Compressor Nebulizer

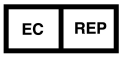
Instruction Manual

Model No.: BR-CN001

File NO.: BR-3-SJ-650-001,C0

Table of Contents

1.Explanation of Symbols

Symbols	Meaning	Symbols	Meaning
	Follow instructions for use		ON
	Type-BF device		OFF
	Device class II (electric shock protection class).	IP21	Protection against solid foreign objects and harmful effects due to the ingress of water
	Serial number		Authorized Representative in the European Union
	Manufacturer		Caution/Warning
CE1639	Complies with the European Medical Device Regulation (2017/745. Notified Body is SGS.	~	Alternating Current
	Disposal in accordance with Directive 2002/96/EC (WEEE)		Indoor use only
	Upward		Fragile, handle with care
	Keep dry		Pile Limit 6 layers
MD	Medical device	UDI	Unique device identifier

2.Important safety instructions

⚠ **Warning:** Indicates a potentially hazardous situation which, if not avoided, could result in serious injury.

⚠ **Caution:**Indicates a potentially hazardous situation which if not avoided, may result in minor or moderate injury, or physical damage.

⚠ **Caution:**

1) Federal Law restrict this device for sale or use on the order of a physician.

2) Follow the instruction of your physician to operate this unit.

3) This product is a nebulizer system for the inhalation of medical aerosols and is suitable for children used solutions. Use only the type and amount of medication prescribed by patient's doctor. Non professionals should use the medication after it has been prescribed by professionals.

4) This product is intended for aerosol therapy only. And other use is not recommended.

5) Have not untwist the nebulizer cup during operation.

⚠ Warning: To Reduce the risk of electrocution.

1) Always unplug the unit immediately after using.

2) Do not use while bathing.

3) Do not place or store the unit where it can fall or be pulled into a tub or sink.

4) Do not place or drop into water or other liquid.

5) Do not reach for a product that has fallen into water .Unplug immediately.

⚠ Warning :To Reduce the risk of burns, electrocution, fire or injury

1) Electrical Shock Hazard—do not open the cover.

2) Disconnect the power cord from the electrical outlet before cleaning or servicing.

3) Do not place this equipment near hot, sparking or burning objects.

4) Do not use oil or grease on or near this device.

5) Turn the unit off when it is not in use.

6) Keep the cord away from HEATED or HOT surfaces.

7) NEVER drop or insert any object into any opening.

8) NEVER block the air openings of the product or place it on a soft surface ,such as a bed or couch, where the air openings may be blocked.

9) Avoid operating in wet or damp locations.

10) Unplug the unit before filling the nebulizer.

11) When using this product near TV, microwave oven ,pulse telephone X ray or other strong electric field, it will be disturbed, suggested to be far away from these device.

⚠ Warning: To reduce the risk of infection

1) The Nebulizer accessory kit is intended for single-patient reuse.

2) Cleaning of the nebulizer is recommended after each aerosol treatment.disinfecting is recommended once a week. Please follow cleaning and disinfecting instructions in this manual.

3) This unit is not suitable for use in anaesthetic breathing systems

4) This unit is not suitable in suspension or high viscosity form. In such cases information should be sought from the drug supplier

3.Introduction

3.1 Intended use

This product is designed to deliver the prescribed medication solution to treat patient respiratory disorders , The nebulizer converts the medication solution into an aerosolized mist which is inhaled by the patient through the mouthpiece or mask.

3.2 Patient population

a) Age: 2years old to geriatric

b) Health: Patients with respiratory diseases

c)PATIENT state: Treat patient respiratory disorders, such as asthma, allergies and bronchitis.

