OPERATING INSTRUCTIONS MANUAL

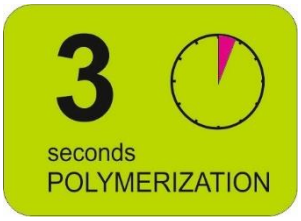
BLUEDENT XPRESS cable
24V / 12V / 220V

Dental curing light

Ref.#200-008b24, #200-008b12, #200-008m

BG LIGHT LTD

Thank you for trusting our products!
Carefully read this Operating instructions manual
before installing and operating the unit
to use and maintain it successfully!
Save this Operations guide for your reference it in the future.



CONTENTS:

I. UNIT DESCRIPTION AND FUNCTION

Dental curing light BLUEDENT XPRESS cable is a medical device - specialized light source for intraoral polymerization of dental materials, sensitive to the blue part of the light spectrum.

The device is intended for use only by a qualified dental practitioner and in a dental practice.

BLUEDENT XPRESS cable consists of Handpiece with cable (and adapter for 220V version) and Holder for attaching to the dental chair.

The device is produced in conformity with MDR (EU) 2017/745.

II. TECHNICAL DATA

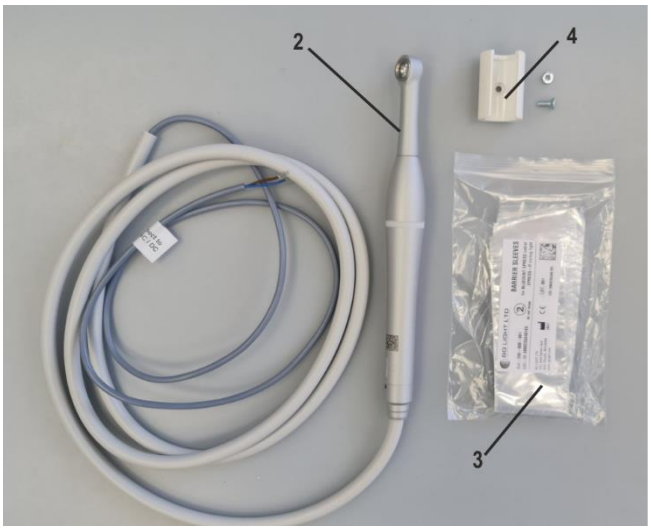
1. Operating voltage:
– 24V AC/DC or 12V AC/DC or 110-240V / 50-60Hz
(depending on specification of device)
2. Power consumption:
- 24V AC/DC – 0,35A
- 12V AC/DC – 0,55A
- 110-240V / 50-60Hz – 0,115A
3. Dimensions of handpiece:
- Head of emitting handpiece – 14 x 16 mm
- max diameter of handpiece – 25 mm
- Length - 225 mm
4. Weight of handpiece – 150g
5. Polymerization modes – RAMP (R), HYPER (H)
6. Emitted light – blue, visible spectrum, 410-490 nm
7. Light source – 2 band LED module with reflector optics.
8. Light intensity:
- RAMP mode – up to 1500 mW/sq.cm with gradual increase of intensity
- HYPER mode – up to 3500 mW/sq.cm with immediate increase of intensity
9. Emitting time:
- RAMP mode - 10 / 20 sec. /±10%
- HYPER mode - 3/3+3* sec. /±10% - *with 1sec pause
10. Visual indication - color indication ring and audible signal every 10 sec / 3 sec depending on chosen work mode.
11. Working mode (1 min. work / 10 min. pause)
12. The device has an option to turn off the sound signal:
- Turning off sound signal: Hold down the Start / Stop button before turning on the power. The power of the device is switched on (with the Start / Stop button pressed) and it is held for about 5 seconds until a sound signal is heard. From this moment the device is in quiet mode. The sound is turned on in the same way.

The manufacturer of this unit declares to provide on request all additional necessary technical documentation / information which will help the user's technical staff to service the parts of the unit which the manufacturer has claimed to be a subject for repair.

