# OPERATING INSTRUCTIONS MANUAL

## BLUEDENT POWER PEN (COLOR) cordless

Dental LED curing light

Ref.#200-003(p)



BG LIGHT PRO
the power of light

*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.*

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## I. UNIT DESCRIPTION AND FUNCTION

Dental LED curing light BLUEDENT POWER PEN (COLOR) 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 POWER PEN (COLOR) consists of Wireless handpiece with stand and Charging adapter.

BLUEDENT POWER PEN (COLOR) 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

**European Conformity**
Indicates conformity with local laws and regulations within the European Economic Area.

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**Caution**
To indicate that caution is necessary when operating the device or control close to where the symbol is placed.

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**Refer to instruction manual/booklet**
To signify that the instruction manual/booklet must be read.

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**Electronic instructions for use**
To indicate on product or product packaging that relevant information for use of the product is available in electronic form rather than, or in addition to, printed paper form.

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**Dangerous voltage**
To indicate hazards arising from dangerous voltage.

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**Hazardous light emission**
To indicate hazards arising from light radiation.

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**Hazardous thermal effects**
To indicate hazards arising from thermal effects.

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**Manufacturer**
Indicates the device manufacturer.

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**Date of manufacture**
Indicates the date when the device was manufactured.

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**Catalogue number**
Indicates the manufacturer's catalogue number so that the device can be identified.

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**Serial number**
Indicates the manufacturer's serial number so that a specific device can be identified.




**Batch code**
Indicates the manufacturer's batch code so that the batch or lot can be identified.

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**Applied part type B** according to electric safety classification.

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**IP20**
IEC - IP rating

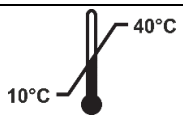
**For indoor use in dry conditions.**
Protection against solid objects larger than 12.5mm; no protection against water.
(Ingress Protection rating)

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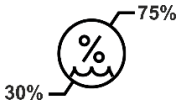
**For indoor use only**
To identify electrical equipment designed primarily for indoor use.

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**Temperature limit**
Indicates the temperature limits to which the device can be safely exposed.

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**Humidity limitation**
Indicates the range of humidity to which the device can be safely exposed.

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**Keep away from sunlight**
To indicate that transport package shall not be exposed to sunlight.

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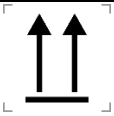
**Keep away from rain**
To indicate that the transport package shall be kept away from rain and in dry conditions.

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**Fragile; handle with care**
To indicate that the contents of the transport package are fragile and the package shall be handled with care.

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**This way up**
To indicate the correct upright position of the transport package.

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**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. It must be sent to separate collection facilities for recovery and recycling.

## III. SAFETY PRECAUTIONS



### GENERAL WARNINGS:

BLUEDENT is a Class I medical device and it meets the 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 adapter from the power supply at the end of the working day.
- 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 wiping with a swab soaked in disinfectant is acceptable.
- Do not get it wet and store it in a dry place to avoid electric shock or damage to the device.
- The device should not be used if any of its parameters are not within the norm.
- 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 outlet or another room, even in another building.
- Opening and repairing the device may only be carried out by service technicians authorized by the manufacturer.
- When replacing defective parts, only original parts must be used. The device or any of its parts must not be disassembled while it is connected to the power supply!
-  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 device, make sure that the voltage and the type of plug correspond to the mains supply in the country. Use only the original adapter type SYS1638-0605-W2E.
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!

If there is a problem with the power adapter or its cable, replace the adapter with a new one.
During thunderstorms, the device should not be charged from the power supply.

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 intense light in the blue range, to which the human eye is highly sensitive. Irradiation of the eyes and skin with intense light carries a risk of damage. This leads to the serious measures that must be taken to protect patients and medical staff.
The light should never be directed at the eyes! Irradiation should be limited to the work area. Do not irradiate soft tissues.

It is mandatory to use special filters or protective glasses that meet the requirements:
- Glasses should tightly cover the eyes and temples, even if the person is wearing optical glasses.
- be made of volumetric colored impact-resistant plastic.
- block light with a wavelength of 410 - 490 nm at least 100 times.
- have a stable mechanical structure, have no scratches, cracks or damage to its surface.

The device can only be used after medical consultation on or by persons suffering from photo-biological reactions; persons taking photosensitive medications; persons operated on for cataracts, persons with retinal diseases, etc.

