ZMI Electronics Ltd.
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EC Declaration of Conformity CE

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:	**mdi Europa GmbH**
Authorized Representative Address:	Langenhagener Str. 71, 30855 Langenhagen, Germany
SRN (Single Registration Number):	DE-AR-000006218
Basic UDI-DI:	471987233PRUSA, 471987233LPYV, 471987233VECQV, 471987233SPSSF, 471987233WPCS3, 471987233VELRF, 471987233SAEQ6, 471987233OTHRH
Name of the Device (s):	Electrotherapy Accessories – [Electrodes, Sponges and Leadwires]
Product Model:	Please see list attached.
Intended Purpose	Electrodes, sponges and lead wires are intended for use as a reusable conductive interface between the patient's skin and the marketed electrical stimulators (i.e. TENS (Transcutaneous Electrical Nerve Stimulation), EMS (Electrical Muscular Stimulation), IF (Interferential) or PGF (Pulsed Galvanic Stimulation) for transmitting electrical current.
Classification:	**Class I**, according to rule 1 in Annex VIII of (EU) MDR 2017/745
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;
Conformity Assessment Route:	ZMI Electronics Ltd.uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745 **Annex II + III**

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 Regulation (EU) MDR 2017/745 for medical devices. All supporting documentation is retained at the premises of the manufacturer.

.....	17.08.2023 Taiwan(R.O.C)	.....	17.08.2023 Taiwan(R.O.C)
Yuta Lee President	Place and date	Lawrence Liu PRRC	Place and date

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Attachment to declaration of conformity– Device List

Device List

Model # (Ref)	Product name
PRU-XXXXXX	Electrotherapy Electrode
LP-XXXXXXXX	Electrotherapy Electrode
VEC-XXX	Electrotherapy Electrode
SPS-XXXXXXX	Cellulose Sponge
WPC-XXXXXXX	Electrotherapy Leadwire
VEL-XXXXXXX	Electrotherapy Leadwire
SAE-XXXXXXXX	Self-adhesive Electrode
OTH-XXXXXX	Electrotherapy Electrode