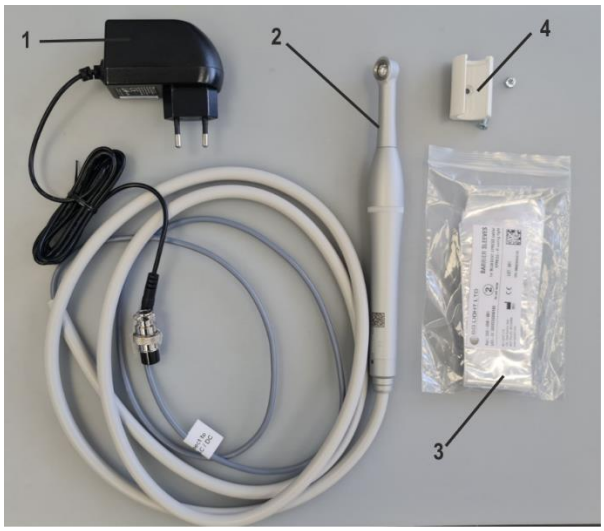
III. COMPLETE SET

1. Charge 100-240V AC / 24V DC - 1 pc. (for 220V model with adapter)
2. Emitting handpiece - 1 pc.
3. Barrier sleeves - 50 pcs.
4. Holder - 1 pc.
5. Operations guide - 1 pc.

Version 24V and 12V



Version 220V with adapter



<u>Control and indication:</u>

1. Emitting LED module
2. Start / Stop button
3. Illuminated indicator ring
4. Cable

IV. SAFETY PRECAUTIONS

GENERAL WARNINGS:

BLUEDENT is a Class I medical device and it meets the strict requirements of the Medical Devices Regulation - MDR (EU) 2017/745. In order to be used safely for staff and patients, the following rules must be observed:

- Do not allow unauthorized and untrained personnel to use the device to avoid risks.
- Disconnect the device from the mains after completing the procedures.
- Do not use or store the device in a dusty environment.
- Do not expose the device to direct sunlight.
- Do not spray disinfectant directly into the device - only rubbing with a swab drained of disinfectant is acceptable.
- Do not get wet or drop liquid on the device, cables, adapter to avoid electric shock or damage to the device.
- Store the device in a dry place, moisture can cause electric shock and damage.
- In case of a problem, disconnect the device from the mains, do not to make attempts to repair, take the device to a service center.
- The device must not be used if any of its parameters are not normal (timer, light intensity, heat radiation).
- The device must not be covered, the cooling openings must not be closed so as not to cause the device to overheat and ignite.
- Strong electromagnetic fields in the building can cause interference and malfunction of the device. If their source cannot be determined, change the location of the device and plug it into another socket or other room, even in another building.
- Opening and repairing the appliance may only be carried out by authorized service technicians from the manufacturer.
- Only original BLUEDENT parts must be used when replacing defective parts. The warranty of the device does not cover the damage caused by the use of non-original spare parts. The device or any of its parts must not be disassembled while it is connected to the mains!
- Before each patient, the emitting window must be disinfected (with a disinfectant).
-  According to Directive 2012/19/EEC, this symbol indicates that the product should not be disposed as a general waste at the end of its lifespan. The product must be taken to a specialized center for the separate collection of electrical and electronic equipment according to local regulations. Proper disposal of equipment that is no longer used prevents negative consequences for the environment and human health!

- In accordance with the requirements of MDR 2017/745, user and / or the patient must report any serious accident that have occurred during us of the device to the manufacturer and the competent authority of the Member State in which the user/patient is established.
- All packaging materials of the product must be kept away from children to avoid risks of injury / suffocation.

SAFETY MEASURES AND RISKS

The device must be used in strict accordance with the Operating Instructions Manual.

1. Electrical safety

Before starting the appliance, make sure that the voltage and the type of plug correspond to the mains supply in the country. Electrical safety is ensured by class II protection against electric shock according to EN 60601-1.
BLUEDENT must only be operated indoors, under the following conditions:
- temperature from + 10 ° to + 40 ° C;
- relative humidity 30 - 75%;
- lack of dust in the room;
- atmospheric pressure 700 - 1060 hPa;
- absence of chemically active and flammable substances;
- no part of the device should be wetted or immersed in water;
- the device or any of its parts must not be disassembled while it is connected to the mains!

Protect the cables of the appliance from insulation damage and breakage from sharp objects, strong pulling, rodents, chemicals. If such damage is noticed on the electrical cables, it is necessary to take the device immediately to the company service. The device must not be used with damaged cables.
In case of thunderstorms, the procedures must be stopped and the plug must be disconnected from the mains.
Risk: Failure to comply with these instructions may result in electric shock to users of the device.

2. Light radiation

BLUEDENT is a source of extremely intense light in the blue range, to which the human eye has a high sensitivity. This results in serious measures to be taken for patients, medical staff and accidentally nearby people, animals and plants.
As such, use protection goggles for the operator, and for the patient goggles, mask and high-factor sunscreen.