The risk of unlawful exposure is severe eye irritation, temporary spots in the visual field, severe vision damage in case of direct exposure, including loss of vision.



**3. Thermal radiation**

The thermal effect is a consequence of the absorption of the energy of the blue light in the tissues, in which the energy is converted into heat. Irradiate only the dental tissue without the surrounding soft tissues. Take breaks in case of sensitivity. The risk of overheating and burning occurs only with prolonged continuous overdose of irradiation.

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 cleaning agents to penetrate the device, as this may cause damage and fire.
- 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 and burns.

**5. Prohibitions for using the device:**

The device can only be used after medical consultation on or by: persons suffering from photobiological reactions; persons taking photosensitizing medications; persons having cataract surgery; persons with retinal diseases; persons with allergies; people who have recently undergone surgical or cosmetic operations on the face or lips, including hyaluronic acid or Botox injections; persons with very sensitive skin or dermatitis, etc. If photosensitizing agents or medications are being taken, check the package insert of the medicine.

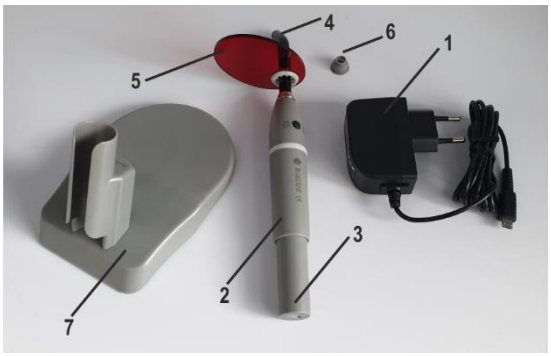
## IV. TECHNICAL DATA

1. Operating voltage - 3.7V Li Ion battery type 14500 (800mAh capacity)
2. Power consumption - mains adaptor: SYS1638-0605-W2E
- 110-240VAC / 50-60Hz input voltage
- Output: 5VDC / 1.2A micro USB socket
3. Dimensions of cordless handpiece:
- min. diameter – 18mm, max diameter - 25mm
- length - 148 mm (without lightguide)
4. Weight of cordless handpiece (with lightguide and protection filter)
- POWER PEN COLOR (plastic handpiece) - 80g
- POWER PEN (metal handpiece) - 100 g
- Holder – 276g
5. Polymerization mode – RAMP mode – with soft start.
6. Light source – 2 band LED module with reflector optics.
7. Emitted light – visible spectrum, 410-490 nm.
8. Light intensity - up to 1100 mW/sq.cm
Intensity is constant and not dependent on battery charge level.
9. Emitting time:
- 10 / 20 / 30 sec. /±10%
10. Working ability after fully charged battery - up to 2100sec. (210 cycles x10sec).
11. Charge time - 3 hours for full charge and 2 hours to 80% charge.
12. Visual indication - color indication ring and audible signal every 10 sec.
13. Low battery warning. Fully discharged battery indication.
14. Fiberoptic lightguide (rotatable 360 degrees)
15. Working mode (1 min. work / 10 min. pause)
16. 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.

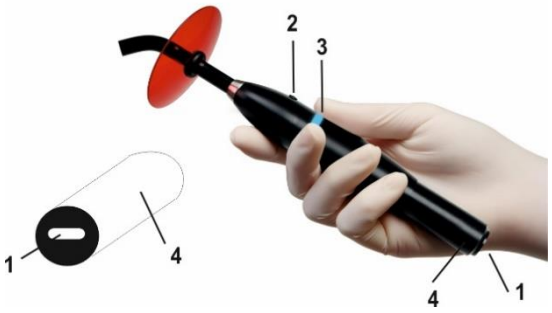
## V. COMPLETE SET

1. Charge adapter with micro USB output 5V DC / 1.2A - 1 pc.
2. Cordless handpiece - 1 pc.
3. Battery pack - 1 pc.
4. Lightguide - 1 pc.
5. Protection shield - 1 pc.
6. Protection cap - 1 pc.
7. Holder (2 parts) - 1pc.
8. Operations guide - 1 pc.




