



PHOTON 4 HEALTH

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

Unique identification number of this DoC: P4H-MINDWS-01012024

We (manufacturer or authorised representative):

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



Declare under our sole responsibility that the device:

UDI-DI/Ean: 08721398265162
EMDN code: Z12040202
BRAND: PHOTON 4 HEALTH®
SUN-BRAND: BRAINHEALER®
Model (device) name: **MIND WELLNESS SYSTEM®**
Intended purpose: GENERAL WELLNESS
Basic UDI-DI: 10069124-WELLNESS-13DP
Reference/Catalogue number: P4H-MINDWS-01012024

Special note: This product is registered in EUDAMED under MDR (EU) 2017/745 solely to comply with administrative obligations regarding UDI registration. The product is a wellness device and is not intended, presented, or claimed as a medical device. No medical claims are made and the device is intended exclusively for relaxation, wellness, and general use

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:

- MDR (REGULATION (EU) 2017/745 on 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) (Electromagnetic compatibility and safety)
- 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 - PHOTON 4 HEALTH B.V.

