| BG LIGHT LTD<br>**TECHNICAL FILE**<br>**BLUEDENT**<br>**LED curing light** | **Declaration of conformity**<br>*Developed in conformity with MDR (EU) 2017/745* | **TD 7.2**<br>*Revision **02***<br>*Page **1** of **1*** |
|---|---|---|

Manufacturer: **BG LIGHT LTD**

Address: 155, Vasil Aprilov blvd., 4027 Plovdiv, Bulgaria
Tel.: +359 32 644089, +359 888 809256
BULSTAT 115841960, VAT N: BG115841960

| Product: | Product code: | Name: |
|---|---|---|
| **BLUEDENT**<br><br>**dental curing light** | **200-002** | **BLUEDENT LED – cable powered** |
| | **200-003** | **BLUEDENT POWER PEN – cordless** |
| | **200-003p** | **BLUEDENT POWER PEN COLOR – cordless** |
| | **200-004** | **BLUEDENT SMART – cordless** |
| | **200-006** | **BLUEDENT SMART XPRESS – cordless** |
| | **200-006ort** | **BLUEDENT SMART XPRESS ortho – cordless** |
| | **200-008** | **BLUEDENT XPRESS – cable powered** |
| | **200-009** | **BLUEDENT XPRESS – cordless** |
| | **200-009ort** | **BLUEDENT XPRESS ortho – cordless** |
| | **200-009R** | **BLUEDENT XPRESS-R – cordless** |

Basic UDI: 3800501374200000VX
Classification: Active device of Class I of the Regulation on medical devices - MDR (EU) 2017/745

Classification is done by the manufacturer according to Regulation on medical devices - MDR (EU) 2017/745, Rule 13, Annex VIII.

Notified body: TUV NORD Polska Sp. z o.o., ul.Mickiewicza 29, 40-085 Katowice, Poland.

This Declaration of conformity is valid only in combination with our certificates of Notified body TUV NORD Polska Sp. z o.o. Certificates N: AC090 100/1971/4047/2020, AC090 MD/1971/4047/2020.

The manufacturer declares under its sole responsibility that the products are developed and produced in conformity with MDR (EU) 2017/745 and the following applicable standards:

| | |
|---|---|
| **EN 60601-1:2006 +AC:2010+A1:2013+A12:2014** | Medical electrical equipment - Part 1: General requirements for safety |
| **EN 60601-1-2:2015** | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests |
| **EN 62304:2018** | Medical device software. Software life cycle processes. |
| **EN 62353:2015** | 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. |
| **EN ISO 14155:2011+AC:2011** | Clinical investigation of medical devices for human subjects - Good clinical practice |
| **EN ISO 14971:2020** | Medical devices – Application of risk management to medical devices. |
| **EN ISO 15223-1:2016** | Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements |
| **EN ISO 20417:2021** | Medical devices — Information to be supplied by the manufacturer |
| **EN ISO 10993-1:2018** | Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process |
| **2012/19/EC** | Directive on waste electrical and electronic equipment (WEEE) |

All company products are manufactured under the current Quality Management System, ISO 9001:2015 and ISO 13485:2016.

Dipl. Eng. Plamen Karaivanov
Manager
BG LIGHT LTD

01.06.2021
Plovdiv, Bulgaria