Irradiation of the eyes and skin with intense light carries a risk of damage from light and heat.
The light should never be directed at the eyes! Irradiation should be limited to the workplace area. The special safety goggles from the set that meet the requirements must be used:
- to cover the eyes and temples tightly, even if the person is wearing optical glasses.
- be made of volumetric colored impact-resistant plastic.
- do not transmit light with a wavelength of 380 - 600 nm.
- reduce the intensity of the blue spectrum by more than 100 times.
- have a stable mechanical structure, no scratches, cracks and damage to its surface.
The device can be used only after a doctor's consultation on or by persons suffering from photo-biological reactions; persons taking photosensitive drugs; persons undergoing cataract surgery, persons with retinal diseases, etc.
The risk of improper irradiation is severe eye irritation, temporary spots in the visual field, severe visual impairment in direct radiation, to loss of vision.

3. Thermal radiation

The thermal effect is due to the absorption of the energy of the blue light in the tissues, during which the energy is converted into heat. The risk is only with prolonged overdose.
Risk of pain, burning of soft tissues.

4. Fire safety

- Keep the device away from solvents, flammable liquids and powerful heat sources.
- Do not expose to direct sunlight.
- Do not allow liquids and detergents to enter the device, as this may cause a short circuit and fire or cause potentially dangerous damage.
- If the product emits an odor or smoke – disconnect from the mains, do not attempt to repair it, take it to a service center.
Risk of fire, explosion and damage.

5. Contraindications:

- The device can be used only after medical consultation on or by: persons with implanted cardiac pacemaker; persons suffering from photobiological reactions; persons taking photosensitive drugs; persons undergoing cataract surgery; persons with retinal diseases; people with allergies; people who have recently undergone cosmetic surgery on the face or lips, including injections of hyaluronic acid or botox; people with very sensitive skin or dermatitis, etc. If you are taking photosensitizers or medicines, check the package leaflet.

V. PREPARATION AND SEQUENCE OF OPERATION

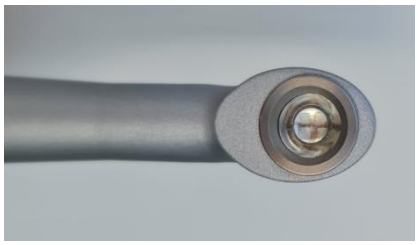
BLUEDENT XPRESS cable is designed for use as a cable powered unit to be built-in the dental chair (version 24V and 12V) or as a free-standing device (version 220V with adapter).

1. Take the curing light out of the packing. The stand is fixed on a suitable vertical surface with the included fasteners.

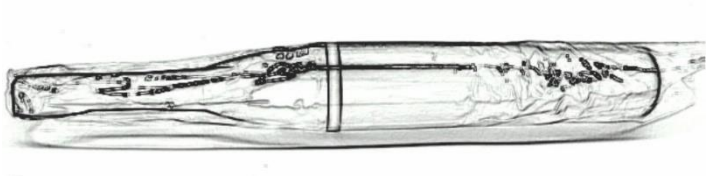
2. By turning off the power to the dental chair, the power to the BLUEDENT XPRESS cable (version 24V and 12V) is also turned off.

For version 220V - at the end of the day the charging adapter should be disconnected from the mains.

The front of the Emitting handpiece does not rotate!
Do not use physical force and try to rotate it.



3. A new barrier sleeve is placed on the front of the probe before each patient. It is for single use only and is marked with the appropriate sign.



4. BLUEDENT XPRESS cable has **2 work modes**.

They are indicated according to the color of the illuminated ring on the handle:

GREEN - RAMP mode.
RED color - HYPER mode.
BLUE color - change mode or beep.

The device wakes up by pressing the Start / Stop button once. Select the desired operating mode by pressing and holding (2 sec.) The Start / Stop button.

RAMP mode - smooth start (slow increase in light intensity) helps reduce stress in the photocomposite.

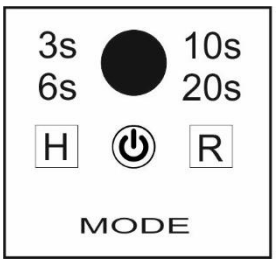
HYPER mode - maximum light intensity - 3500 mW / sq.cm - suitable for working with nano and liquid photocomposites. The protective pause between every 3 seconds. It does not allow thermal damage to the tooth tissues.

