prolife

COMPRESSOR NEBULIZER

Prolife PN Compact

en Instruction manual

MEDICAL DEVICE NAME

Compressor nebulizer **Prolife PN Compact**.

DESCRIPTION

The nebulizer is intended for inhalation administration of medicine for asthma, chronic obstructive pulmonary disease (COPD) and other respiratory diseases. Before inhalation, consult with your doctor about the permissibility of administering the medicine through a nebulizer. Follow your doctor's instructions when choosing the dose and mode of administration of the medicine by inhalation.

Please read carefully this manual before using the nebulizer.

MEDICAL PRECAUTION

The data contained in this document, or this device should not be used for self-diagnosis and treatment, or as a basis for choice of a medicine. At suspicion on any disease requiring inhalation of a medicine, please consult a doctor.

NOTE

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

PRESCRIPTION

Its used for inhalation administration of medicine for respiratory diseases.

APPLICATION AREA

Therapy, otolaryngology and pulmonology.

MAIN TECHNICAL CHARACTERISTICS

Type	**Compressor nebulizer**
Model	**Prolife PN Compact**
Mains adapter	DC 5 V, 2 A
Voltage	AC 100~240 V, 50-60 Hz
Wattage, W	10
Sound level (1 m from Prolife PN Compact), dBA	≤ 45
Operative flow rate, l/min	2.5
Operating temperature	+10 °C – +40 °C
Humidity	10 ~ 95% RH
Operating atmosphere pressure, hPa	700–1060
Storage conditions	-20 °C to +60 °C, 10% to 95% RH
Dimension (LxWxH), mm	98x57x50
Weight (without accessories), g	170
Capacity of medicine cup, ml	6
Particle size (MMAD), µm	≤ 2.9
Average nebulizing rate, ml/min	≥ 0.3 (0.9 % of NaCl)
Complete set	Nebulizer, air hose, mouthpiece, nosepiece, children mask, adult mask, adapter for nozzle, bag
Service life	Main unit – 400 hours; nebulizer, baffle, nebulizer cover, adapter for nozzle – 1 year; air hose, mouthpiece, nosepiece – 1 year; adult/children mask – 1 year

The manufacturer reserves the right for technical changes in the design and the complete set of the device.

Depending on a medicine (aqueous solution, suspension or high-viscosity substance), the aerosol delivery may vary.

COMPLETE SET. SERVICE LIFE

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

Component parts and components of the main product that are not subject to periodic replacement:*

- Main unit – 1 pc.
- Power cable – 1 pc.

Periodically replaced parts and components:*

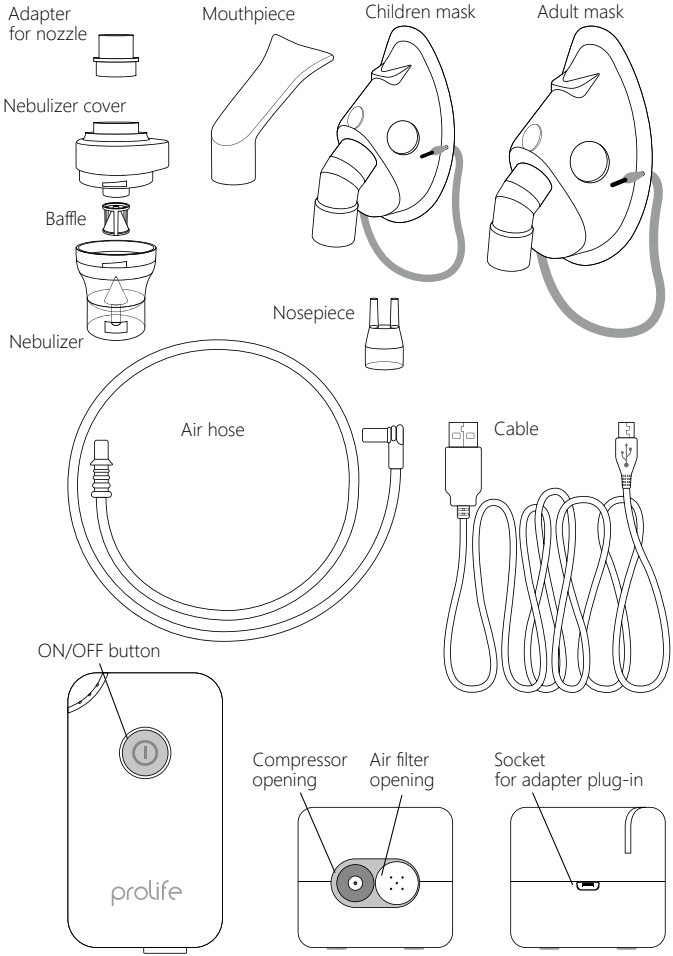
- Children mask – 1 pc.
- Adult mask – 1 pc.
- Nebulizer – 1 pc.
- Baffle – 1 pc.
- Nebulizer cover – 1 pc.
- Mouthpiece – 1 pc.
- Nosepiece – 1 pc.
- Air hose – 1 pc.
- Adapter for nozzle – 1 pc.

