# OPERATING INSTRUCTIONS MANUAL

## BLUEDENT XPRESS built-in
## 24V / 220V

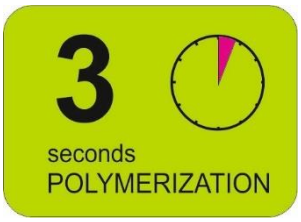
Dental LED curing light

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



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 XPRESS built-in 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 built-in consists of Wireless handpiece with stand and Charging adapter.

The  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

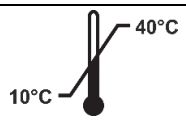
**For indoor use in dry conditions.**
Protection against solid objects larger than 12.5mm; no protection against water.
(Ingress Protection rating)

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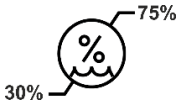
**For indoor use only**
To identify electrical equipment designed primarily for indoor use.

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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 device from the power supply 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 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 type of plug correspond to the power supply in the country. Use only the original adapter type SYS1381N-1224-W2E.
Electrical safety is ensured by class II protection against electric shock according to EN 60601-1.
The built-in device should be connected to the terminals of the dental unit with a voltage of 24VAC/DC +-20%.

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!

In case of a problem with the power adapter (for 220V model) or its cables, the device should be sent to a service center.
During thunderstorms, the device should be disconnected from the power supply (for 220V model) or the dental unit should be turned off (for 24V model).

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 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 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 of the device (according to the device specifications):
– 24V AC/DC ±15% of the dental unit
or with an additional mains adapter: type SYS1381N-1224-W2E with -input voltage 100-240VAC, output voltage 24VDC to the device.

2. Power consumption:
- 24V AC/DC – 0,35A
- 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 – wide 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.

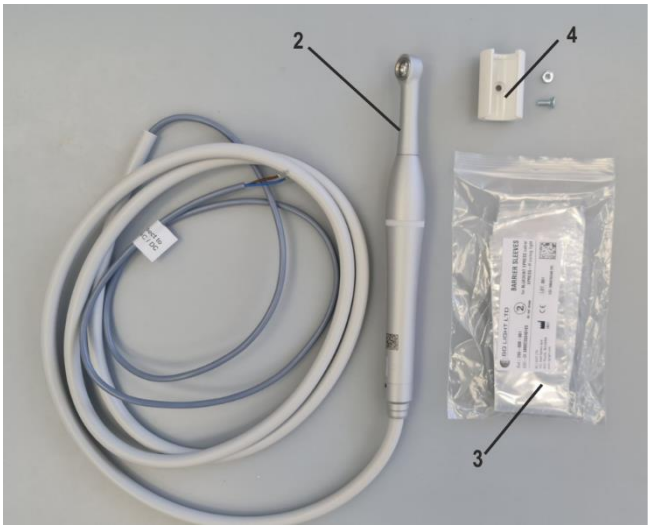
13. Degree of protection against electric current - applied part type B.

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.

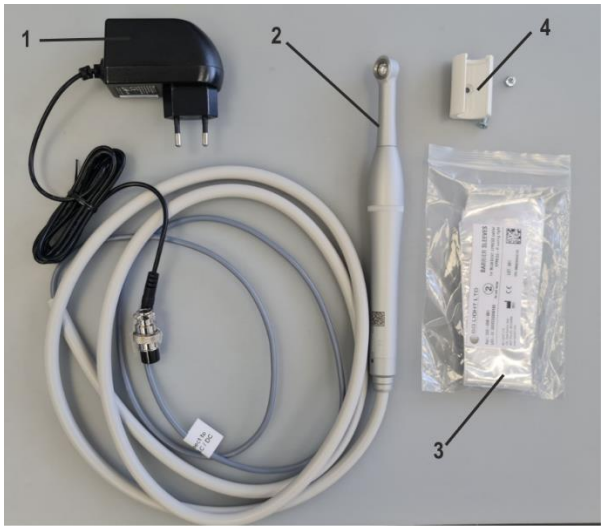
## V. COMPLETE SET

1. Charging adapter SYS1638-0605-W2E - 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**




**Version 220V with adapter**



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



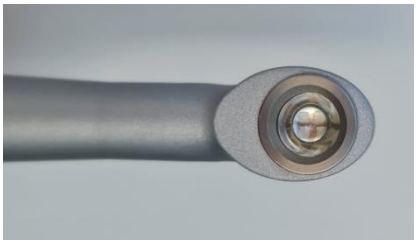

## VI. PREPARATION AND SEQUENCE OF OPERATION

BLUEDENT XPRESS 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.
A dental technician connects the cable to the 24V AC/DC terminal on the dental chair. Important – never connect the device to a higher voltage!

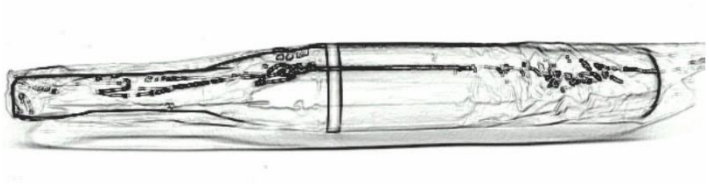
2. The holder is fixed on a suitable vertical surface with the included fasteners.

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 built-in 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 up by pressing the Start/Stop button once.

