



## Declaration of Conformity

**Manufacturers Name:** ZMI Electronics Ltd.

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

**Authorized Representative Name:** Medserve Limited

**Authorized Representative Address:** Bragborough Hall Business Centre Welton Road, Braunston, Daventry, England, United Kingdom, NN11 7JG

**Registration Number:** 31871

**Basic UDI-DI:** 471987233MMPSYSUP

**Name of the Device (s):** Multi-modality physical therapy accessories – [Electrodes, Sponges and Lead-wires]

**Product Model:** PRU / LP / VEC / VNC / SPS / OTH / SAE / SWE / SW / SB / STR / WPC / VEL series,

**Intended Purpose** Electrodes, sponges and lead wires are intended for use as a reusable conductive interface between the patient's skin and the marketed multi-modality physical therapy system (e.g., light-energy, ultrasound, radio-frequency electrical stimulation, and microcurrent electrotherapy).

**Classification:** **Class I**, according to rule 1 in Part II of UK MDR 2002 and Annex IX of EU Directive 93/42

**Common Specification & Harmonized Standards** EN ISO 13485:2016; EN ISO 14971:2019/A11:2021; EN 62366:2015 /A1:2020; EN ISO 10993-1:2020; EN ISO 10993-5:2009; EN ISO 10993-10:2013; EN ISO 10993-17:2009; EN ISO 10993-18:2020; EN ISO 10993-23:2021; EN ISO 15223-1:2021; EN ISO 17664-2:2023

**Conformity Assessment Route:** ZMI Electronics Ltd. uses the following procedures for the UKCA-labeling of their products according to the **Part II** of the UK MDR 2002, Annex VII (as modified by Part II of Schedule 2A to the UK MDR 2002)

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 UK The Medical Devices Regulations 2002 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

Tuta Lee  
President

04.06.0.2024  
Taiwan(R.O.C)

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Place and date