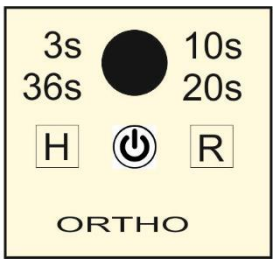
5. The curing light is activated by briefly pressing the Start / Stop button on the handpiece.

Choice of time:

In RAMP mode:
- with a single press (1x) - 10 sec.
- when pressed twice (2x) - 20 sec.

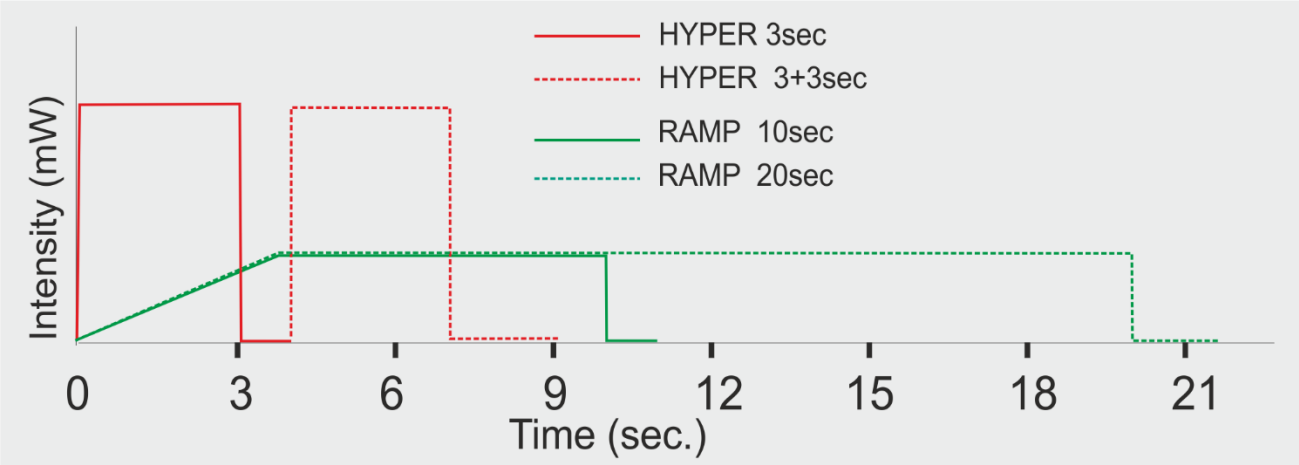
In HYPER mode:
- with a single press (1x) - 3 sec.
- when pressed twice (2x) - 3 + 3 sec.





After activating the button, blue light appears.

In HYPER mode, after each cycle 3 / 3 + 3 sec., there is a 3 sec pause which is a protective time against overheating of the dental pulp. The light ring flashes and the device cannot be activated.



6. Indication

- Color indication ring

Deactivated mode - Color indication ring is not lit.	
RAMP mode	
HYPER mode	
Protection pause in HYPER mode	
Sound signal.	
Overheating – **Thermal protection activated**, wait until device cools down.	

7. The handpiece is directed to the place designated for irradiation, as the tip of the device is brought as close as possible to the object of irradiation /4 to 7 mm/, and after a few seconds can also be irradiated by contact.

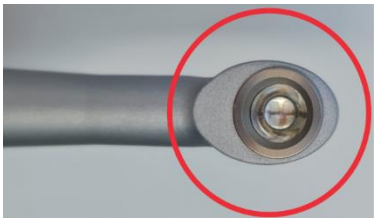
8. Stop the curing light at any time by pressing the Start / Stop button again.
If device is not stopped preliminary, it will stop after preselected 10/20 or 3 / 3 + 3 seconds.

9. The curing light is switched off at the end of the day after turning off power of the dental chair or disconnection of the adapter from the mains (depending on specification of device).

10. **Overheating protection**
The unit is equipped with overheating protection, which is activated if the temperature of the LED module rises up to 40-45°C. When overheating protection is activated the color ring will blink in yellow next 60sec, then is deactivated until the temperature of the handpiece reaches 35°C. It is necessary to wait for the device to cool down.