3.3 Intended users

a) Education:

— at least 18 years old and 8years intensive reading experience(school)

b) Knowledge:

At least:

- Can read and understand text and Arabic numerals;
- Can understand this manual before use.

c) Language understanding:

— languages used the intended USER' official language

d) Experience:

- person above 18 years old
- other: no

e) Permissible impairments

— mild reading vision impairment or vision corrected to log MAR 0,2(6/10 or 20/32)

— impaired by 40% resulting in 60% of normal hearing at 50 Hz to 2 kHz

f) This device only needs to read the manual to operate, and does not need additional training

⚠ Warning

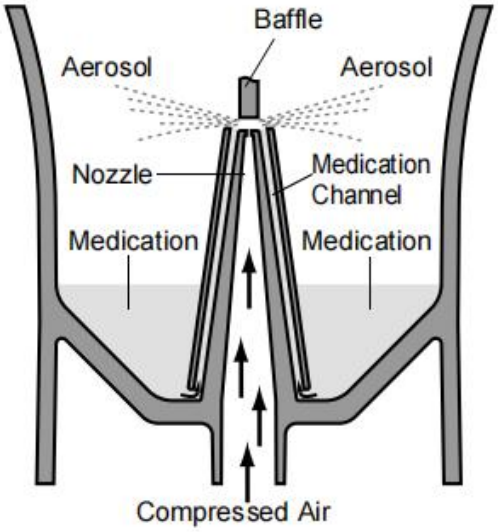
--Expected used in conscious patients only

--The patients with serious lack of oxygen or respiratory failure are prohibited to use

--History of chronic disease, admission to an intensive care unit in the last year and/or hospitalization history in the last 6 months should be used under the doctor's supervision

3.4 Operating Principle

The medication that is pumped up through the medication channel is mixed with compressed air which is generated by a compressor pump. The compressed air mixed with medication is tuned into fine particles and sprayed by being impacted to the baffle.



3.5 Contraindication

No

3.6 Side effect

No

4.Specifications

Power supply	~230V / 50Hz
Input Power	160VA
Rate Current	0.7A
Operating pressure range	9~16 psi (62~110 kPa)
Operating flow range	5~8 lpm
Max. pressure range	≥35 psi (241kPa)
Nebulization rate	0.20~0.60mL/min （by weight loss）
Particle size MMAD	2.4μm
Noise level	≤58 dB(A) (at 1meter distance)
Max Capacity of Medicine cup	6mL(cc)
Residual volume	≤1.0mL
Device life	3 years or 1000 h
Unit Size	230x150x190 MM
Weight	1.37kg
Shelf life of accessories(Nebulizer cup, mask, mouth piece/nosepiece)/use	3years/ 5 times

times	
Type of protection against electric shock	Class II
Degree of protection against electric shock	Type BF device
Mode of operation	Continuous operation
IP Class	IP21
Operation Condition	+5℃ to + 40℃，30% R.H. to 85% R.H.
Transportation and storage conditions	-20℃~60℃,10%R.H.~93%R.H
Operating atmospheric pressure range	70～106 kPa
Treatment Time	15-20 min/once
Treatment Frequency	1-2 times/day

The specific treatment time and frequency shall be subject to the final recommendation of the doctor.

5.Description

The compressor nebulizer consists of the compressor, nebulizer accessory kit and air filters. The accessories include nebulizer cup, air tube, adult mask, child mask, mouthpiece and nosepiece.

Connection method:

1) Fill the nebulizer cup with the inhalation solution as per your doctor’s instructions. Ensure that you do not exceed the maximum level(6mL).

