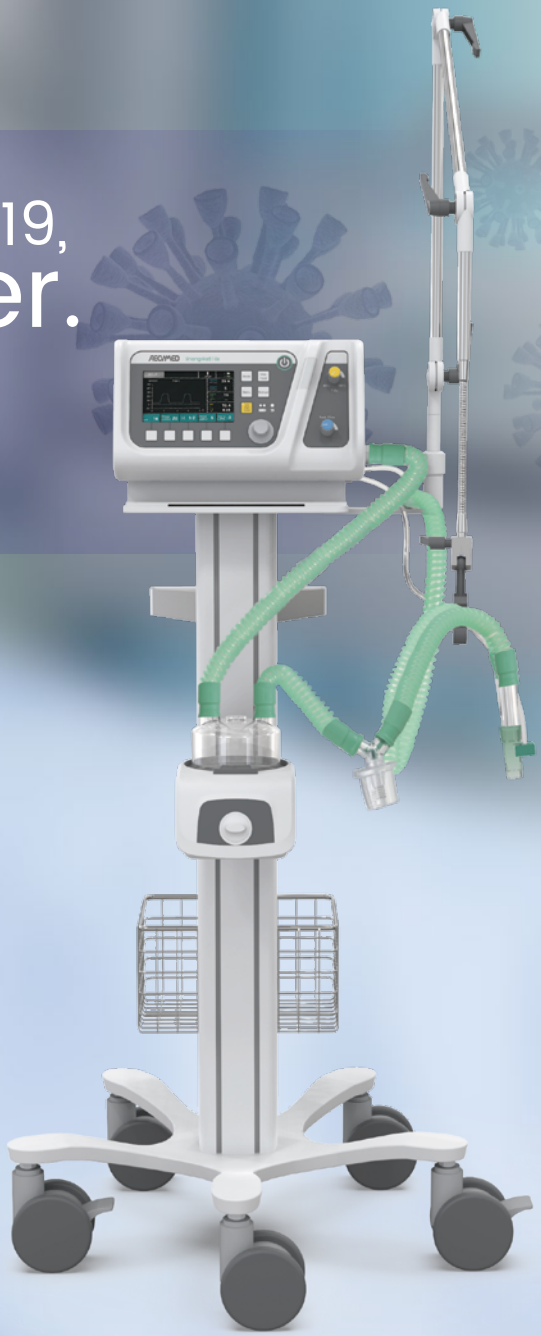
2019-12-19
（出具单位盖章）

出口销售证明书申请表 附件

产品名称		规格型号		注册号
中文	英文	中文	英文	
麻醉机	Anaesthetic Machine	Aeon7500A	Aeon7500A	国械注准20153541987
麻醉机	Anaesthetic Machine	Aeon7900D	Aeon7900D	国械注准20153541986
麻醉机	Anaesthetic Machine	Aeon7200A、Aeon7200、Aeon7600A	Aeon7200A、Aeon7200、Aeon7600A	国械注准20163540322
急救呼吸机	Emergency ventilator	Shangrila935、Shangrila930、Shangrila920	Shangrila935、Shangrila930、Shangrila920	国械注准20153542338
呼吸机	Ventilator	Shangrila510S、Shangrila515、Shangrila510	Shangrila510S、Shangrila515、Shangrila510	国械注准20163540321
OP系列电动手术台	OP Series Operating Table	OP830、OP330	OP830、OP330	京械注准20152541026
电动手术台	Operating Table	OP850、OP350	OP850、OP350	京械注准20152541027
LED手术无影灯	LED Shadowless Surgical Light	OL6570/70、OL6570/50、OL6550/50、OL6570、OL6550、OL9570/70、OL9570/50、OL9550/50、OL9570、OL9550	OL6570/70、OL6570/50、OL6550/50、OL6570、OL6550、OL9570/70、OL9570/50、OL9550/50、OL9570、OL9550	京械注准20152541021
整体反射手术无影灯	Overall reflection shadowless operation lamp	OL2570/70、OL2570/50、OL2550/50、OL2570、OL2550	OL2570/70、OL2570/50、OL2550/50、OL2570、OL2550	京械注准20152541025
输液泵	Infusion pump	Epump500	Epump500	京械注准20152541022
输液泵	Infusion pump	EP520	EP520	京械注准20152541019

Fighting against COVID-19, we are together.

With the massive global outbreak of COVID-19, Aeonmed customized this respiratory work station to save more lives according to the clinical requirements.



Shangrila 510S

Integrated Respiratory Work Station

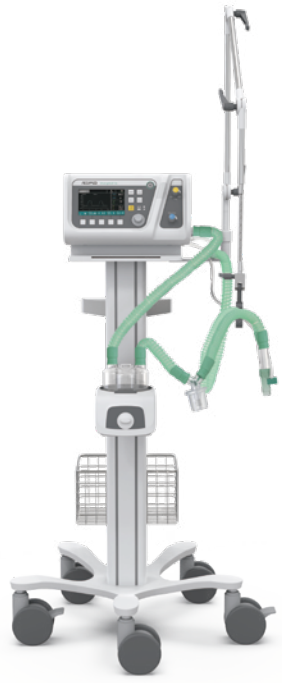
AEONMED

Reliable Quality Thoughtful Service

With advanced technology and versatile ventilation functions, 510S respiratory work station meets the breathing requirements of adult and pediatric.

Shangrila 510S

Integrated Respiratory Work Station



Complete Ventilation Modes

- The device hosts six ventilation modes.
- Besides the conventional Volume-Controlled ventilation mode, it also has Pressure-Controlled ventilation mode,
- SIMV and CPAP modes.
  The machine can provide a precise tidal volume.
- It also provides inspiration hold and manual breath, one-button operation, and is thus incredibly convenient.

