

Supplier's declaration of conformity (DoC) (CE declaration)

Unique identification number of this DoC: H4H-4500PRO-01012024

We (manufacturer or authorised representative):

Business name: **PHOTON 4 HEALTH B.V.**
Registered trade name: **HYDRO 4 HEALTH ®**
Address: Zwartewaterallee 56, 8031 DX,
Zwolle, Netherlands
RSIN: 862969001
EORI: NL862969001
CoC: 83720464
TAX-ID: NL862969001B01



Declare under our sole responsibility that the device:

EAN - Basic UDI-DI: 8720892535481
EMDN code: Q01040101
Device name/Trade name: **4500 PRO**
Intended purpose: GENERAL WELLNESS

Special note: This device is not classified as a medical device under Regulation (EU) 2017/745 and does not carry any medical claims. It is intended for general wellness use. It is not intended for medical use or to treat or diagnose any disease.

To which this declaration relates is classified as risk class I, according to the rules as set out in Annex VIII is in conformity with the following relevant Union harmonisation legislation:

- Regulation (EU) 2017/745 relating to medical devices
- Directive 2001/95/EC on General Product Safety
- Directive 2014/30/EU on Electromagnetic Compatibility (EMC)
- Directive 2014/35/EU on Low Voltage Equipment (if applicable)

Standards and/or technical specifications applied:

- IEC 60335 (General safety for household appliances)
- EN 60825-1 (Laser safety)
- EN 55014 and EN 61000 (EMC)
- ISO 13485 (Quality management system for medical devices)

Place and date of issue (of this DoC): ZWOLLE - NETHERLANDS - JAN – 1st - 2024

Signed for and on behalf of the manufacturer



M. Seubers - General Director - Authorized Representative Bio Energie Therapie BV, HYDRO 4 HEALTH ®

