prolife

COMPRESSOR NEBULIZER

Prolife PN Active

en Instruction Manual

CONTENTS

1 INTRODUCTION

Please read this manual carefully before operating the device.

The information contained in this document is subject to change without prior notice. Thank you for purchasing Compressor nebulizer **Prolife PN Active**. The properly used nebulizer will ensure reliable medical treatment for many years.

2 LIST OF SYMBOLS

Symbols	Meaning
CE 0123	The product complies with Directive 93/42/EEC on Medical Devices.
	WEEE (Waste Electrical and Electronic Equipment Directive). The symbol on the product or its package means that this product does not fall under the category of domestic waste. To avoid possible damage to the environment and human health, separate such wastes from others and dispose of them in accordance with accepted standards.
EC REP	European Authorized Representative.
	Manufacturer.
	Note/Warning.
IP21	Ingress protection rating. Leading digit (protection against ingress of solid foreign objects): 2 – protection against ingress of solid objects more than 12 mm in size; fingers or other objects with a maximum length of 80 mm, or solid objects. Second digit (protection against vertically falling water drops): 1 – Vertically falling water drops should not impair the operation of the device.
	Type-BF device.
	Device class II (electric shock protection class).

Read and understand the instruction manual.

Keep away from direct sunlight.

Importer in the EU.

3 FIELD OF APPLICATION

Compressor nebulizer **Prolife PN Active** is a medical device. Please use the device only under your doctor's and/or pulmonologist's direction.

Compressor nebulizer **Prolife PN Active** operates from the mains. It provides comfortable, rapid and safe treatment.

This device is suitable for all ages. Please read carefully this manual to familiarize yourself with the nebulizer features.

NOTE

The nebulizer is designed for inhalation therapy of asthma, chronic obstructive pulmonary disease (COPD) and other respiratory tract diseases. Please consult your doctor before using the nebulizer for inhalation therapy. Follow the doctor's instructions regarding a dose and schedule of a medicine inhaled administration.

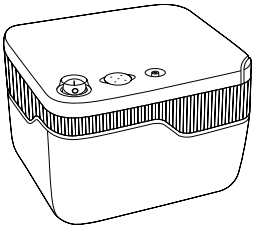
Please observe safety measures when using the nebulizer. The device must be used only for its intended purpose and with the prescribed medicines; according to this manual; under the care of a doctor and in accordance with a doctor's instructions. This device is not intended for artificial lung ventilation and inhalation anesthesia.

4 COMPLETE SET

The complete set includes the following components. If you discovered any missing components, please contact the seller immediately.

The nebulizer system consists of the following components:

Compressor (main unit)
Prolife PN Active



Parts and components replacement interval is determined by their service life specified in the following section «Main technical characteristics».*

Pediatric mask
Prolife PN Active

Adult mask
Prolife PN Active

Nebulizer kit
Prolife PN Active

5 spare air filters
Prolife

x 5

Airtube Prolife

Mouthpiece
Prolife PN Active

Nosepiece
Prolife PN Active

*Parts and components replacement interval is determined by their service life specified in the following section «Main technical characteristics».

5 MAIN TECHNICAL CHARACTERISTICS

Electrical requirements	230 VAC, 50Hz
Particle size, MMAD	3.50 µm
Sound level	52 dBA 1m
Wattage	100 W
Weight	1500 g
Safety system	High temperature compressor shutdown
Length	140 mm
Height	105 mm
Width	170 mm
Maximum pressure	33 psi
Operative flow rate	4 l/min
Nebulization rate	0.37 ml/min
Storage conditions	-13 °F to 158 °F (-25 ° to 70 °C); 10 to 95% RH
Operating conditions	50 °F to 104 °F (10 °C to 40 °C); 10 to 95% RH
Altitude	0 to 6500 ft (2000 m) above sea level
Mode of operation	Intermittent use (30 min. ON/30 min. OFF)
Service life*:	
- Compressor (main unit) Prolife PN Active	5 years
- nebulizer kit Prolife PN Active	6 months
- spare air filter Prolife	30 hours** **Note: the air filter service life may be significantly reduced when using the device in an environment with increased dust concentration
- pediatric mask Prolife PN Active; adult mask Prolife PN Active	1 year
- airtube Prolife	1 year
- mouthpiece Prolife PN Active	1 year
- nosepiece Prolife PN Active	1 year

*The service life of the components may vary depending on the intensity of use. The table shows the service life when using the device for spraying 2 ml of saline 2 times a day for 10 minutes at room temperature (23 °C). The device service life may depend on operational environment.