***Parts and components replacement interval is determined by their service life specified in the section below.**

The service life of the components may vary depending on the intensity of use. When using the device for spraying 2 ml of saline 2 times a day for 10 minutes at room temperature (23 °C), the service life of the components is as follows:

- main unit — 400 hours
- nebulizer, baffle, nebulizer cover, adapter for nozzle — 1 year
- air hose, mouthpiece, nosepiece — 1 year
- adult/children mask — 1 year

***Note: the service life of the air filter can be significantly lower than specified due to the use of the device in a dusty environment.**


Adapter
for nozzle
Mouthpiece
Children mask
Adult mask
Nebulizer cover
Baffle
Nebulizer
Nosepiece
Air hose
Cable
ON/OFF button
prolife
Compressor
opening
Air filter
opening
Socket
for adapter plug-in

PREPARATION FOR USE

Before first use or after long-term non-use of the nebulizer it must be prepared for use according to the instructions set in the «Cleaning» section of this manual.

NOTE

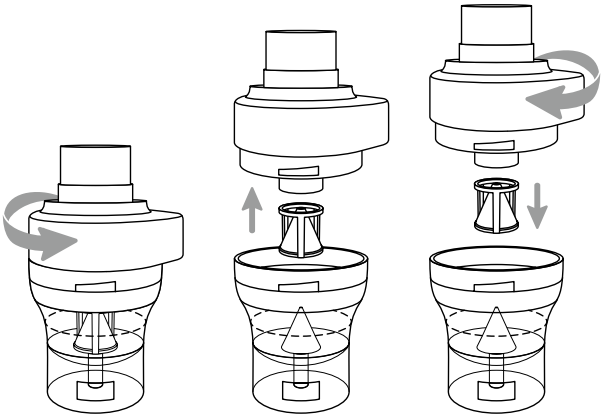
Before cleaning, assembling and after each use of the device make sure it is turned off and unplugged.

1 Place the main unit on a flat, stable surface.

2 Gently open the nebulizer cover.

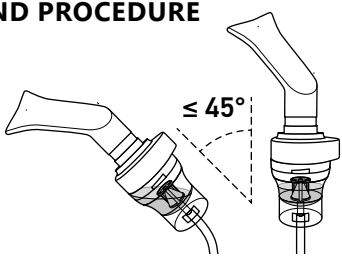
3 Be sure the baffle is properly installed in the sprayer. The rod inside the nozzle should fit into the groove in the bumper.