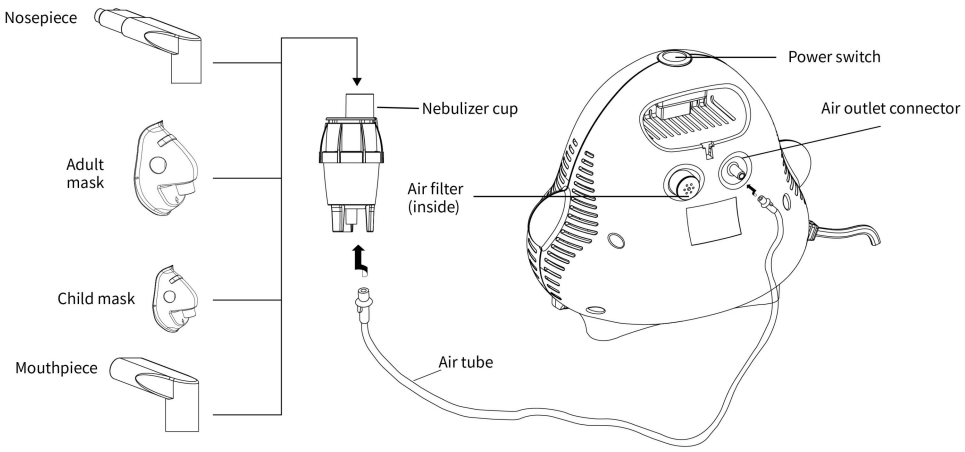
2) Connect one side of the air tube to the bottom of the nebulizer cup and the other side to air outlet connector of the compressor.

3) Choose one of adult mask, child mask, mouthpiece or nosepiece as per your doctor’s instructions and connect it to the nebulizer cup cover.

4) Extract air inlet cover and Install air filter inside.

5) And plug the power lead into the socket (230V 50 Hz AC).

For example (BR-CN001):



The compressor nebulizer connected figure 1

6.Unit and Accessories

Compressor	Nebulizer accessory kit					Air filters
	Air tube	Adult mask	Child mask	Nebulizer cup	Mouthpiece + Nosepiece	
						

The compressor nebulizer includes compressor, air filters and nebulizer accessory kit, And the nebulizer accessory kit includes nebulizer cup, air tube, mouthpiece, nosepiece and Adult/Pediatric Mask.

7.Operation Instructions

(1) Preparation and Usage of this Device Prior to using the device for the first time, we recommend cleaning it as described in the section “Cleaning and Disinfecting”.

(2) Fill the nebulizer cup with the inhalation solution as per your doctor’s instructions. The recommended fill volume 5mL for use, Ensure that you do not exceed the maximum level(6mL).

(3) Connect the nebulizer system with the air tube to the compressor’s air outlet ,The mask or mouthpiece assemble with nebulizer cup, see the figure 1.and plug the power lead into the socket (230V 50 Hz AC).

- The mouthpiece gives you a better drug delivery to the lungs.

- Choose between adult or child face mask and make sure that it encloses the mouth and

nose area completely.

(4) To start the treatment, set ON/OFF switch into the “I” position.

(5) During inhalation, the tilt of the nebulizer cup should not exceed 45°,sit upright and relaxed at a table and not in an armchair, in order to avoid compressing your respiratory airways and impairing the treatment effectiveness. Do not lie down while inhaling. Stop inhalation if you feel unwell.

(6) After completing the inhalation period recommended by your doctor, switch the ON/OFF switch to position “O” to turn off the device and unplug it from the socket.

(7) Empty the remaining medication from the nebulizer cup and clean the device as described in the section “Cleaning and Disinfecting”.

Liquid drugs that can be applied to compressor nebulizer manufactured by our company include Nonsteroidal anti-inflammatories, such as Cromolyn sodium; Antibiotics, such as Tobramycin inhalation solution, Colistin inhalation solution (Promixin1), Aztreonam inhalation solution (Cayston1); β2-adrenergic agonists such as Formoterol fumarate inhalation (Perforomist1), Salbutamol inhalation solution, Arformoterol tartrate (r-formoterol) inhalation solution, Levalbuterol (r-salbutamol) inhalation solution, Metaproterenol sulfate (Alupent1); Corticosteroids such as Budesonide inhalation suspension and Fluticasone inhalation suspension; Mucolytics such as Recombinant human DNase (Pulmozyme1), Hypertonic saline inhalation solution Hyper-SalTM, MucoClear1 and HyanebTM; Prostacyclin such as g Iloprost (Ventavis1); Anticholinergics such as Ipratropium bromide (Atrovent1); a Anti-infective, such as Pentamidine (NebuPent1).

