



The undersigned company:

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

declares that the **germicidal lamps, special version type:**

**NBV 55 N; NBV 3x30 P;**

in realization: **N** – wall mounted, **S** – ceiling mounted, **P** – on mobile stand

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 conform the harmonized European standards:

- |                       |  |
|-----------------------|--|
| • <b>EN 60601-1</b>   | <b>Medical electrical equipment</b> -- Part 1: General requirements for basic safety and essential performance   |
| • <b>EN 60601-1-2</b> | <b>Medical electrical equipment</b> – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests |
| • <b>EN 60598-1</b>   | Luminaires – Part 1: General requirements and tests  |
| • <b>EN 61547</b>     | Equipment for general lighting purposes - EMC immunity requirements  |
| • <b>EN 60529</b>     | 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