

Manufacturer: **BG LIGHT LTD**Address: 155, Vasil Aprilov blvd., 4027 Plovdiv, Bulgaria
Tel.: +359 32 644089, Fax: +359 32 641913
BULSTAT 115841960, Tax N: 1165887138Products: **SUPERLITE POWER PEN – cordless LED curing light**
SUPERLITE COLOR PEN - cordless LED curing light
SUPERLITE 1300 – cordless LED curing light
A.M.EDELINGH – cordless LED curing light

Classification: Active device in Class I of the Medical Device Directive 93/42/EEC+AC:2007

Classification is done by the manufacturer according to Medical Device Directive 93/42/EEC+AC:2007, Rule 12, Annex IX.

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 100/0951/4047/2014, AC090 MD/0951/4047/2014.

The manufacturer declares under its sole responsibility that the products are developed and produced in conformity with MDD 93/42/EEC+AC:2007 and the following applicable standards:

- EN 60601-1 Electrical safety,
- EN 60601-1-2 Electromagnetic compatibility
- EN 62304 Medical device software. Software life cycle processes.
- EN 62353 Medical electrical equipment. Recurrent test and test after repair of medical electrical equipment
- EN 62366 Medical devices. Application of usability engineering to medical devices.
- EN ISO 14155-1 Clinical investigation of medical devices for human subjects. General requirements.
- EN ISO 14155-2 Clinical investigation of medical devices for human subjects. Clinical investigation plans.
- EN ISO 14971 Medical devices – Application of risk management to medical devices
- EN ISO 15223-1 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
- EN 1041 Information supplied by the manufacturer with medical devices
- EN ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

Dipl. Eng. Plamen Karaivanov
Manager
BG LIGHT LTD08.08.2019
Plovdiv, Bulgaria