DECLARATION OF CONFORMITY

The undersigned company:

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

declares that the products – **phototherapy lamps FOTOVITA, type**:

FV 10L; FV 10M; FV 10S

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

- 93/42/EEC and 2007/47/EC **(MDD)**,
- 2014/30/EC **(EMC)**.

The products, marked with the **CE** mark, are medical devices of Class IIa, rule 9, according to Annex IX of Medical Devices Directive 93/42/EEC and 2007/47/EC and meet the essential requirements stated in Annex I of this directive.

The conformity assessment was carried out with the participation of Notified Body ID No. 2274:

TÜV NORD Polska Sp. z .o.o.
ul. Mickiewicza 29, 40-085 Katowice

according to Annex II (without section 4) of Council Directive 93/42/EC.

The products covered by this declaration of conformity and EC Certificate acc. 93/42/EEC Annex II (w.o. 4) Reg.-No. TNP/MDD/0241/828/2018 are supervised by the Notified Body ID. No. 2274 TÜV NORD Polska Sp. z o.o. (ul. Mickiewicza 29, 40-085 Katowice) in accordance with the art. 120 Regulation (EU) 2017/745 of the European Parliament and of the Council (MDR) and its amendment according to Regulation (EU) 2023/607 of the European Parliament and of the Council.

The devices conforms the harmonized European standards:

- **EN IEC 60601-2-83**
- **EN 60601-1**
- **EN 60601-1-2**
- **EN 60601-1-11 (without p. 6 and p. 8.3.1.)**

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**

on behalf of ULTRA–VIOL Spółka jawna

W. Pietras

Wiesław Pietras
GENERAL MANAGER

Zgierz, 19th October 2023