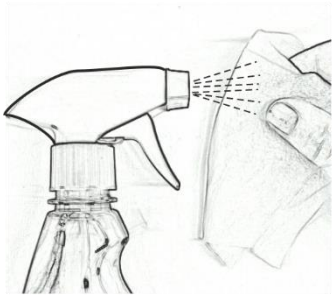
VI. ROUTINE CARE AND MAINTENANCE

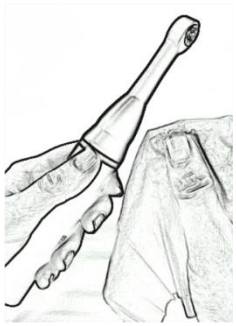
1. Cleaning the emitting tip
Clean the emitter glass daily with an alcohol swab dipped in alcohol. Adhesive photocomposite is not allowed - if there is one, it should be carefully removed with a blunt, non-metallic object.



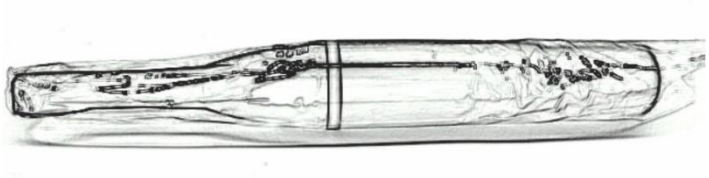
2. Cleaning of the unit.
For disinfection of the unit, spray the disinfection agent onto a piece of soft cloth / cotton and clean the handpiece and power adapter.
Do not use abrasives or solvents as these may damage the plastic parts of the unit!

Do not spray directly onto handpiece or in button / USB charge connector!





To avoid cross-contamination, it is mandatory to use disposable barrier sleeeve on the handpiece, new one for each patient.



VII. WARRANTY CONDITIONS

1. Warranty period of BLUEDENT dental curing light is 24 (twenty four) months from the date of purchase. If date of purchase is not written, warranty starts at date of production.

2. During the warranty period the replacement of the defective parts is done free of charge by manufacturer's service. Lightguide is not covered by warranty. LED module and battery have 6 months warranty.

3. If during the guarantee period the unit is damaged, due to incorrect operation (mechanical, chemical, thermal or electrical damages), damage caused by improper use, storage or any other reasons in user's fault, the repair is paid by the user. If any damage is noticed on electric cables, the device must be brought immediately to manufacturer's service. The device must not be used if cables are damaged.

3.1 If liquids, aggressive and flammable substances and their vapors have entered the device, the battery must be removed immediately and sent to the manufacturer’s service where the damages are established. In case of such damage, the warranty is lost.

3.2 No damages or complaints are accepted as a result of electric shocks, thunderstorms, non-compliance with electrical safety measures or insufficient protection of patients, personnel and other persons from light radiation.

3.3 Claims due to improper or insufficient security and care, protection and security during transport, unpacking, relocation, operation and storage of the device are not accepted. The warranty is void for the above events.

3.4 The device must only be transported to manufacturer’s service only in original packaging in order to avoid unwanted damage. The light guide must be packed separately from the cordless handpiece. The warranty card must be presented (this Guide, with completed Chapter XII BLUEDENT data) or a copy of the sales invoice showing the serial number of the device.

3.5 When carrying out repairs by unauthorized persons outside the company service or if non-original elements / parts are used, the user loses the right to free service.

4. The manufacturer provides its customers once a year (and in case of a situation - immediately) to check in the company service whether the performance of the devices is within the acceptable limits.

5. The manufacturer does not owe compensation for lost profits in case of damage or incompleteness operation of the device, whatever the cause.

6. In case of disputes in connection with the application and interpretation of this Operating instruction manual, they will be decided by the court in Plovdiv, by virtue of the current Bulgarian legislation.

7. The warranty service is performed in the company service at the address:

BG LIGHT LTD
155, Vasil Aprilov blvd
4027 Plovdiv
Bulgaria
tel: +359 32 644089, +359 888 809256
email: office@bglight.com
www.bglight.com

VIII. SERVICE DATA

IX. SYMBOLS

	Manufacturer BG LIGHT LTD, 155, Vasil Aprilov blvd., 4027 Plovdiv, Bulgaria
	Pursuant to Directive 2012/19/EU, this symbols shows that the product must not be disposed of as urban waste at the end of its operating life.
	Pay attention to the instructions accompanied by this symbol.
	Fragile!
	Product with CE mark.
	Applied part type BF according to the classification for electrical safety
Ω	Ohm (electric resistance unit)
s	Second (time unit)
W	Watt (power unit)
Hz	Hertz (frequency unit)
mm	Millimeter (length unit)
A	Amper (electric current unit)
V	Volt (electric voltage unit)
Pa	Pascal (atmosphere pressure unit)
°C	Degrees Centigrade (temperature unit)
g	Gram (weight unit)
SN	Serial number
LOT	Lot

