

DECLARATION OF CONFORMITY

The undersigned company:

ULTRA – VIOL Spółka jawna 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 60/60

NBVE 110;

NBVE 110/55;

NBVE 110/110

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
٠	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

on behalf of ULTRA-VIOL Spółka jawna

Wiesław Pietras GENERAL MANAGER

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Zgierz, 16th August 2021