⚠ **Caution/Warning:**

- The device requires no calibration.
- No modification to the device is permitted
- The nebulizing cup maximum temperature maybe reached 40°C in operating condition ,
- The compressor must be disconnected from the power source, prior to dismantling and reassembling.
- The nebulizer cup functional test(s) to be carried out after reassembly and before use;
- The nebulizing is not suitable for use in a anaesthetic breathing system or a ventilator

breathing system.

- The nebulizer system shall be disconnected from the power source after use.
- Dismantling and reassembling shall be carried out with the power source disconnected.

8.Cleaning and Disinfecting

Before and after each treatment follow carefully the cleaning and disinfecting instructions of the accessories as they are very important to the performance of the device and success of the therapy.

8.1 Cleaning the compressor

Thoroughly clean all components to remove medication residuals and possible impurities after each treatment.

(1) Use a soft and dry cloth with non-abrasive cleaners to clean the compressor .

(2) Make sure that the internal parts of the device are not in contact with liquids and that the power plug is disconnected.

8.2 Cleaning and disinfecting of the accessories

(1) Turn the power off and unplug from the wall outlet .

(2) Remove the air tube from the nebulizer cup and air outlet connector.

the recommended methods of cleaning and disinfection prior to reuse shall following:

(3)TO CLEAN: Cleaning the nebulizer accessory kit with dish detergent and water. Disassemble mouthpiece, nebulizer cup or mask and wash this items in water with dish-washing detergent Rinse these items thoroughly to remove the detergent.

(4)TO DISINFECT:

Soak in 70% isopropyl alcohol for 5 min.
Soak in 3% hydrogen peroxide for 30 min.

（5）Rinse with sterile water.

（6）Air-dry thoroughly prior to storage

There is no need to clean the air tube. If necessary wipe the surface regularly.

CAUTION:The nebulizer cup must be changed if it gets clogged.
CAUTION:Do not boil Air tube, nebulizer cup and mask (PVC).
Warning:the compressor must be disconnected from the power source, prior to cleaning, disinfection

9.Maintenance, Care, and Service

Order all spare parts from your dealer or pharmacist.

9.1 Replacement of the nebulizer cup

Replace the nebulizer cup after a long period of inactivity, in cases where it shows deformities, breakage, or when the vaporiser head is obstructed by dry medicine, dust, etc.
We recommend to replace the nebulizer cup after use 5 times.

Caution:

Only use original nebulizer accessory kit !

9.2 Replacement of the air filter

In normal conditions of use, the air filter must be replaced approximately after 200 working hours or after each year. We recommend to periodically check the air filter (10 - 12 treatments) and if the filter shows a grey or brown colour or is wet, replace it.(Extract air inlet cover and the filter , replace filter with a new one).

Caution:

- Do not try to clean the filter for reusing it.
- The air filter shall not be serviced or maintained while in use with a patient. Only use original filters! Do not use the device without filter!

10.Guarantee

This device is covered by 1 year guarantee from the date of purchase. During this guarantee period, at our discretion, Bi-rich will repair or replace the defective product free of charge.
Opening or altering the device invalidates the guarantee.
The following items are excluded from the guarantee:

