Manufacturer: **BG LIGHT LTD**
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BULSTAT UIC 115841960, VAT N: BG115841960

CE

| Product: | Product code: | Name: |
|---|---|---|
| **Dental LED curing light** | **200-002** | **BLUEDENT POWER PEN – built-in** |
| | **200-003** | **BLUEDENT POWER PEN – cordless** |
| | **200-003p** | **BLUEDENT POWER PEN COLOR – cordless** |
| | **200-004** | **BLUEDENT SMART – cordless** |
| | **200-005** | **BLUEDENT SMART – built-in** |
| | **200-006** | **BLUEDENT SMART XPRESS – cordless** |
| | **200-006ort** | **BLUEDENT SMART XPRESS ortho – cordless** |
| | **200-008** | **BLUEDENT XPRESS – built-in** |
| | **200-009** | **BLUEDENT XPRESS – cordless** |
| | **200-009ort** | **BLUEDENT XPRESS ortho – cordless** |
| | **200-009R** | **BLUEDENT XPRESS-R – cordless** |

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***<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:

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|---|---|
| **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/** | Medical devices. Application of usability engineering to medical devices. |

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| **A1:2020** | |
| **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