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

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

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

EN ISO 13485:2016 +/AC:2017/ /AC:2018/ A11:2022 +/AC:2017/ /AC:2018/ A11:2022	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 9001:2015	Quality management systems - Requirements
EN ISO 60601-1:2006 /A1:2013/AC:2014/A2:2022	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
EN 60601-1-2:2015/A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
EN 60601-1-6:2010+ /A1:2015 / /A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-8:2007+ /A1:2013 /A11:2017 /A2:2021	Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN ISO 10650:2018	Dentistry - Powered polymerization activators
EN 62304:2006/A1:2015	Medical device software. Software life cycle processes.
EN 62353:2014	Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment
EN 62366-1:2015+ AC:2016/ A1:2020	Medical devices. Application of usability engineering to medical devices.

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

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

The declaration of conformity is issued in implementation of Annex IV “EU Declaration of conformity” of EU Regulation 2017/745, based on the results of tests carried out and assessment of compliance with the General safety and performance requirements defined in Annex I, implemented and certified Quality Management System - certificates No: AC090 100/1971/4047/2020, AC090 MD/1971/4047/2020 issued by 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
02.06.2023

Dipl. Eng. Plamen Karaivanov
Manager
BG LIGHT LTD