OPERATING INSTRUCTIONS MANUAL

BLUEDENT XPRESS+ (ortho) cordless

Dental LED curing light

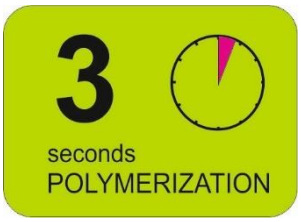
Ref.#200-009(+)(ort)



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 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 consists of Wireless handpiece with stand and Charging adapter.

BLUEDENT XPRESS 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.



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



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



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.



Dangerous voltage
To indicate hazards arising from 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 device manufacturer.



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



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



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.



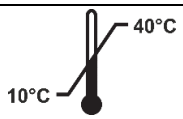
Applied part type B according to electric safety classification.

IP20
IEC - IP rating

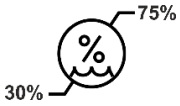
For indoor use in dry conditions.
Protection against solid objects larger than 12.5mm; no protection against water.
(Ingress Protection rating)



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



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



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



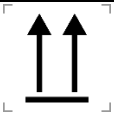
Keep away from sunlight
To indicate that transport package shall not be exposed to sunlight.



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



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



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



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.
- The device should be disconnected from the power supply after 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 18650 (2600mAh capacity)
2. Charging adapter: SYS1638-0605-W2E
- 110-240VAC / 50-60Hz input voltage
- Output: 5V DC / 1.2A micro USB socket
- 0.5 A max power consumption
3. Dimensions of cordless handpiece:
- Head of emitting handpiece – 14 x 16 mm, max diameter of handpiece - 27mm, length - 215 mm
4. Weight of cordless handpiece – 165 g
5. Polymerization modes – RAMP (R), HYPER (H)
6. Emitted light – blue, visible spectrum, 410-490 nm
7. 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
Intensity is constant and not dependent on battery charge level.
8. Light source – 2 band LED module with reflector optics.
9. Emitting time:
- RAMP mode - 10 / 20 sec. /±10%
- HYPER mode - 3/3+3* sec. /±10% - with 1sec pause
- HYPER ORTHO mode - 3/36*sec/±10% - with 2 sec pause – for ORTHO program
With the Start / Stop button it is possible to stop the device at any time.
10. Visual indication - color indication ring and audible signal every 10 sec / 3 sec depending on chosen work mode.
11. Working ability after fully charged battery - up to 4000sec (in RAMP mode):
- up to 400 cycles x 10 sec
- up to 200 cycles x 20 sec

12. Charge time – 6-7 hours for full charge and 3-4 hours to 80% charge.
13. Low battery warning. Fully discharged battery indication.
14. Working mode (1 min. work / 10 min. pause)
15. 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 adapt - SYS1638-0605-W2E - 1 pc.
2. Cordless handpiece - 1 pc.
3. Battery pack - 1 pc.
4. Barrier sleeves - 50 pc.
5. Holder (2 parts) - 1 pc.
6. 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 XPRESS is intended for use as a wireless stand-alone device.

1. Remove the device from its packaging. Assemble the stand by inserting the two parts into each other. Place it on a stable horizontal surface.



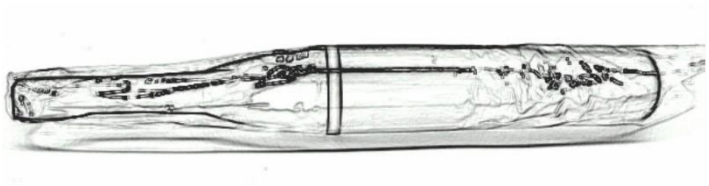




2. The emitting head does not rotate!
Under no circumstances should you attempt to pull, rotate or apply physical force to it.



3. Before each patient, a new protective plastic barrier sleeve is placed on the front of the probe. It is for single use and is marked with the appropriate symbol.





4. BLUEDENT XPRESS 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.

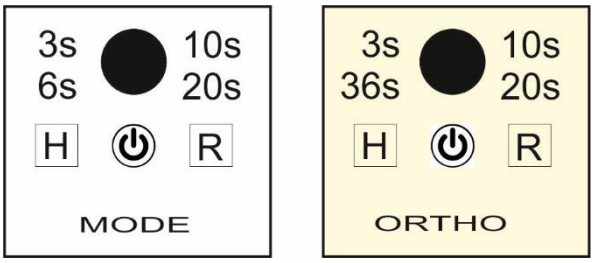
The device wakes up up by pressing the Start/Stop button once.

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

5. Timer selection

In **RAMP mode** - The device has a soft start (slow increase in light intensity) to reduce stress on the photocomposite.

