BG LIGHT LTD **TECHNICAL FILE** **BLUEDENT 12 BL** **LED bleaching unit**	**Declaration of conformity** *Developed in conformity with MDR (EU) 2017/745*	**TD 7.2** *Revision* ***02*** *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

CE **2274**

Product: **BLUEDENT 12 BL – bleaching unit**
Product code: 600-001
Basic UDI: 3800501374600000XK
Classification: Active device of Class IIa of the to 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 9, Annex VIII. Device also belongs to description in Annex XVI, p.5.

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, TNP/MDD/0334/4047/2020.

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
Directive 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