



The undersigned company:

ULTRA – VIOL Sp. j. Pietras Purgał Wójcik
ul. Stępowizna 34; 95-100 Zgierz,

declares that the non-medical devices **germicidal flow lamps, type:**

NBVE 60; **NBVE 60/30;**
NBVE 110; **NBVE 110/55;**

in realization: **N** – wall mounted, **S** – ceiling mounted, **P** – on mobile stand
(-) – without work time counter;
L – with work time counter without display;
LW – with work time counter with display;
LW ST – with work time counter with display and switch-key;
RC – with remote control; **MD** – with motion detector

marked with **CE** mark, are electrical devices that conform the essential requirements stated in the following EC – Directives:

- **2014/35/EC (LVD),**
- **2014/30/EC (EMC),**
- **93/42/EEC and 2007/47/EC (some requirements).**

The devices conforms the harmonized European standards:

- | | |
|-----------------------|--|
| • EN 60601-1 | Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance |
| • EN 60601-1-2 | Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests |
| • EN 60598-1 | Luminaires – Part 1: General requirements and tests |
| • EN 61547 | Equipment for general lighting purposes - EMC immunity requirements |
| • EN 60529 | Degrees of protection provided by enclosures (IP code) |

We declare with full responsibility that the products meet the requirements of the **RoHS directive 2011/65/EU** (including all its changes and amendments). Conformity assessment was carried out according to standard **EN 50581**.

Quality Management System of ULTRA-VIOL certified by TUV Nord meets requirements of:

- **EN ISO 13485:2016 - Medical devices** – Quality management systems – Requirements for regulatory purposes

04 – year of marking with CE mark

on behalf of ULTRA-VIOL Sp. j.



Wiesław Pietras
GENERAL MANAGER

Zgierz, 5th November 2018