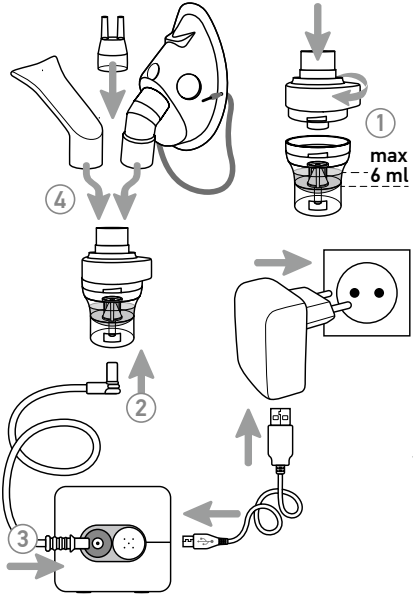
Gently twist two parts of sprayer. Be sure the two sections are fit securely.



OPERATION PRINCIPLE AND PROCEDURE

The Compressor nebulizer may be operated at an inclination angle of the nebulizer of up to 45 ° against the vertical line. If the inclination angle exceeds 45 °, aerosol will not be generated.





1 Add the inhalation solution to the sprayer. Capacity of the sprayer is 6 ml.

2 Connect one end of the air hose to the air hose connector.

3 Connect the other end of the air hose to the compressor opening.

4 Attach the mouthpiece, mask or nosepiece to the adapter for nozzle.

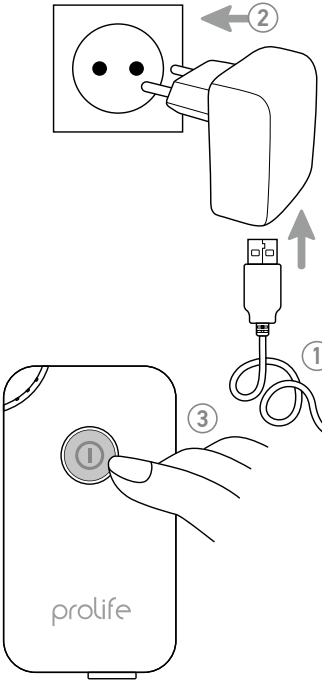
NOTE

If several inhalation sessions are required, it is recommended to make a 30-minute break after each session.

After each use:

- turn off the device and unplug the power cable;
- let the device cool down completely;
- gently disconnect the air hose from the nebulizer and empty the residues of residual liquid from nebulizer;
- clean the device according to the instructions of this manual.

ADAPTER FOR MAINS*



1 Connect the power cable to the power supply unit and the nebulizer. Use only an adapter with the characteristics recommended by the manufacturer (see chapter 12 of this manual).

2 Insert the adapter plug into the socket.

3 Press ON/OFF button to turn on the device.

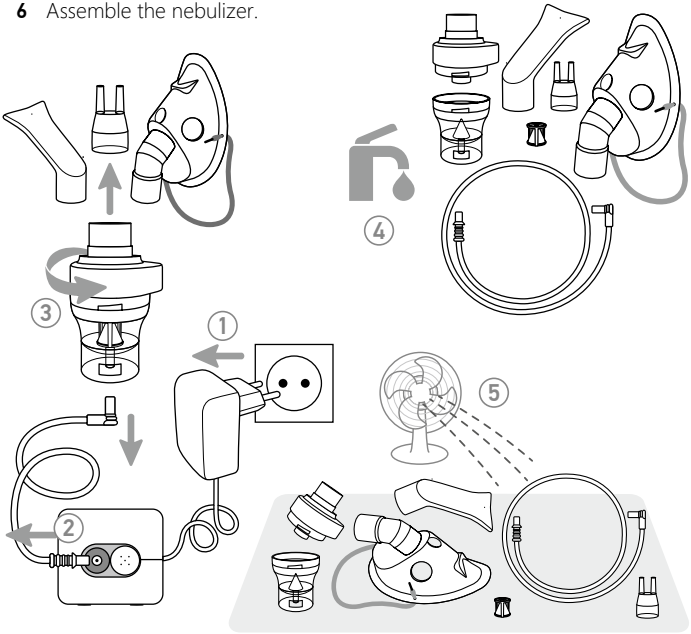
NOTE

*The adapter for connecting to the mains is supplied optionally.

CLEANING

Flush the device after each procedure or before its first use.