<u>Control and indication:</u>

1. USB charging connector
2. Start / Stop button
3. Illuminated indicator ring
4. Battery pack




## VI. PREPARATION AND SEQUENCE OF OPERATION

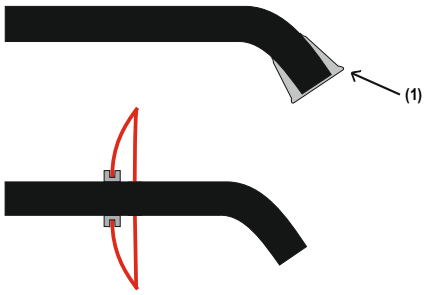
BLUEDENT POWER PEN (COLOR) is designed for use as a battery powered unit.

1. Take the curing light out of the packing and assemble the holder by inserting the upper part into the base part (as shown on picture below). Place on a stable horizontal surface.





2. Mount lightguide and protection shield or protection cap.
See VII. ROUTINE CARE AND MAINTENANCE




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

For polymerization of anterior teeth / general application – Protection filter

## 3. Indication

### 3.1. Color indication ring shows the parameters of the device.

| | |
|---|---|
| **Deactivated mode** - Color indication ring is not lit. |  |
| **Work mode** – polymerization. |  |
| **Battery charge / sound signal.** |  |
| **Fully charged battery** – device can be unplugged from adapter. |  |
| Overheating – **Thermal protection activated**, wait until device cools down. |  |
| **Battery is completely discharged** - several quick short blue flashes when attempting to start. |  |

### 3.2 LED module

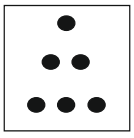
LED module indication:



LED blinking indicates that the battery is almost empty and the device will soon turn off.

### 4. Choosing timer mode

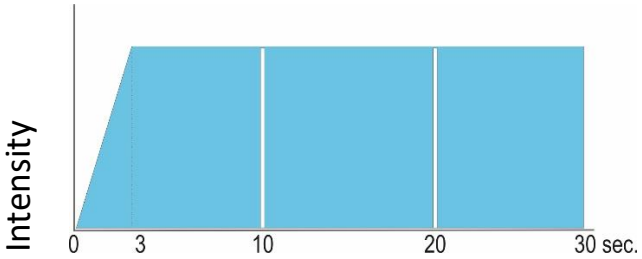
After the initial press of the button, the device is in standby mode.
Select the timer:

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

Irradiate from a distance of at least 1 mm from the polymerization area.

**Diagram of curing mode**

RAMP - gradual increase in intensity during the first 3 seconds.




(Sound signal at 10, 20, 30 sec.)

### 5. End of cycle

After the set time has elapsed, the device will turn off the emitting light.
If desired, the dentist can interrupt the cycle by pressing the Start/Stop button again.

### 6. Overheating protection

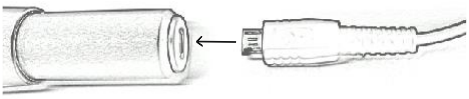
Thermal protection is activated if the temperature of the LED module rises to 50°C.
Then the color ring will flash yellow until the device cools down.

### 7. Battery – maintenance, charging and replacement

The device uses Li-Ion battery type 14500 / 3,7V / 800 mAh.

**Charging the battery** - by connecting the charging adapter to the mains.
Attention! Connect properly to the socket!

Unplug the adapter after charging.



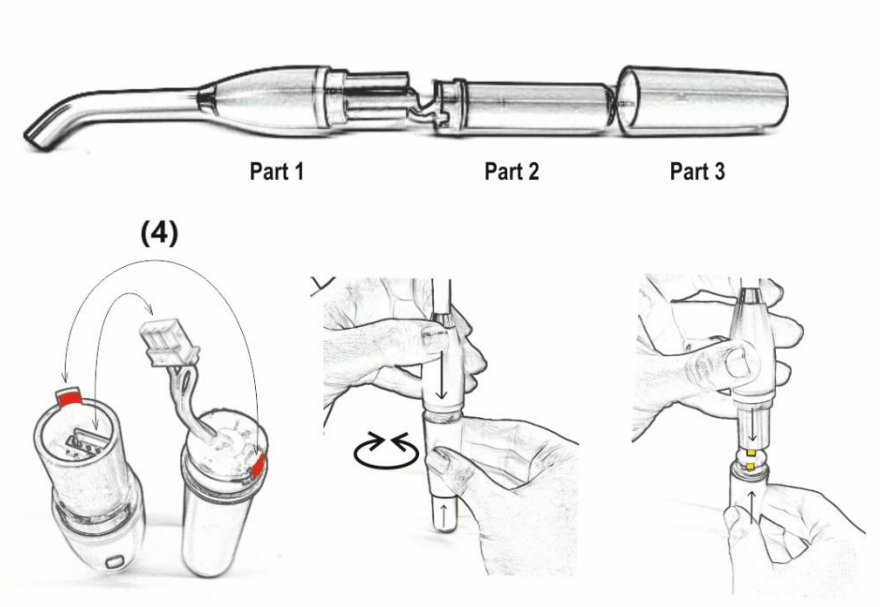
Charging is done with the SYS1638-0605-W2E adapter - 100-240VAC input voltage and 5VDC output voltage, with the output socket being micro USB.
Do not use other chargers!

