OPERATING INSTRUCTIONS MANUAL

BLUEDENT POWER PEN built-in
24V / 220V

Dental LED curing light

Ref.#200-002b, #200-002m

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 in the future.

CONTENTS:

I. UNIT DESCRIPTION AND FUNCTION

Dental LED curing light BLUEDENT POWER PEN built-in is an accessory to a medical device - specialized light source for intraoral polymerization of dental materials, sensitive to the blue part of the light spectrum.

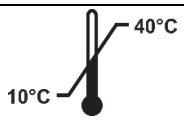
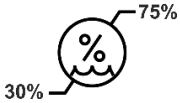
The device is intended for use only by a qualified dental practitioner and in a dental practice.

BLUEDENT POWER PEN built-in consists of Handpiece with cable (and adapter for 220V version) and Holder for attaching to the dental chair.

BLUEDENT POWER PEN built-in is manufactured in conformity with the requirements of Regulation on medical devices MDR 2017/745 and standards ISO 13485:2016, ISO 9001:2015.

II. SYMBOLS

	**Caution!** Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	**Consult instructions for use** Indicates the need for the user to consult the instructions for use.
	**Dangerous voltage** To indicate hazards arising dangerous voltage.
	**Hazardous light emission** To indicate hazards arising from light radiation.
	**Hazardous thermal effects** To indicate hazards arising from thermal effects.
	**Manufacturer** Indicates the medical device manufacturer.
	**Date of manufacture** Indicates the date when the medical device was manufactured
	**Medical Device** Indicates the item is a medical device
	**Unique Device Identifier** Indicates a carrier that contains Unique Device Identifier information
	**Catalogue number** Indicates the manufacturer's catalogue number so that the medical device can be identified.
	**Serial number** Indicates the manufacturer's serial number so that a specific medical device can be identified.

	**Batch code** Indicates the manufacturer's batch code so that the batch or lot can be identified.
	**Applied part type B** according to electric safety classification
	**Temperature limit** Indicates the temperature limits to which the medical device can be safely exposed.
	**Humidity limitation** Indicates the range of humidity to which the medical device can be safely exposed.
	**Waste Electrical and Electronic Equipment (WEEE)** According to Directive 2012/19/EU, this symbol indicates that the product should not be disposed of as urban waste at the end of its operating life.
	**Fragile** Indicates a medical device that can be broken or damaged if not handled carefully.
	**European Conformity** Indicates conformity with local laws and regulations within the European Economic Area

III. SAFETY PRECAUTIONS

GENERAL WARNINGS:

BLUEDENT is a Class I accessory to a 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 bleaching head 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!

-  Fragile! Use caution when transporting, using and storing the device!

-  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 (EU) 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.

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.

IV. TECHNICAL DATA

1. Operating voltage:
– 24V AC/DC or 110-240V / 50-60Hz
(depending on specification of device)

2. Power consumption:
- 24V AC/DC – 0,35A
- 110-240V / 50-60Hz – 0,115A

3. Dimensions of emitting handpiece:
- diameter of handpiece – min 18 mm, max 25 mm
- Length - 245 mm

4. Weight of handpiece (incl. lightguide and protection filter) – 100g

5. Polymerization modes – RAMP mode – with soft start.

6. Light source – 2 band LED module with reflector optics.

7. Emitted light – blue, visible spectrum, 410-490 nm.

8. Light intensity – up to 1300 mW/sq.cm

9. Emitting time:
- 10 / 20 / 30 sec. /±10%

10. Fiberoptic lightguide (360 degrees rotatable)

11. Working mode (1 min. work / 10 min. pause)

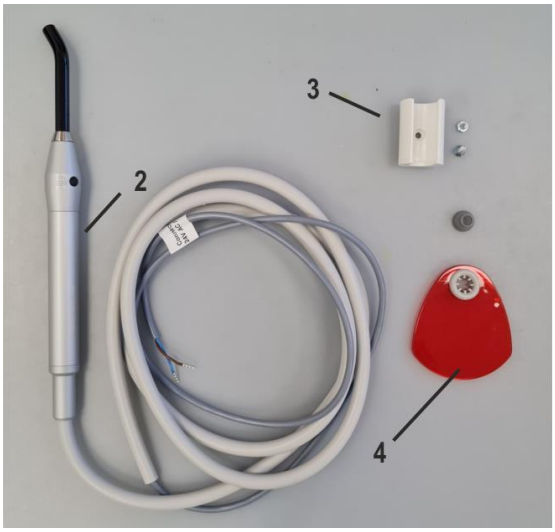
12. Degree of protection against electric current - applied part type B.

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.