NOTE

Technical characteristics and appearance are subject to change without prior notice for purposes of improvement.

6 GUIDELINES FOR SAFE OPERATION

NOTE

ELECTRICAL SHOCK HAZARD

- Protect the device against water ingress in order to prevent electrical shock.
- Do not immerse the device in liquid.
- Do not use while bathing.
- Do not touch the device that has fallen into water. Unplug immediately.
- Do not use the previously immersed in water or dropped device with damaged parts (including power cable and plug). Please contact your service center to eliminate failures.
- Do not use the device when a malfunction is detected until the device is repaired.
- Do not touch the power switch with wet hands.

OPERATION

- Do not use the device in areas with presence of flammable gases, oxygen or aerosol products.
- Do not use the device with empty medicine cup.
- Do not block the air openings. Do not place the device on a soft surface as the air openings may be blocked.
- Unplug the device before cleaning, filling and after each use.
- Unplug the device when not in use.
- Do not turn down or shake the device during operation.
- Use only accessories recommended by the manufacturer.
- Do not disassemble or attempt to repair the device yourself.
- Do not use water in the nebulizer for inhalations.
- Clean and disinfect the nebulizer chamber, mouthpiece, air tubing, nosepiece or face mask before using them for the first time after purchase, if the device has not been used for a long time, or if the same device is being used by several persons.

- Rinse all parts after use, make sure they are properly disinfected and dried, and store them in a clean place.
- Keep out of the reach of children. The device contains small parts that can be swallowed.
- Do not cover the compressor with a blanket, towel, etc. during operation.
- Always remove any medicine residues from the cup after inhalation. Use only fresh medicine for inhalation.
- Do not use or store the device in a room with very high humidity, for instance, in a bathroom.
- This device is not intended for use by people (including children) with physical, neurological or mental disorders, or who have lack of experience and knowledge, except when these persons are supervised or instructed on the use of the device by the person responsible for their safety. It is necessary to supervise children in order to prevent games with the device, its accessories, as well as with factory package.
- The manufacturer will not be liable for any loss and damage caused by non-observance of safety regulations, improper or unintended use.

STORAGE PRECAUTIONS

- The accessories must be used only with a single patient; it is not recommended to use them with several patients to avoid cross contamination
- Keep away from direct sunlight, high temperatures and humidity.
- Keep out of the reach of children.
- Unplug the device when not in use.

CLEANING NOTE

- Check air filter, mouthpiece, nebulizer and other components before each use. Contaminated or worn out components must be replaced.
- Do not immerse the device in liquid to avoid its damage.
- Unplug the device before cleaning.
- Clean all necessary accessories after each use according to the instructions in this manual.
- Remove any medicine residues from the cup after each use. Always check the expiration date of medicines before inhalation.
- Do not store wet airtube or airtube with medicine residues. This may cause bacterial infection.

RISK OF ELECTRIC SHOCK

- DO NOT disassemble the device.

Please contact qualified service personnel.

- Do not leave the device unattended when plugged in.
- Close supervision is necessary when the device is used by children and physically challenged people.
- Use the device only for its intended purpose as described in this manual and only with the prescribed medicines. Use the device only under a doctor's direction.
- NEVER insert any objects into openings or tubes.

The compressor nebulizer system uses the surrounding air to effectively administer the prescribed medicine through the nebulizer. The user should be aware of environmental conditions so as not to have contaminated air filtered through the compressor nebulizer system.

- DO NOT use the device without filter.
- Avoid operating the device in a dusty environment. Otherwise, the compressor may fail prematurely.

NOTE

Clean and rinse the nebulizer before the first use of the device.

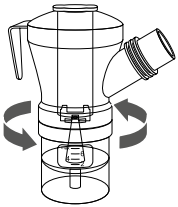
7 PREPARATION FOR USE

Place the device on a table or other flat, stable surface. Be sure you can easily reach the switch in a seated position.

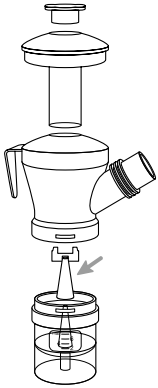
ATTENTION

Make sure the power switch is set to **«O»** position.