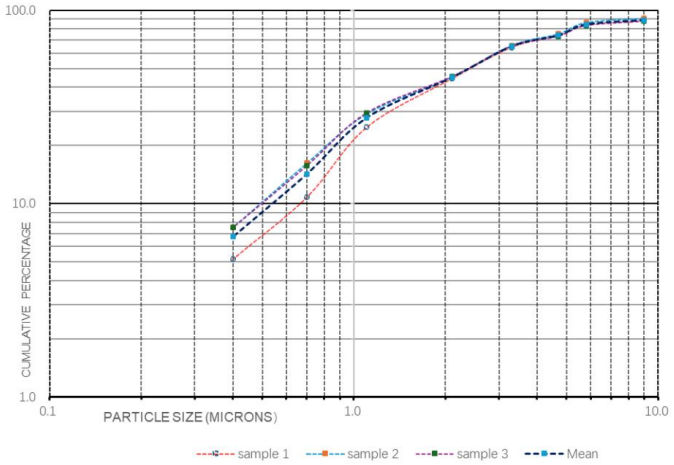
- Transport costs and risks of transport.
- Damage caused by incorrect application or non-compliance with the instructions for use.
- Damage caused by accident or misuse.
- Packaging/storage material and instructions for use.
- Regular checks and maintenance.
- Accessories and wearing parts: Nebulizer cup, masks, mouthpiece, nose piece, tube, filters.

Should guarantee service be required, please contact the dealer from where the product was purchased.
Compensation is limited to the value of the product. The guarantee will be granted if the complete product is returned with the original invoice. Repair or replacement within guarantee does not prolong or renew the guarantee period. The legal claims and rights of consumers are not limited by this guarantee.

11. Technical data

Particle Size: *MMAD * approximately 2.4μm
Appropriate Medication Quantities: 2mL minimum -6mLmaximum
Geometric standard deviation (GSD): 2.778

Aerosol Output:1.345(5mL, Albuterol 0.1% (M/V) concentration in 0.9% sodium chloride solution)
Aerosol Output Rate:0.096mL/min
Respirable fraction (%) (< 5 μm): 76.95,%<2 um:43.23.
Percentage of fill volume emitted in 1min (%/min):1.9
Compressor nebulizer the particle size distribution curve as well:
Result of cascade impactor **measurements for particle size with Compressor and nebulizer kit



Plot of cumulative size distribution, Average value of three sample

MMAD = Mass Median Aerodynamic Diameter
Independently measured by SGS-CSTC Standards Technical Services Co., Ltd., Guangdong, China, according to ISO 27427:2023

Caution:

The device is designed to nebulize solution.
Using a solution, suspension, or emulsion different from that recommended . in particular, a suspension and/or high-viscosity solution, can alter the particle size distribution curve, the mass median aerodynamic diameter (MMAD), aerosol output, and/or aerosol output rate.
The above disclosures for performance are based upon testing that utilizes adult ventilatory patterns and are likely to be different from those stated for paediatric or infant populations.

12.Important information regarding Electro Magnetic Compatibility (EMC)

1* WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally."

2* WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation."

3* WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BR-CN1001, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result."

4* The functioning of the device may be affected by electromagnetic interference exceeding the levels specified in IEC 60601-1-2.

Table 1

declaration - electromagnetic emission	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Table 2

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines
Surge IEC 61000-4-5	± 0.5kV, ± 1 kV line(s) to lines	± 0.5kV, ± 1 kV line(s) to lines
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles	0 % UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycles
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m
NOTE: UT is the a.c. mains voltage prior to application of the test level.		

Table 3

declaration - electromagnetic immunity		
Immunity test	IEC 60601 test level	Compliance level
Conducted RF IEC 61000-4-6	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur bands between 0.15 MHz and 80 MHz	3 V 0.15 MHz to 80 MHz 6 V in ISM and amateur bands between 0.15 MHz and 80 MHz
Radiated RF IEC 61000-4-3	10V/m 80 MHz to 2.7 GHz	10V/m

Table 4

declaration - IMMUNITY to proximity fields from RF wireless communications equipment					
Immunity test	IEC60601 test level				Compliance level
	Test frequency	Modulation	Maximum power	Immunity level	
Radiated RFIEC 61000-4-3	385 MHz	**Pulse Modulation: 18Hz	1.8W	27 V/m	27 V/m
	450 MHz	*FM+ 5Hz deviation: 1kHz sine	2 W	28 V/m	28 V/m
	710 MHz 745 MHz 780 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m
	810 MHz 870 MHz 930 MHz	**Pulse Modulation: 18Hz	2 W	28 V/m	28 V/m
	1720 MHz 1845 MHz 1970 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	2450 MHz	**Pulse Modulation: 217Hz	2 W	28 V/m	28 V/m
	5240 MHz 5500 MHz 5785 MHz	**Pulse Modulation: 217Hz	0.2 W	9 V/m	9 V/m

Note* - As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.
Note** - The carrier shall be modulated using a 50 % duty cycle square wave signal.