<u>When is it necessary to replace the battery:</u>
- with reduced capacity - frequent charging is necessary;
- when the battery fails to work.
- with a damaged charging connector.

**To replace the Li-Ion battery:**
- Disconnect the adapter from the outlet and from the USB socket.
- Place the handle on a non-slip surface and unscrew Part 3. Release Part 2. Carefully remove the connector (4).
- Installing a new battery is done in the reverse order.
- When assembling the handle - place Part 2 (containing the battery) on a non-slip surface and press Part 1 firmly against Part 2. At the same time screw the cylindrical Part 3 back onto the front conical Part 1.

Note: The parts of the assembly between 1 and 2 must be aligned!
Do not twist the battery cables!

**Use only original Li-Ion batteries by the device manufacturer**



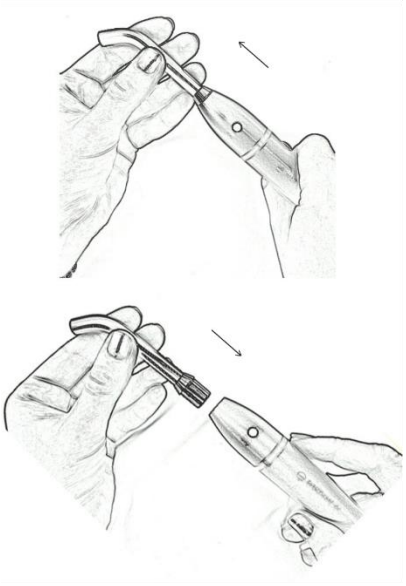
The battery must not be short circuited, mechanically damaged, immersed in water or to be heated or thrown into a fire.
- Non-functioning batteries should be taken to battery collection points.
- When disposing of the battery, observe the environmental protection regulations!

## VII. ROUTINE CARE AND MAINTENANCE

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

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 lightguide (only it, without the handpiece) must be mechanically cleaned of adhering composite 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.



The ligh guide is installed/dismounted by inserting/pulling and can be rotated 360 degrees.

The lightguide must be checked daily for:
- adhered photocomposite on the front of the light guide (cleaned carefully with a blunt non-metallic object)
- mechanical damage.

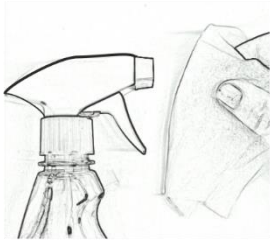
**Check for light conduction:** Remove the light guide and look through it at a strong light - if there are darkened areas over 10% of the area, replace it with a new one.

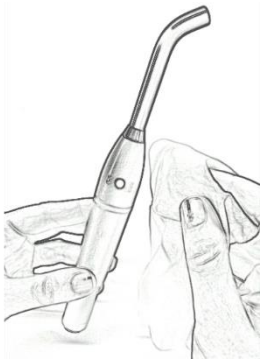
OK 

Defective 

2. **Cleaning of the device**

To disinfect the device, spray disinfectant onto a piece of cotton/soft cloth and clean the probe.
You can also use disinfecting wipes.





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!



**VIII. WARRANTY CONDITIONS**

1. The warranty period for the BLUEDENT dental photopolymerization device is 24 (twenty-four) months from the date of purchase. If the date of purchase is not filled in and warranty documents are missing, the warranty begins to run from the date of manufacture.

2. During the warranty period, the replacement of defective elements is carried out free of charge by the manufacturer. The light guide is not subject to warranty service. The battery has a 6-month warranty period.

3. If during the warranty period the device is defective due to improper operation (mechanical, chemical, thermal, electrical damage, use not for its intended purpose), improper storage and other reasons due to the user's fault, the repair is not covered by warranty.