1. Connect the device to the mains.
2. Gently twist the nebulizer to separate it into two sections (pic. 1).
3. Be sure the pick-up funnel is in place in the bottom section of the nebulizer (pic. 2).



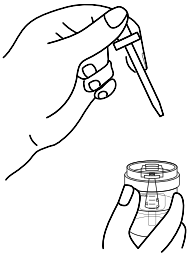
Picture 1



Picture 2

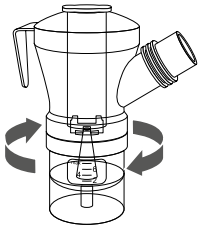
ATTENTION

- DO NOT add over 8 ml of medicine to the cup.
- The maximum capacity of the nebulizer medicine cup is 8 ml.



Picture 3

4. Add the prescribed amount of medicine to the cup using an eyedropper, pre-measured dose or ampoule (pic. 3).
5. Gently twist the top and bottom sections together to assemble the nebulizer. Be sure the two sections fit securely (pic. 4).

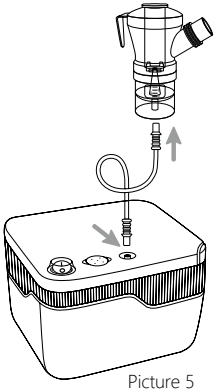


Picture 4

6. Connect one end of the airtube to the airtube connector on the front of the compressor (pic. 5).
7. Connect the other end of the airtube to the base of the nebulizer (pic. 5).

WARNING

In case of high humidity, condensation may form inside the tubing. Run the device for two minutes before connecting the nebulizer to the tubing.



Picture 5

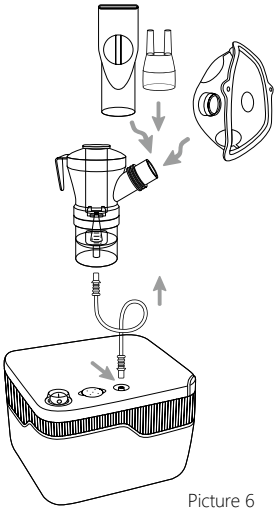
8. Attach the mouthpiece to the top section of the nebulizer (pic. 6).

NOTE

Before starting the device leave it in a heated area to reach the room temperature.

WARNING

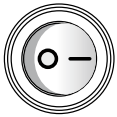
The device is for intermittent use: 30 min. **«**ON**»**/30 min. **«**OFF**»**. Failure to operate within these limits may damage the device beyond repair.



Picture 6

8 OPERATION PRINCIPLE AND PROCEDURE

1. Turn the device on by pressing the O/I switch. (pic. 7)
2. When spraying begins – breathe smoothly (pic. 8).

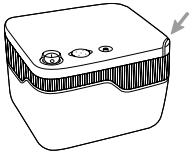


Picture 7

NOTE

If you need to rest during a treatment, place the nebulizer in the holder.

Picture 8

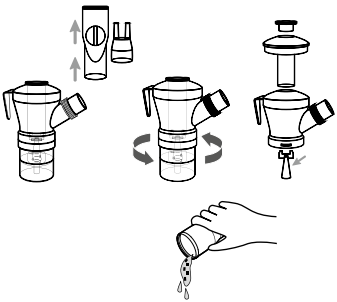


NOTE

Tighten caps on medicinal jars.

3. When treatment is complete, set the switch to the **«**O**»** position and unplug the device.
4. Before storing supplies between treatments, clean and dry the nebulizer and accessories.

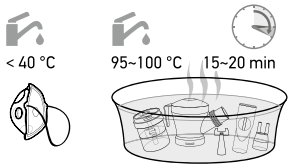
9 CLEANING AND DISINFECTION



Rinsing technique (performed after each treatment or before first use).

1. Make sure that the power-switch has been turned to the «OFF» position and the unit has been disconnected from the power source.
2. Disconnect the air tube from the nebulizer device.
3. Gently twist and pull up the cover of the nebulizer kit to open and separate.
4. Rinse the nebulizer kit and components with hot tap water.

5. Dry with clean towels or completely air dry.
6. Reassemble the nebulizer kit.



NOTE

For the first time cleaning or after the unit has been stored for an extended period of time, thoroughly clean all components, including the air tube. The nebulizer kit is dishwasher safe.