13.Malfunctions and Actions to take

Check the following if your unit should fail during operation. You can also refer to the pages of this manual for complete instructions.

Problem	Cause	Remedy
Nothing happens when the power switch is pressed.	Is the AC plug connected correctly to the an electrical outlet and the compressor?	Check that the plug is inserted in an electrical outlet. Unplug then reinsert the plug if necessary.
No nebulization or low nebulization rate, when the power is on.	Is there medication in the medication tank?	Add the correct amount of medication to the medication tank.
	Is there too much/little medication in the medication tank?	
	Is the vaporiser head missing and not assembled correctly?	Attach the vaporiser head correctly.
	Is the nebulizer kit assembled correctly?	Assemble the nebulizer kit correctly.
	Is the nozzle blocked?	Make sure that the nozzle is free of blockages.
	Is the nebulizer kit tilted at a sharp angle?	Make sure that the nebulizer kit is not tilted at an angle of more than 45 degrees.
	Is the air tube connected correctly?	Make sure that the air tube is correctly connected to the compressor and nebulizer kit.
	Is the air tube folded or damaged?	Make sure that the air tube does not contain kinks.
	Is the air tube blocked?	Make sure that the air tube is free of blockages.
	Is the air filter dirty?	Replace the air filter with a new one.
The device is abnormally loud.	Is the air filter cover attached correctly?	Attach the air filter cover correctly.
The device is very hot.	Is the compressor covered?	Do not cover the compressor with any type of cover during use.

Note: If the suggested remedy does not solve the problem, do not try to repair the device- no parts of the unit are user serviceable.Return the unit to an authorized retail outlet or distributor.

14.  Disposal statement

Correct Disposal of this product (Waste Electrical & Electronic Equipment)

This marking shown on the product or its literature, indicates that it should not be disposed of , with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources. Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can take this item for environmentally safe recycling .

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial wastes for disposal.

15. Storage

Storage environment:store in accordance with the storage environment conditions specified in this manual, avoid moisture, high temperature, falling, dust, sun exposure, vibration, chemicals or corrosive gas, etc.

16. Standard list

Shenzhen Bi-rich Medical Devices Co.,Ltd. declares that the Compressor Nebulizer complies with following regulations and normative documents/standards:

(EU)2017/745 Medical device regulation	
EN 15223-1	Symbols for use in the labeling of medical devices
EN ISO 20417	Medical devices-Information to be supplied by the manufacturer
EN 60601-1	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
EN 60601-1-2	Medical electrical equipment -- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
EN 60601-1-6	Medical electrical equipment – Part1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
EN 60601-1-11	Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in home healthcare environment
EN SO 27427	Anaesthetic and respiratory equipment- Nebulizing systems and components
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

17. Reporting adverse events

If users/ patients/ customer think that they or someone in they family has experienced a serious incident that has occurred in relation to the device, users/ patients/ customer are encouraged to report the incident to the manufacturer and the competent authority of the Member State in which the users/ patients/ customer is established.

CE 1639

Shenzhen Bi-rich Medical Devices Co.,Ltd

Address:The 1st building of No. 10, Xinqiao GangZai Road, Xinqiao Street, Bao'An District ,5

18125, Shenzhen City,Guangdong Province, P. R. China

Web: www.bi-rich.cn

EC REP **:SUNGO Europe B.V.**

Add: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

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