1. Make sure the device is turned off and unplugged.
2. Disconnect the air hose from the main unit of teh nebulizer and the sprayer.
3. Gently twist and pull the nebulizer cover to open it.
4. Rinse the nebulizer sections under running hot water. The air tube should be wiped with a damp cloth on the outside. Do not flush the air tube under any circumstances.
5. Wipe the sections with a clean towel or allow them to dry completely in the air.
6. Assemble the nebulizer.



NOTE

Clean thoroughly all the nebulizer sections and pieces/caps, during the first cleaning and after a long-term storage of the device.

CLEANING OF THE MAIN UNIT

Wipe the dirty the main unit with a soft cloth.

NOTE

Any other cleaning method or use of a detergent may affect the appearance and performance of the device.

GUIDELINES FOR SAFE OPERATION

- Protect the device against water ingress 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 with empty sprayer.
- 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 touch the power switch with wet hands.
- Do not disassemble or attempt to repair the device yourself.

USAGE PRECAUTIONS

- 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

any improper use of with the device, its accessories, as well as factory package.

- Avoid contact of medicines, vapours or aerosol with eyes.
- The maximum capacity of the sprayer is 6 ml. Do not exceed this amount.
- Always check the expiration date of medicines before inhaling.
- Unplug the device as soon as you feel discomfort or experience reduced general condition during inhalation.
- Do not use the device if the air hose is curved.

STORAGE PRECAUTIONS

- Keep away from direct sunlight, high temperatures and humidity.
- Keep out of the reach of children.
- Unplug the device when not in use.

CLEANING PRECAUTIONS

- Check mouthpiece, nebulizer and other auxiliary components before each use. Contaminated or worn out components must be replaced.
- Do not immerse the device in liquid.
- 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 medicine cup after each use.
- Do not store wet air hose or air hose with medicine residues. This may cause bacterial infection.

TROUBLESHOOTING

Please note that some problems can be solved without a specialist involvement.

Problem	Solution
The device does not turn on	Make sure the adapted is plugged into the socket
The device does not nebulize or it nebulizes weakly	Check the medicine in the cup
	Check the nebulizer for damage
	Check the position of the baffle inside the nebulizer
	Make sure the air hose and other auxiliary accessories are properly connected
	Check for medication in the nebulizer.
	Check the position of the baffle inside the sprayer.
	Make sure the air tube and other accessories are properly connected.
	Replace sprayer.
	Check the adapter for compliance with the recommended parameters (see chapter 12 of this manual)

Electric shock protection class:

 Device class II.

Type-BF device:

 Mouthpiece and mask.

Ingress protection rating:

IP21.

Degree of safety in the presence of flammable aesthetic agents or oxygen:

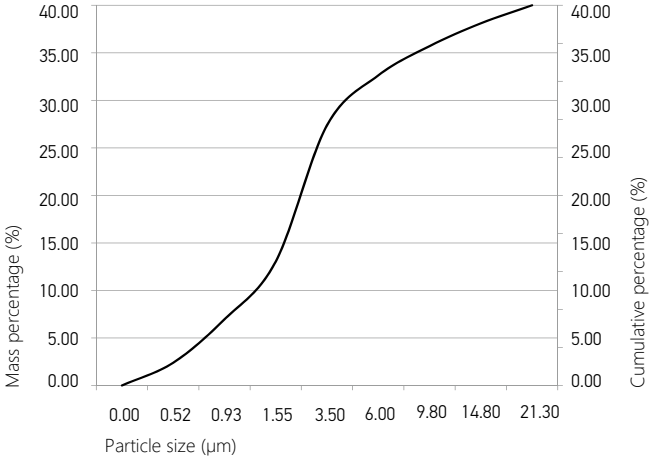
Not AP/APG (do not use with flammable aesthetic agents or oxygen).