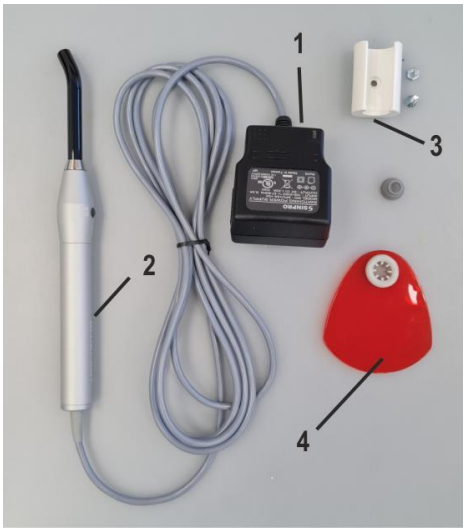
V. COMPLETE SET

1. Charging adapter 100-240V AC / 24V DC - 1 pc. (for 220V model with adapter)
2. Emitting handpiece - 1 pc.
3. Holder - 1 pc.
4. Protection filter and cap – 1 pc.
5. Operations guide - 1 pc.

Version 24V

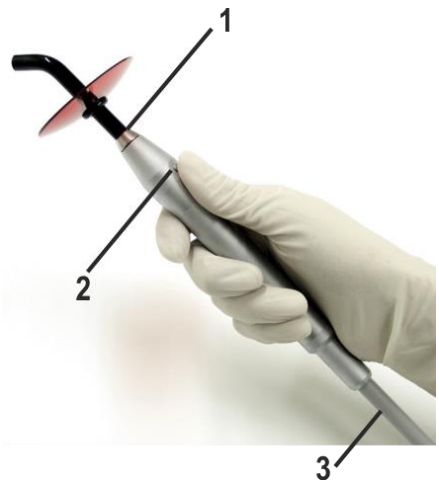


Version 220V with adapter



<u>Control and indication:</u>

1. Emitting LED module
2. Start / Stop button
3. Cable



VI. PREPARATION AND SEQUENCE OF OPERATION

BLUEDENT POWER PEN built-in is designed for use as a cable powered unit to be built-in the dental chair (version 24V) or to be powered by the mains (version 220V with adapter).

1. Take the curing light out of the packing. The holder 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 POWER PEN built-in(version 24V) is also turned off.

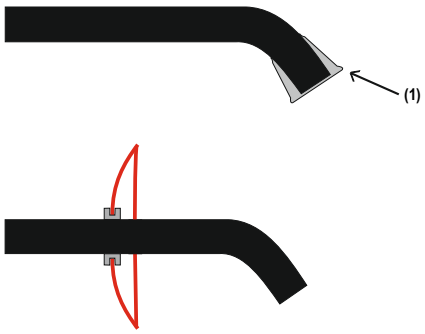
For version 220V - at the end of the day the charging adapter should be disconnected from the mains.

3. Mount lightguide and protection shield or protection cap.
See VII. ROUTINE CARE AND MAINTENANCE for instructions of initial cleaning and mounting.

NOTE: Lightguide and protection cap must be sterilized before every use!

They are delivered in a non-sterile state and must be sterilized beforehand first use.

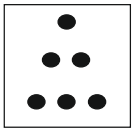
Before each patient, the light guide (only it, without the handpiece) must be cleaned mechanically and then with a disinfectant (e.g. Desident CaviCide or another approved by the Ministry of Health) and sterilized by autoclaving at 134 ° C for 5 minutes.



For polymerization of posterior teeth
(attach as shown)
(1) Protection cap

For polymerization of anterior teeth /
general application

4. Choosing timer mode:

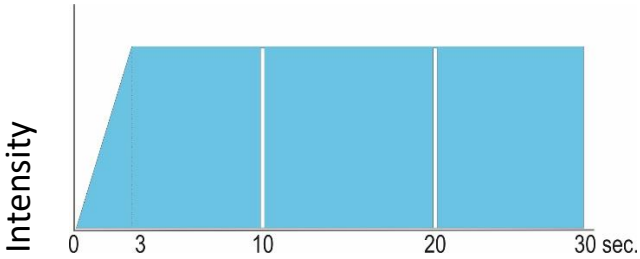
- SINGLE Press the Start / Stop button - 10 sec.	
- DOUBLE Press the Start / Stop button - 20 sec.	
- TRIPLE Press the Start / Stop button - 30 sec.	

After the set time has elapsed, the unit will turn off the output light.

If desired, the dentist can interrupt the cycle by pressing the Start / Stop button again.

During operation, the fiberoptic lightguide must be at a distance of at least 2 mm from the obturation.

Diagram of curing mode – RAMP

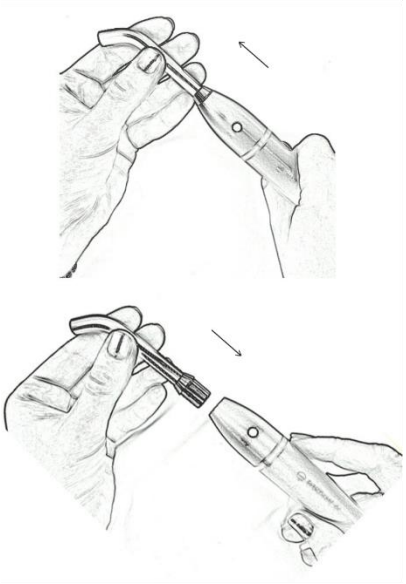


5. Overheating protection

The unit is equipped with overheating protection, which is activated if the temperature of the LED module rises up to 50°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 device's cooling down.