4. Damage and complaints due to electric shocks, thunderstorms, failure to comply with electrical safety measures are not accepted.

5. The device must be transported to the service center only in the original packaging to avoid unwanted damage. The light guide must be packed separately from the probe. The warranty card (this Manual, with chapter XII BLUEDENT Data completed) or a copy of the sales invoice showing the serial number of the device must be presented.

6. If repairs are carried out by unauthorized persons outside the company service center or if non-original elements and assemblies are used, the user loses the right to warranty service.

7. Disclaimer: The manufacturer is not liable for compensation and lost profits in the event of damage or incomplete functioning of the device, regardless of the cause or in the event of problems arising from failure to comply with safety measures in the event of risks (chapter III, Risks)

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

BG LIGHT PRO Ltd
155, Vasil Aprilov blvd
4027 Plovdiv
Bulgaria
tel: +359 32 644089
office@bglight.com
www.bglight.com

9. The device's service life is set at 5 years from the date of purchase. After the end of its life cycle, the user must discontinue use of the device.
At the user's request, the life cycle can be extended. For this purpose, the device must be returned to the manufacturer BG LIGHT PRO LTD, where its characteristics must be checked and all main elements (emitters, adapter, electronic boards) tested and replaced.

10. In the event of disputes arising in connection with the application and interpretation of these Operating Instructions, they will be resolved by the Plovdiv District Court, in accordance with the current Bulgarian legislation.

## IX. SERVICE DATA

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| |

## X. FAQ

| Problem | Solution |
|---|---|
| **The device does not activate when the button is pressed.** | Fully discharged battery. You must connect to the charger to start charging. Only use the original adapter type SYS1638-0605-W2E. If the device still does not work - send the device to the service center. |
| **The button does not respond properly** | Clean around the button with an alcohol swab. If the button still does not respond properly, send the device to a service center. |
| **Weak curing effect** | It is necessary to clean the front of the light guide with a non-metallic object and clean the adhered composite with alcohol. If the result is poor - send the device to the service center. |
| **The patient experiences discomfort during the prolonged polymerization process of 20-30 sec.** | It is necessary to polymerize with short cycles - 10sec or less, with short pauses 1-3sec. The sensitivity is higher if the light is close to the dental pulp and decreases with each layer. |
| **The power adapter is damaged.** | Replace with a new adapter. |
| **Liquid entering the device** | Send to service center. |
| **After falling to the floor, the device does not work** | Send to service center. |

# XI. DECLARATION OF CONFORMITY

| BG LIGHT PRO<br>**TECHNICAL FILE**<br>**BLUEDENT**<br>**LED curing light** | **EU Declaration of conformity**<br>*Developed in conformity with MDR (EU) 2017/745* | **TD 7.2**<br>*Revision* ***03*** |
|---|---|---|

Manufacturer: **BG LIGHT PRO LTD**
SRN:
Address: 155, Vasil Aprilov blvd., 4027 Plovdiv, Bulgaria
Tel.: +359 32 644089, email: office@bglight.com
BULSTAT UIC 208000520, VAT N: BG208000520

CE

| Product: | Product code: | Name: |
|---|---|---|
| **Dental LED curing light** | **200-003** | **BLUEDENT POWER PEN – cordless** |
| | **200-003p** | **BLUEDENT POWER PEN COLOR – cordless** |

Basic UDI: 38001748200000G8
EMDN code: Q0190

Classification: Active invasive 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).

The manufacturer declares that the medical devices covered by the Declaration are in compliance with the provisions of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.

The applicable GENERAL REQUIREMENTS FOR SAFETY AND PERFORMANCE, defined in Appendix I of the normative act described below and of normative technical documents, are met when the medical device is 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***<br><br>*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*<br><br>*(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 - ISO 9001:2015 certificate – No AC090 100/2409/6029/2025, ISO 13485:2016 – No AC090 MD/0008/6029/2025 from TUV NORD Polska Sp. z o.o. (NB 2274).

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

BG LIGHT PRO 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
08.05.2025

Dipl. Eng. Plamen Karaivanov
Manager
BG LIGHT PRO LTD

## XII. BLUEDENT DATA

| | |
|---|---|
| **SN:** | |
| **LOT:** | |
| **DATE OF PRODUCTION:** | |
| **QC:** | |
| **DATE OF PURCHASE:** | |

Last revision: 22.07.2025
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