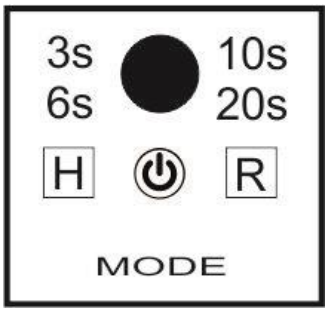
The illuminated ring indicates the current program. To change the operating mode, press and hold (3-4 sec.) the Start/Stop button.

**RAMP mode** - smooth start - up to 1500 mW/кв.см (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. Choice of timer:

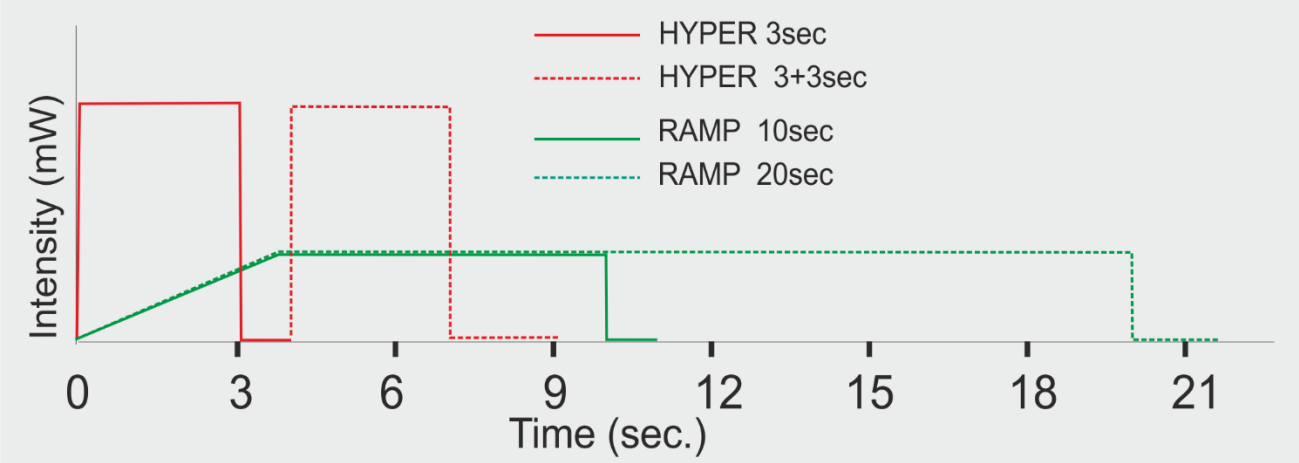
**In RAMP mode:**
- with a single press (1x) - 10 sec.
- when pressed twice (2x) - 20 sec.




**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**
Constant green light



**HYPER mode**
Constant red light



**Protection pause in HYPER mode**
3 sec blinking in red



**Charging**
**Sound signal**
Blinking in blue

**Thermal protection activated**
Blinking in blue until the device cools down



7. The handpiece tip is directed to the place designated for irradiation /minimum distance 1mm/. Emitting starts after short press of Start/Stop button.

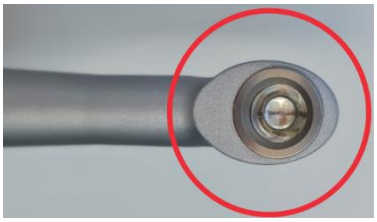
8. Stop the curing light emitting at any time by pressing the Start / Stop button again. If emitting is not stopped preliminary, it will stop after preselected time.

9. The curing light is switched off at the end of the working 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 50°C.
It is necessary to wait for device's cooling down.

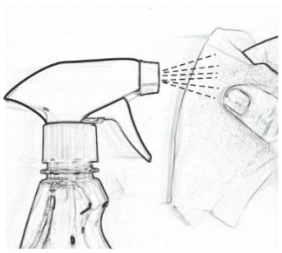
## VII. ROUTINE CARE AND MAINTENANCE

**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.



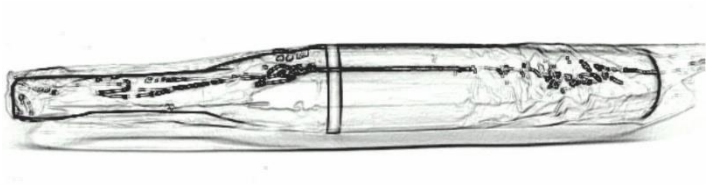
**2. Cleaning of the unit.**
For disinfection of the unit, spray the disinfection agent onto a piece of soft cloth / cotton and clean the handpiece and silicone tube.
Do not use abrasives or solvents as these may damage the parts of the unit!

Do not spray directly onto handpiece or in button!





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



## VII. 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.

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 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

## X. FAQ

| Problem | Solution |
|---|---|
| **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. You need to clean around button with a cotton swab soaked in alcohol. If the 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. |
| **Weak curing effect** | It is necessary to clean the emitting tip with a non-metallic object and to clean the adhered composite 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 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* ***02*** |
|---|---|---|

Manufacturer: **BG LIGHT PRO LTD**
SRN:
Address: 155, Vasil Aprilov blvd., 4027 Plovdiv, Bulgaria
Tel.: +359 32 644089, +359 888 809256, email: office@bglight.com
BULSTAT UIC 208000520, VAT N: BG208000520

CE

| Product: | Product code: | Name: |
|---|---|---|
| **Dental LED curing light** | **200-008b** | **BLUEDENT XPRESS built-in 24V** |
| | **200-008m** | **BLUEDENT XPRESS built-in 220V** |

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