VII. ROUTINE CARE AND MAINTENANCE

1. **Examining of lightguide / protection cap.**



Lightguide is mounted / dismounted by pulling (360 degrees rotatable).

Every day the lightguide tip should be examined for:
- stuck restorative material (it should be removed very carefully with blunt non-metal object);
- mechanical damages on the lightguide.

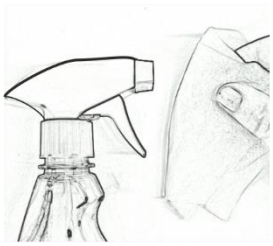
Remove the light guide and looking through it at strong light: if there are darkened areas over 10% of the area, replace it with a new one.

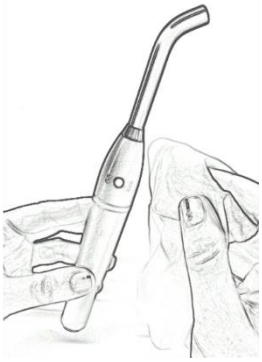
OK  Defective 

Lightguide should be sterilized by autoclave at 134° C for 5 min.
The same must be done for protection cap.
The protective filter is wiped only with disinfectant.

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 metal and plastic parts of the unit!

Do not spray directly onto handpiece or in button!

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

IX. SERVICE DATA

X. FAQ

Problem	Solution
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 slow blinking blue - in charging mode quick blinking blue 2sec - fully discharged 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 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 **TECHNICAL FILE** **BLUEDENT** **LED curing light**	**EU Declaration of conformity** *Developed in conformity with MDR (EU) 2017/745*	**TD 7.2** *Revision* ***02***

Manufacturer: **BG LIGHT LTD**
SRN: BG-MF-000019812
Address: 155, Vasil Aprilov blvd., 4027 Plovdiv, Bulgaria
Tel.: +359 32 644089, +359 888 809256, email: office@bglight.com
BULSTAT UIC 115841960, VAT N: BG115841960

CE

Product:	Product code:	Name:
Dental LED curing light	**200-002b**	**BLUEDENT POWER PEN – built-in 24V**
	200-002m	**BLUEDENT POWER PEN – built-in 220V**

Basic UDI: 3800501374200000VX
EMDN code: Q0190

Classification: Active invasive device (accessory for medical device) of **Class I** of the Regulation on medical devices - MDR (EU) 2017/745

Intended purpose: BLUEDENT is designed for photopolymerization of composites and materials used in dental practice (irradiation of blue light 410-490 nm). BLUEDENT is accessory for a medical device as described in Article 2, p.(2) as it performs its intended purpose together with dental composite (material).

The manufacturer declares under its own responsibility that the specified medical device complies with the applicable GENERAL SAFETY AND PERFORMANCE REQUIREMENTS, defined in Annex I of the normative act described below and normative technical documents, when used for its intended purpose and in accordance with the safety requirements.

Document	Title	Edition / date of issue
Regulation (EU) 2017/745	***REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL*** *of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC*	*05.05.2017* *(last change 24.04.2020)*

To achieve compliance, the requirements of the following standards are met:

EN ISO 13485:2016 +/AC:2017/ /AC:2018/ A11:2022 +/AC:2017/ /AC:2018/ A11:2022	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 9001:2015	Quality management systems - Requirements
EN ISO 60601-1:2006 /A1:2013/AC:2014/A2:2022	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2:2015/A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+ /A1:2015 / /A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-8:2007+ /A1:2013 /A11:2017 /A2:2021	Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN ISO 10650:2018	Dentistry - Powered polymerization activators
EN 62304:2006/A1:2015	Medical device software. Software life cycle processes.
EN 62353:2014	Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment

EN 62366-1:2015+ AC:2016/ A1:2020	Medical devices. Application of usability engineering to medical devices.
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14971:2019+/A11:2022	Medical devices – Application of risk management to medical devices.
CEN ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971 (ISO/TR 24971:2020)
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
Directive 2012/19/EC	Directive on waste electrical and electronic equipment (WEEE)

Classification is done by the manufacturer according to Regulation on medical devices - MDR (EU) 2017/745, Annex VIII, Rule 13. Conformity assessment procedure according to article 52, paragraph 7 of MDR (EU) 2017/745.

The declaration of conformity is issued in implementation of Annex IV “EU Declaration of conformity” of EU Regulation 2017/745, based on the results of tests carried out and assessment of compliance with the General safety and performance requirements defined in Annex I, implemented and certified Quality Management System - certificates No: AC090 100/1971/4047/2020, AC090 MD/1971/4047/2020 from TUV NORD Polska Sp. z o.o. (NB 2274).

BG LIGHT LTD maintains data on the provision, evaluation and maintenance of compliance of the medical device, according to the requirements of Annex II "Technical documentation" of MDR (EU) 2017/745.

Plovdiv, Bulgaria
01.01.2023

Dipl. Eng. Plamen Karaivanov
Manager
BG LIGHT LTD

XII. BLUEDENT DATA

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

Last revision: 01.01.2023
Follow www.bglight.com for updated revision of this Operating instructions manual.