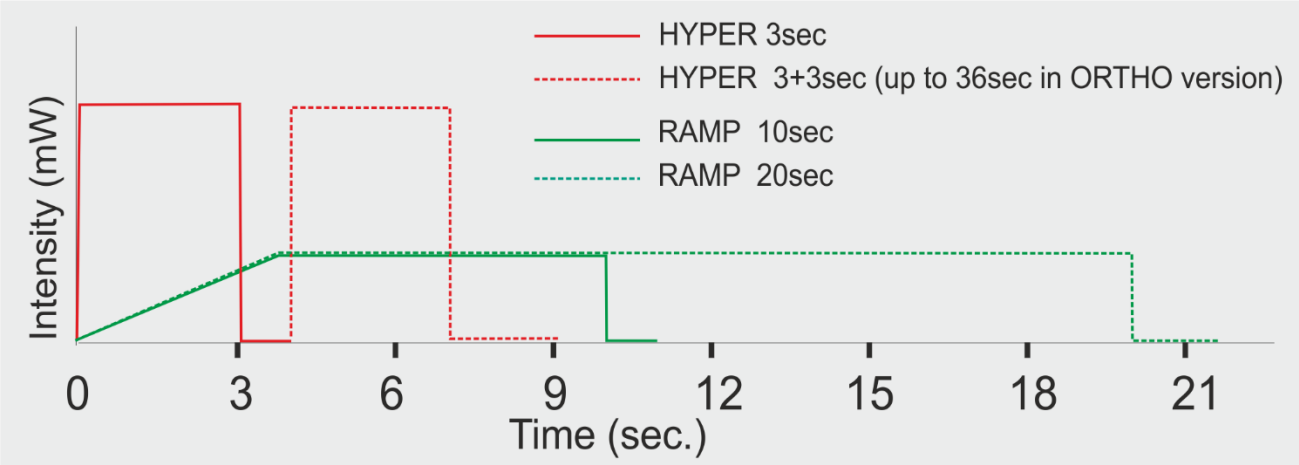
- with a single press (1x) - 10 sec.
- when pressed twice (2x) - 20 sec.



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

In HYPER mode, after each end of cycle of 3 / 3+3 sec., there is a pause of 3 sec. which is a protective time against accidental activation. The illuminated ring flashes red and the device cannot be activated.

In the ORTHO version, there is a difference only in the HYPER mode:
- when pressed once (1x) - 3 sec.
- when pressed twice (2x) - 12 times for 3 sec with a pause of 1 sec between each two flashes.



6. Indication

- Color indication ring

Deactivated mode - Color indication ring is not lit	
RAMP mode - lights up green	
HYPER mode - lights up red	
Protection pause in HYPER mode – flashes red	
Battery charge - flashes blue **Sound signal -** flashes blue	
Fully charged battery – lights up blue	
Overheating of device – flashes yellow	
Battery is completely discharged - several quick short blue flashes when attempting to start.	

- LED module

LED module indication:



Its blinking indicates that the battery is low and will soon turn off. Requires charging!

7. The handpiece is directed to the designated area for irradiation and started, maintaining a minimum distance of 1 mm to the obturation.

8. Stopping the photopolymerization device at any time is done by pressing the Start/Stop button again. If it is not stopped in advance, the device will stop after the selected time has elapsed.

9. Some time after the last start, the device goes into sleep mode until the next use. The luminous ring goes out.

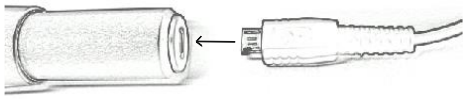
10. Overheating protection
Thermal protection is activated if the temperature of the LED module rises to 50 ° C. Then the colored ring will flash yellow until the device cools down.

11. Battery – maintenance, charging and replacement

The device uses Li-Ion battery type 18650 / 3,7V / 2600 mAh.

Charging the battery - by connecting the charging adapter to the mains.

Attention! Connect properly to the socket!



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

Monitor the battery charge and if a low level is indicated, charge it. After fully charging the device or at the end of the working day, disconnect the charging adapter from the power supply.

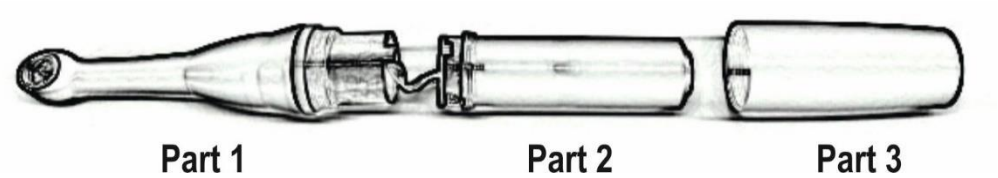
When is it necessary to replace the battery:
- with reduced capacity - frequent charging is necessary;
- if the battery fails to work.
- with a damaged USB charging connector.

