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: Single and dual-purpose flow germicidal lamps
NBVE 60; NBVE 60/30; NBVE 110; NBVE 110/55

Versions:
N - wall mounted; S - ceiling mounted; P - on mobile stand;
L – with counter; RC - remote control, MD - with motion detector

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.*

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 TÜV Nord Polska meets requirements of:

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

Wiesław Pietras
GENERAL MANAGER

05.10.2015 r.