Ideal O_2 Delivery

- With its advanced technology, the range of FiO2 can be set from 40% to 100%.
- Furthermore, this range can be adjusted continuously.

Clinical Enhancements

- Manual breath
- Inspiratory hold
- Alarm silence
- Pre-use test

Working Scenarios

- Ward, Emergency Department, Sub-acute Care Unit

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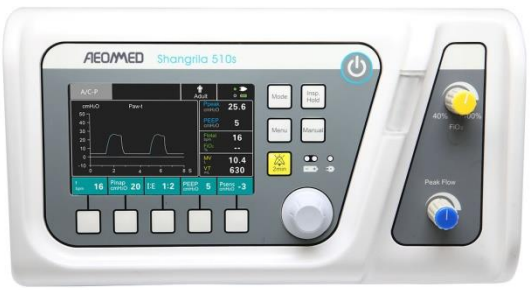
HQ: Building 9, No.26 Outer Ring West Road, Fengtai District, Beijing 100070, China
Science Park: No. 10, Chaobai Street, Yanjiao Development Zone, Sanhe City, Hebei Province 065201, China
TEL: +86-10-5841 1198 FAX: +86-10-6371 8989
Http: //www.aeonmed.com E-mail: marketing@aeonmed.com

The information contained in this leaflet is correct at the date to publication. The policy of Beijing Aeonmed Co., Ltd. is one of the continued improvement to its products. Because of this policy, Aeonmed reserves the right to make any change, which may affect the information in this leaflet without giving prior notices.

Shangrila 510S-202003

Shangrila 510S is a universally used model. Not only for emergency ventilation, but also it is suitable for ideal transport ventilation. The circumstances include on-site emergency treatment, pre-hospital transport, inter-hospital transport, and even intra-hospital transport.



Patient Type

Adult, Child, Infant (>3.5 kg)

Ventilation Modes

A/C-V with Sigh	A/C-P
SIMV-V	SIMV-P
SPONT/PSV	CPAP
MANUAL	

Enhancements

Apnea back-up ventilation	Manual breath
Alarm silence	

Parameter Setting

Tidal volume (Vt)	0-2000 mL
Pinsp	5-50 cmH_2O
Psupp	0-50 cmH_2O
CPAP (NIV)	0-30 cmH_2O
PEEP	0-30 cmH_2O
Pressure trigger	-20-0 cmH_2O
Flow trigger	2-30 L/min
Frequency (f)	1-120 bpm (A/C) 1-40 bpm (SIMV)
I:E ratio	4:1-1:10
Pause time (Tpause)	0-5 s
O_2 concentration	40-100 %
Inspiration flow	Max. 90 L/min

Monitoring Data

MV	VT	Frequency (f)
FiO_2	Ppeak	PEEP

Waveform Display

P-T	F-T

Alarm Setting

High MV	OFF, 1-25 L
Low MV	OFF, 0-24 L
High FiO_2	OFF, 50-100 %
Low FiO_2	OFF, 35-99 %
High Paw	6-80 cmH_2O
Low Paw	0-40 cmH_2O
AC power failure	Gas supply down
O_2 deficiency	MV high
Low battery	No VT
Apnea	CP high

Language	
Chinese	English
Spanish	Italian
Turkish	Other languages

Environmental Requirements	
Temperature	
Operating condition	-18-50 °C
Storage condition	-20-60 °C
Relative humidity	
Operating condition	15-95 %
Storage condition	10-95 %
Barometric pressure	
Operating condition	70-110 KPa
Storage condition	50-110 KPa

Electrical	
AC voltage	100-240 V, 50/60 Hz
DC voltage	12 V
One battery run time	Minimum 4.5 hours
Two batteries run time	Minimum 10 hours

Gas Supply	
Supply pressure (O2)	250-600 kPa
Flow	Max. 180 L/min

Physical Specifications	
Total Weight	8 kg
Dimension (H*W*D):	168* 156 *300 mm
LCD screen	5" TFT
Communication Ports	RS232

AEONMED
Reliable Quality Thoughtful Service

HQ: 11B2, Fengtai Science Park, Beijing, China(100070)
Science Park: No. 10, Chaobai Street, Yanjiao Development Zone, Sanhe City, Hebei Province, China (065201)
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Edition: V201901

Shangrila510S Ventilator Configuration List (European Std 112000142)

Standard

	Part Number	Name	Description	Qty
	112000142	**Shangrila510S Ventilator**	**Ventilator Main Unit and Accessory**	1
	122009660	**Shangrila510S Main Unit**		1
	122013595	**Standard Accessory**		1
	230000101	Y-branch fitting		1
	230000114	Steam trap		2
	240000425	530 silicone thread line package		1
	230000394	Silicone circuit	1.4m,Φ3x1.5	1
	240001253	Expiratory valve		1
	230000113	Elbow		1
	230000131	Mask	Adult size	1
√	230000078	Head band	Adult size	1
	230000072	Test lung 1L		1
	130016649	Vapor lock connector		1
	210003487	Fuse	5*20	2
	130000948	Filter		2
	122009640	Oxygen pipeline	2m,European standard	1
	122009700	Power adapter cable		1
	210003484	Power Cable	European standard	1
	130015829	Operation prompt card	English	1
	122009641	Sampling silicone tube		1
	230000092	Flow sampling probe		1
	130015824	Shangrila510S user manual		1
√	**230000952**	800-51900-11Bacterial filter	Reusable	2
√	**210001975**	Oxygen sensor		1
√	**240000474**	VHB10 Humidifier	European Standard	1
√	**130020038**	Cart assembly（220V）	Include cart, power supply unit and etc. European standard.	1
	240000030	Arm		1
Total price				

The buyers: _____ The sellers: _____ Sold price: CNY._____

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.