



# PHOTON 4 HEALTH

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

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

### We (manufacturer or authorised representative):

Business name: **PHOTON 4 HEALTH B.V.**  
Registered trade name's: **PHOTON 4 HEALTH® REDPOWER®**  
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: 08721398265063  
EMDN code: Z12040202  
BRAND: **PHOTON 4 HEALTH®**  
SUB-BRAND: **REDPOWER®**  
Device name/Model name: **MINI ATP**  
Intended purpose: GENERAL WELLNESS  
Basic UDI-DI: 10069124-WELLNESS-7PF  
Reference/Catalogue number: P4H-RPMAP-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 - 1<sup>st</sup> - 2024

Signed for and on behalf of the manufacturer

M. Seubers - General Director - Authorized Representative - PHOTON 4 HEALTH B.V.