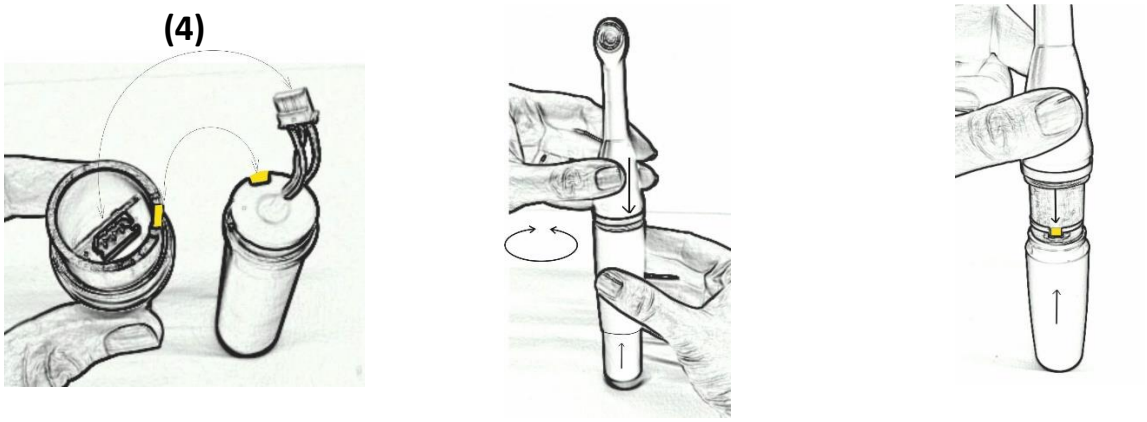
When is it necessary to replace the battery:
- with reduced capacity - frequent charging is necessary;
- when the battery fails to work.
- with a damaged charging connector.

To replace a Li-Ion battery:
- Disconnect the adapter from the socket and the USB socket.
- Place the handpiece on a non-slip surface and unscrew Part 3. Release Part 2. Carefully remove the connector (4).
- The installation of a new battery is done in the reverse order.
- When assembling the handpiece - place Part 2 (containing the battery) on a non-slip surface and press Part 1 to Part 2 at the same time. At the same time, screw the cylindrical Part 3 back to the front conical Part 1.

Note: The parts of the assembly between 1 and 2 must fit!
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 can be taken to battery collection points.
- When disposing of the battery, observe the environmental protection regulations!

VII. ROUTINE CARE AND MAINTENANCE

1. **Cleaning the emitting tip**

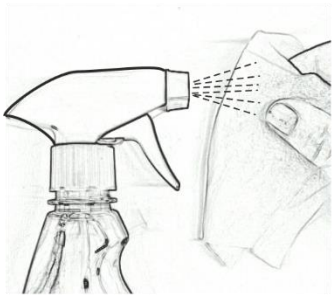
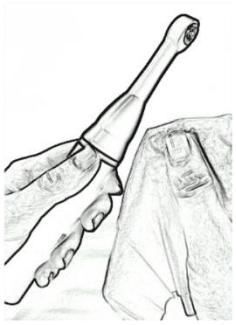
Clean the emitter's exit glass daily with a cotton swab dipped in alcohol. No adhered photocomposite is allowed - if there is any, carefully remove it with a blunt, non-metallic object.



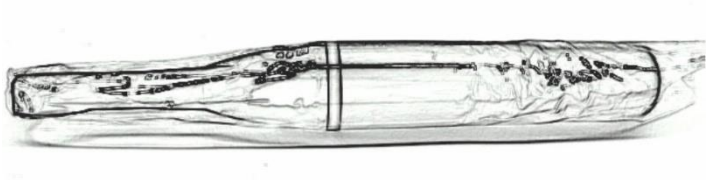
2. **Cleaning the device**

To disinfect the device, spray disinfectant on a piece of cotton / soft cloth and clean it. You can also use disinfectant wipes.
Do not use abrasives or solvents, as they may damage the parts of the device!

Do not spray directly into/on the handpiece or into the button or micro USB connector!


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



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 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 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 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	Use barrier sleeves while working with the device. 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 glass window of the LED module with a non-metallic object and remove the stuck 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 of 1-3sec. Sensitivity decreases as the light moves away from the dental tissues.
The power adapter is damaged.	Replace with a new adapter. Check the USB connector.
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 LTD **TECHNICAL FILE** **BLUEDENT** **LED curing light**	**EU Declaration of conformity** *Developed in conformity with MDR (EU) 2017/745*	**TD 7.2** *Revision* ***03***

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	**200-009(+)**	**BLUEDENT XPRESS (+) - cordless**
	200-009ort	**BLUEDENT XPRESS ortho - 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*** *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 - 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:	

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