X. FAQ

Problem	Solution
No response by button starting	Lack of power supply – check power supply of dental chair or mains. Defective button or mechanically damaged - check for dust or liquid entered around the button. If button continues not to respond - send the device to service.
The button does not respond properly	When working without barrier sleeves, the problem with the button may be the entry of composite, adhesive or disinfectant liquid when the device is used without protective nylons. You need to clean with a cotton swab soaked in alcohol. If button still does not respond correctly - send the device to service.
Does not allow starting in HYPER mode, the ring flashes red.	In this mode there is a 3sec protection time during which the device cannot be started in order to prevent soft tissue overheating.
Meaning of INDICATION ring colors:	green - RAMP mode - 1500mW/cm2 red – HYPER mode 3500mW/sq.cm red blinking – protection pause blue continuously - 100% charged battery yellow - LED module overheating
Slow blinking of blue light of main LED	This is indicator that battery will allow only 5-10 cycles before full discharge. Need urgent charge.
Weak curing effect	It is necessary to clean the window of emitting tip with a non-metallic object and to clean the adhered composite or other

	with alcohol. If the result is poor - send the device to the service.
The patient feels discomfort during curing process especially during long curing time 20-30sec	Need to cure at short cycles 10sec or less with short pauses 1-3sec. Sensibility is higher if light is near dental pulp and is decreased by every layer. Use RAMP mode.
Power cord or mains adaptor is damaged	Send to service.
Entering some liquid into device	Send to service.
After drop on the floor device is not working properly	Send to service.

XI. DECLARATION OF CONFORMITY

BG LIGHT LTD Bulgaria, 4027 Plovdiv 155, Vasil Aprilov blvd. office@bglight.com	**Declaration of conformity**	**TD 7.2** *Revision* ***02***

CE

Manufacturer: **BG LIGHT LTD**

Address: 155, Vasil Aprilov blvd., 4027 Plovdiv, Bulgaria
Tel.: +359 32 644089, Fax: +359 32 641913
BULSTAT 115841960, VAT N: BG 115841960

Product: **BLUEDENT XPRESS cable – LED curing light**

Basic UDI: 3800501374200000VX
Classification: Active device of Class I of the to Regulation on medical devices - MDR (EU) 2017/745
Classification is done by the manufacturer according to Regulation on medical devices - MDR (EU) 2017/745, Rule 13, Annex VIII.

Notified body: TUV NORD Polska Sp. z o.o., ul.Mickiewicza 29, 40-085 Katowice, Poland.

This Declaration of conformity is valid only in combination with our certificates of Notified body TUV NORD Polska Sp. z o.o. Certificates N: AC090 100/1971/4047/2020, AC090 MD/1971/4047/2020, TNP/MDD/0334/4047/2020.

The manufacturer declares under its sole responsibility that the products are developed and produced in conformity with Regulation on medical devices - MDR (EU) 2017/745 and the following applicable standards:

EN 60601-1:2006 +AC:2010+A1:2013+A12:2014	Medical electrical equipment - Part 1: General requirements for safety.
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
EN 62304:2018	Medical device software. Software life cycle processes.
EN 62353:2015	Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment.
EN 62366-1:2015+AC:2016	Medical devices. Application of usability engineering to medical devices.
EN ISO 14155:2011+AC:2011	Clinical investigation of medical devices for human subjects. Good clinical practice.
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices.
CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971.
EN ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements.
EN ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer.
EN ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
ZMI	Закон за медицинските изделия на РБългария (от 31.05.2015)
ISO 9001:2015	Quality management systems – Requirements.
ISO 13485:2016	Medical devices. Quality management systems. Requirements for regulatory purposes.
Directive 2012/19/EC	Directive on waste electrical and electronic equipment (WEEE).

All company products are manufactured under the current Quality Management System, ISO 9001 and ISO 13485.

Dipl. Eng. Plamen Karaivanov
Manager
BG LIGHT LTD

BG LIGHT LTD
БГ ЛАЙТ ООД

01.09.2021
Plovdiv, Bulgaria

XII. BLUEDENT DATA

SN:	
LOT:	
DATE OF PRODUCTION:	
QC:	
DATE OF PURCHASE:	

Last revision: 01.09.2021
Follow www.bglight.com for updated revision of this Operating instructions manual.