CLEANING THE COMPRESSOR

Wipe the compressor daily using a soft cloth.

NOTE

Any other form of cleaning or cleaning agents may damage the finish of the unit.

10 MAINTENANCE

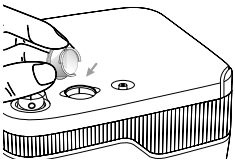
- DO NOT subject the device or its parts to any strong shocks.
- DO NOT store the device at extremely high or low temperatures, high humidity or under direct sunlight.

STORAGE AREA

NOTE

Store the packaged device in a dry area.

FILTER CHANGE



1. The filter MUST be replaced after approximately 30 operating hours or when it turns grey.
2. Open the filter holder.
3. Replace the filter with a new one.
4. Close the filter holder.

WARNING

- DO NOT use cotton or any other material.
- DO NOT wash or clean the filter.
- DO NOT operate the device without the air filter.
- The air filter SHALL NOT BE serviced or maintained while in use by a patient.

11 TROUBLESHOOTING

Problem	Solution
The device does not switch «ON»	1. Make sure the plug is firmly fitted to the wall socket. 2. Try plugging into another wall socket that is known to work. 3. Contact your service center
The device does not nebulize or it nebulizes weakly	1. Make sure the air tubing ends are properly connected to the compressor and the nebulizer base. 2. Check the amount of medicine in the cup (max. 8 ml). 3. Check whether the nebulizer nozzle is obstructed. 4. Check whether the funnel is inserted. If these possible solutions DO NOT work, contact your medical dealer

12 STORAGE, TRANSPORTATION AND OPERATION REQUIREMENTS

- The device shall be transported within the temperature range from -10 °C to +40 °C with relative humidity up to 95%.
- The device shall be operated within the temperature range from +10 °C to +40 °C with relative humidity up to 95%.
- The device shall be stored within the temperature range from +10 °C to +30 °C with relative humidity up to 95%.
- Do not expose to thermal shock.

WARNING!
After transporting or storing at low temperatures, keep the device at room temperature for at least 2 hours before switching on.

13 DISPOSAL

The symbol on the product or its package means that this product does not fall under the category of domestic waste.

- Proper disposal of the device will prevent adverse environmental and human health effects.
- In order to protect the environment, the device must not be disposed of together with domestic (household) waste. Disposal shall be provided in accordance with local regulations.
- The device must be disposed of in accordance with the EU Directive 2012/19/EU WEEE (Waste Electrical and Electronic Equipment).

If you have any questions, please contact the local waste disposal authority.

14 CERTIFICATION

This product conforms to the provisions of the EU Medical Device Directive (93/42/EEC).

Electromagnetic emissions: Guidance and manufacturer's declaration

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions		
The Device is intended for use in the electromagnetic environment specified below. The customer or the user of the Device should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class [B]	The Device is suitable for use in all establishments Including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity			
The Device is intended for use in the electromagnetic environment specified below. The customer or the user of the Device should assure that it is used in such an environment			
Immunity Test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: 2 kV Input/output lines: 1 kV	Power supply lines: ±2 kV	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	Line(s) to line(s): 1 kV. Line(s) to earth: 2 kV. 100 kHz repetition frequency	Line(s) to line(s): ±1 kV. 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (>95% dip in UT) for 5s	5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycle 70% UT (30% dip in UT) for 25 cycle <5% UT (>95% dip in UT) for 5s	Mains power quality should be that of a typical commercial or hospital environment
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
NOTE: U_T is the a.c. mains voltage prior to application of the test level			

Table 3

Guidance and manufacturer's declaration – electromagnetic Immunity				
The Device is intended for use in the electromagnetic environment specified below. The customer or the user of the Device should assure that it is used in such an environment				
Immunity Test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment - guidance**	
Conduced RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Device, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. **Recommended separation distances:** d=1.2√P; d=2√P	
Radiated RF IEC61000-4-3	10V/m	10V/m	80MHz to 800MHz: d=1.2√P 800MHz to 2.7GHz: d=2.3√P	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, d is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people				

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **Prolife PN Active** is used exceeds the applicable RF compliance level above, the **Prolife PN Active** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the **Prolife PN Active**.

b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the Prolife PN Active

The Device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Device as recommended below, according to the maximum output power of the communications equipment

