

# EC Declaration of Conformity



**Manufacturers Name:** ZMI Electronics Ltd.

**Manufacturers Address:** 6F-1 No. 286-4 Shin Ya Road, Chien Chen District, Kaohsiung Taiwan 806

**SRN (Single Registration Number):** TW-MF-000003571

**Authorized Representative Name:** Sunsam Finance AB

**Authorized Representative Address:** Industrigatan 4B 2TR, SE-11246 Stockholm, Sweden

**SRN (Single Registration Number):** SE-AR-000002037

**Basic UDI-DI:** 471987233LIGHTCWCC4

**Name of the Device (s):** CareWear Light Patch series

**Product Model:** CWC-1

**Intended Purpose:** The CareWear light patch is a wearable medical device that uses PhotoBioModulation (PBM) to treat pain and soft tissue injury, relieve stiffness in muscles and joints, and accelerate recovery from exercise by increasing blood circulation and elevating tissue temperature. Its uses LEDs on reusable hydrogel patches powered by a rechargeable wireless controller.

**Classification:** Class IIa, according to rule 9 in Annex IX of MDD 93/42/EEC

**Common Specification & Harmonized Standards** EN ISO13485:2016; EN ISO14971:2012; EN 62304:2006; EN 62366:2008; EN 60601-1:2006/A1:2013; EN 60601-1-2:2015; EN 60601-1-11:2010; EN 60601-2-57:2011; EN ISO10993-1:2009/AC:2010; EN ISO10993-5:2009; EN ISO10993-5:2009; EN ISO 15223-1:2016;

**Notified Body name:** DNV Product Assurance AS

**Notified Body Address:** Veritasveien 3, N-1363 Høvik, Norway

**Notified Body Identification number:** 2460

**Conformity Assessment Route:** ZMI Electronics Ltd. uses the following procedures for the CE-labeling of their products according the Medical Device Directive 93/42/EEC:

Class IIa: EC conformity declaration according to annex II

This declaration of conformity is issued under the sole responsibility of ZMI Electronics Ltd. We hereby declare that the medical device(s) specified above meet the provision of the Medical Device Directive 93/42/EEC As Amended by 2007/47/EC for medical devices. This declaration is supported by the Quality System approval to ISO 13485 issued by DNV Product Assurance AS. All supporting documentation is retained at the premises of the manufacturer.

Name / Position:

Signature:

Place and date (dd.mm.yyyy) of issue:

Yuta Lee / President

R.O.C.(Taiwan), 07.06.2022