TECHNICAL DETAILS

Measurements of the particle size using the cascade impactor for **Prolife PN Compact** according to BS EN 13544-2009 «Respiratory equipment – Part 1: Nebulizing systems and their components», Annex CC.3, based on the measurements of the particle size with the cascade impactor are as follows:

Size of nebulized particles	MMAD ≤ 2.9 µm (MMAD – Mass Median Aerodynamic Diameter)
Capacity of medicine cup	Max. 6 ml

Distribution of particles



ELECTROMAGNETIC EMISSIONS: GUIDANCE AND MANUFACTURER'S DECLARATION

Compressor nebulizer **Prolife PN Compact** is intended for use in the electromagnetic environment specified below.

The customer or user of **Prolife PN Compact** should assure that it is used in such environment.

Emission test	Compli-ance	Electromagnetic environment – Guidance
RF emissions CISPR 11	Group 1	Compressor nebulizer **Prolife PN Compact** 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	Compressor nebulizer **Prolife PN Compact** is suitable for use in all establishments other than domestic, and may be used in domestic establishments 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	

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines Not applied	Mains power quality should correspond to the standards of the public power supply networks
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) Not applied	Mains power quality should correspond to the standards of the public power supply networks

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should correspond to the standards of the public power supply networks. If the user of the device requires continued operation during power mains interruptions, it is recommended that **Prolife PN Compact** to be powered from an uninterruptible power supply or a battery
Power frequency magnetic fields (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields of **Prolife PN Compact** should be at levels characteristic of a typical public use systems

NOTE: U_T – is the AC mains voltage prior to application of the test level.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz – 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of **Prolife PN Compact** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.2 \sqrt{P}$, $d = 1.2 \sqrt{P}$ 80 MHz – 800 MHz, $d = 2.3 \sqrt{P}$ 800 MHz – 2.5 GHz, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz – 2.5 GHz	3 V/m	

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 **Prolife PN Compact** is used exceeds the applicable RF compliance level above, **Prolife PN Compact** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating **Prolife PN Compact**.

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

RECOMMENDED SEPARATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND COMPRESSOR NEBULIZER PROLIFE PN COMPACT

Compressor nebulizer **Prolife PN Compact** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of compressor nebulizer **Prolife PN Compact** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and compressor nebulizer **Prolife PN Compact** as recommended below, according to the maximum output power of the communications equipment. For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined 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.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz – 80 MHz $d = 1.2 \sqrt{P}$	80 MHz – 800 MHz $d = 1.2 \sqrt{P}$	800 MHz – 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

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.

WARNING

This symbol on the product means that this product is an electronic device which must be disposed of in accordance with Directive 2012/19/EU at the local waste disposal utility.

WARRANTY

The warranty period is indicated in the warranty certificate. The warranty period is established from the date of sale, providing that all operation conditions specified in this instruction manual are strictly observed. The warranty is valid subject to availability of a warranty card filled out by a duly authorized representative confirming the date of sale and also of the relevant receipt.

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 hose, mouthpiece, nosepiece, package);
- using defective, worn out accessories and pieces;
- force majeure circumstances (accident, fire, flood, electric line fault, etc.).

Date of manufacture and importer information are specified on the individual package.

Manufacturer information:

Globalcare Medical Technology Co., Ltd., 7th Building, 39 Middle Industrial Main Road, European Industrial Zone, Xiaolan Town, 528415 Zhongshan City, Guangdong Province, China.

Authorized Representative in the EU:

EC REP Donawa Lifescience Consulting Srl, Piazza Albania, 10, 00153, Rome, Italy.

Prolife® is the registered trademark by Montex Swiss AG, Tramstrasse 16, CH–9442, Berneck, Switzerland.

LIST OF SYMBOLS

Symbol	Meaning
CE 0123	The product complies with Directive 93/42/EEC on Medical Devices.
EAC	The product complies with TR CU 020/2011 «Electromagnetic compatibility of technical equipment».
	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.
	Type-BF device.
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.
	Device class II (electric shock protection class).
	Note/Warning.
	Keep away from direct sunlight.
	Read and understand the User Manual before use.
EC REP	European Authorized Representative.
	Manufacturer.

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