Rated maximum output power of transmitter, W	**Separation distance according to frequency of transmitter, m**			
	150 kHz to 80 MHz (out ISM and amateur radio bands) $d=1.2\sqrt{p}$	150 kHz to 80 MHz (in ISM and amateur radio bands) $d=2\sqrt{p}$	80 MHz to 800 MHz $d=1.2\sqrt{p}$	800 MHz to 2.7 GHz $d=2.3\sqrt{p}$
0,01	0.12	0.2	0.12	0.23
0,1	0.38	0.632	0.38	0.73
1	1.2	2	1.2	2.3
10	3.8	6.32	3.8	7.3
100	12	20	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

Table 5

Guidance and manufacturer's declaration - electromagnetic Immunity							
The Device is intended for use in the electromagnetic environment specified below. The customer or the user of the Device should assure that it is used in such an environment							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band a) (MHz)	Service a)	Modulation b	Modulation b) (W)	Distance (m)	Immunity Test level (V/m)
	385	380 – 390	TETRA 400	Pulse modulation b) 18 Hz	1,8	0,3	27
	450	380 – 390	GMRS 460, FRS 460	FM c) ± 5 kHz deviation 1 kHz sine	2	0,3	28
	710 745 780	704 – 787	LTE Band 13, 17	Pulse modulation b) 217 Hz	0,2	0,3	9
	810 870 930	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 z	2	0,3	28
	1720 1845 1970	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation b) 217 Hz	2	0,3	28
	2450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation b) 217 Hz	2	0,3	28
	5240 5240 5785	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation b) 217 Hz	0,2	0,3	9

NOTE: If necessary to achieve the **immunity test level**, the distance between the transmitting antenna and the **me equipment** or **me system** may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) 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
The **manufacturer** should consider reducing the minimum separation distance, based on **risk management**, and using higher **immunity test levels** that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher **immunity test levels** shall be calculated using the following equation: $E=6/d\sqrt{P}$. Where P is the maximum power in W, d is the minimum separation distance in m, and E is the **immunity test level** in V/m

15 WARRANTY

The warranty period for the main unit of the Compressor Nebulizer **Prolife PN Active** is 5 years from the date of sale, providing that all operation conditions specified in this instruction manual are strictly observed. The warranty is only valid if there is a cashier's receipt and a warranty certificate completed by an official representative to confirm the date of sale. The warranty does not apply to the consumables, parts and components subject to periodic replacement, such as: pediatric mask, adult mask, replaceable filters, nebulizer, airtube, mouthpiece, nosepiece, package.

AFTER-SALES AND FREE MAINTENANCE SERVICE IS NOT PROVIDED IN CASE OF:

- using the device with violation of requirements specified in the instruction manual;
- damage caused by deliberate or erroneous actions of the consumer due to mishandling or negligence;
- evidence of mechanical damage, dents, cracks, chips, etc. on the device casing, opening of the casing, disassembly, unauthorized repair, ingress of moisture into the casing or effect of corrosive substances, or any other unauthorized interference, as well as in other cases of violation by the consumer of storage, cleaning, transportation and operation requirements specified in the instruction manual;
- ingress of oils, dust, insects, liquids (not intended for use with the device) and other foreign objects into the device.

THE WARRANTY DOES NOT COVER THE DEFECTS OR MALFUNCTION CAUSED BY:

- normal wear and tear of the components with limited service life;
- damage of accessories which are not an integral part of the device (children mask, adult mask, replaceable filters, nebulizer, air tubing, mouthpiece, nosepiece, package);
- using defective, worn out accessories and pieces;
- force majeure circumstances (accident, fire, flood, electric line fault, etc.).

WARNING

Follow the instructions precisely to ensure reliable and long-term operation of the device.

In case of abnormal operation of the device, please contact the seller.

For repair and maintenance, please contact a specialized after-sales service.

The manufacturer reserves the right to make structural changes of the device.

Manufacturer:
Globalcare Medical Technology Co., LTD.
7th Building, 39 Middle Industrial Main Road, European Industrial Zone, Xiaolan Town, 528415 Zhongshan City, Guangdong Province, People's Republic of China.

EC REP **Authorized Representative in the EU:**
Donawa Lifescience Consulting Srl Piazza Albania, 10, 00153 Rome, Italy.

Importer in the EU:
Self Control Ltd. 34, Brezovskaya str., 4003 Plovdiv, Bulgaria.

CE 0123 IP21

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