

# Declaration of Conformity

The undersigned company

**ULTRA VIOL sp. j. Pietras, Purgał, Wójcik**  
**34 Stępowizna Street**  
**95-100 Zgierz**  
**POLAND**

declares that the product

**Product name:** Direct radiation germicidal lamps  
NBV 15; NBV 2x15; NBV 30; NBV 2x30

**Mode of suspension:** N-wall mounted; S-ceiling mounted; P-on mobile stand

**Counters of working time:**

(-) - without counter of working time display;

L - counter of working time without display

LW - counter of working time equipped with digital display

L-O2 - external power switch with counter of working time equipped with digital display

LP-02 - external power switch with programmer and counter of Working time equipped with digital display

Conforms the essential requirements stated in the following EC – Directives:

- MDD Directive 93/42/EEC and 2007/47/EC
- EMC Directive 2004/108/EC

Products are medical devices of class I, rule 12 according to Annex IX of Medical Device Directive MDD 93/42/EEC and 2007/47/EC and conforms the essential requirements stated in Annex I of this directive.

The conformity assessment was carried out according to Annex VII of Council Directive 93/42/EEC and 2007/47/EC.

The devices conforms the harmonized European standards:

- EN 60601-1:2006 + A1:2013 *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 compatibility - Requirements and tests and*

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: 2012.

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

- EN ISO 9001 Quality Management Principles
- EN ISO 13485 Medical devices – Quality management systems.



Wiesław Pietras  
GENERAL MANAGER

20.10.2014 r.