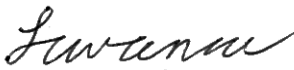
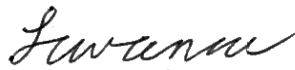


 www.zmi-electronics.com <<<	TECHNICAL DOCUMENTATION EC Declaration of Conformity
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Document No.	PTF_Electrotherapy_Q	Revision	5.4
Product	Electrotherapy Accessories	Date	2026/04/01
Project No.			

	Approved by	Reviewed by	Written by
Name	Yuta Lee	Lawrence Liu	Lawrence Liu
Title / Specialist	President	PRRC / Regulatory Affairs Section Manager	PRRC / Regulatory Affairs Section Manager
Signature			

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: 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, 471987233SAEQ6, 471987233OTHRH, 471987233WPCS3, 471987233VELRF

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 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 to 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.

.....
Yuta Lee
President

01.04.2026
Taiwan(R.O.C)
.....
Place and date

.....
Lawrence Liu
PRRC

01.04.2026
Taiwan(R.O.C)
.....
Place and date

Attachment to declaration of conformity– Device List

Basic UDI-DI: 471987233PRUSA Device List		
ZMI Part No.	Distributor REF Code	Product Name
PRU-030030		Electrotherapy Electrode
PRU-030030-SF		Electrotherapy Electrode
PRU-040028	EL0001	Electrotherapy Electrode
PRU-040028-ST1	PF0105	Electrodes Tensi+
PRU-040060		Electrotherapy Electrode
PRU-040060-DJ1	79966-4	Electrode
PRU-040060-DJ2	79966-40	Electrode
PRU-050050		Electrotherapy Electrode
PRU-050050-EN	3444380	Silicon electrode / Electrotherapy Electrode
PRU-050050FW		Electrotherapy Electrode
PRU-050050-MT		Electrotherapy Electrode
PRU-050050-MTR	012E-114	Rubber Electrodes
PRU-050050-SF		Electrotherapy Electrode
PRU-050050-VLS		Rubber Electrodes for electrotherapy
PRU-050070-BT	EKON-4228000ME0	Electrotherapy Electrode
PRU-050090		Electrotherapy Electrode
PRU-050090FW		Electrotherapy Electrode
PRU-050090-SF		Electrotherapy Electrode
PRU-050090-VLS		Rubber Electrodes for electrotherapy
PRU-060080		Electrotherapy Electrode
PRU-060080-DJ1	79967-4	Electrode
PRU-060080-DJ2	79967-40	Electrode
PRU-075130-SF		Electrotherapy Electrode
PRU-080120		Electrotherapy Electrode
PRU-080120-BT	EKON-4228001ME0	Electrotherapy Electrode
PRU-080120-DJ1	79968-4	Electrode
PRU-080120-DJ2	79968-40	Electrode
PRU-120160		Electrotherapy Electrode
PRU-120160-SF		Electrotherapy Electrode
PRU-160127A-SF		Electrotherapy Electrode
PRU-300300		Electrotherapy Electrode

Basic UDI-DI: 471987233LPYV Device List		
ZMI Part No.	Distributor REF Code	Product Name
LP1117-502-24F-MRD		Electrotherapy Electrode
LP1117A-152-22F-SF		Electrotherapy Electrode
LP34-807M-474	00474	Plate electrode / Electrotherapy Electrode
LP46-152-24F	EKON-4222006ME0	Electrotherapy Electrode
LP46-340446	340446	Electrotherapy Electrode
LP46-502-22FP-ZMR	3444128/256	Rubber Electrode for Electrotherapy
LP46-502-24F		Electrotherapy Electrode
LP68-152-24F	EKON-4222008ME0	Electrotherapy Electrode
LP68-340468	340468	Electrotherapy Electrode
LP68-502-22-42F	340468	Electrotherapy Electrode
LP68-502-22F		Electrotherapy Electrode
LP68-502-22FP-ZMR	3444129/257	Rubber Electrode for Electrotherapy
LP68-502-24F		Electrotherapy Electrode
LP68-502-24F-MRD		Electrotherapy Electrode
LP68-807M-476	00476	Plate electrode / Electrotherapy Electrode
LP68B-152-22F-GU	340703	Electrotherapy Electrode
LP812-152-24F	EKON-4222012ME0	Electrotherapy Electrode
LP812-340481	340481	Electrotherapy Electrode
LP812-502-22F		Electrotherapy Electrode
LP812-502-22FP-ZMR	3444130/258	Rubber Electrode for Electrotherapy
LP812-502-24F		Electrotherapy Electrode
LP812-502-24F-MRD		Electrotherapy Electrode
LP812-807M-478	00478	Plate electrode / Electrotherapy Electrode
LP812B-152-22F-GU	340714	Electrotherapy Electrode
LP812B-152-22F-SF		Electrotherapy Electrode

Basic UDI-DI: 471987233VECQV Device List		
ZMI Part No.	Distributor REF Code	Product Name
VEC-032		Electrotherapy Electrode
VEC-032-PH	00305	Vacustop vacuum electrode / Electrotherapy Electrode
VEC-032P-ZMR	3444509	Vacuum Electrodes
VEC-062		Electrotherapy Electrode
VEC-062P	340626	Electrotherapy Electrode
VEC-062P-4EA		Electrotherapy Electrode
VEC-062P-GU	340626	Electrotherapy Electrode
VEC-062-PH	00300	Vacustop vacuum electrode / Electrotherapy Electrode
VEC-062P-ZMR	3444503/252	Vaco electrodes for Electrotherapy
VEC-092		Electrotherapy Electrode
VEC-092P	340637	Electrotherapy Electrode
VEC-092-PH	00299	Electrotherapy Electrode
VEC-092P-ZMR	3444504/253	Vaco electrodes for Electrotherapy

Basic UDI-DI: 471987233SPSSF Device List		
ZMI Part No.	Distributor REF Code	Product Name
SPS-D-1460266	1460266	Sponge Pockets for Electrotherapy
SPS-D-1460273	1460273	Sponge Pockets for Electrotherapy
SPS-D-1460275	1460275	Sponge Pockets for Electrotherapy
SPS-O-01GU	109944	Cellulose Sponge
SPS-P-050050-PH	00433	Viscose Sponge / Cellulose Sponge
SPS-P-070080		Cellulose Sponge
SPS-P-070080-DJ	79969-4	Sponge
SPS-P-070080-DJ2	79969-40	Sponge
SPS-P-070080P-ZMR	259	Sponge Pockets for Electrotherapy
SPS-P-080100		Cellulose Sponge
SPS-P-080100-MRD		Cellulose Sponge
SPS-P-080100-PH	00435	Viscose Sponge / Cellulose Sponge
SPS-P-080100P-ZMR	260	Sponge Pockets for Electrotherapy
SPS-P-090105		Electrotherapy Electrode
SPS-P-090105-DJ	79970-4	Sponge
SPS-P-090105-DJ2	79970-40	Sponge
SPS-P-100137		Cellulose Sponge
SPS-P-100137-DJ	79971-4	Sponge
SPS-P-100137-DJ2	79971-40	Sponge
SPS-P-100137-MRD		Cellulose Sponge
SPS-P-100137-PH	00437	Viscose Sponge / Cellulose Sponge
SPS-P-100137P-ZMR	261	Sponge Pockets for Electrotherapy
SPS-P-150200-PH	00439	Viscose Sponge / Cellulose Sponge
SPS-R-05031		Cellulose Sponge
SPS-R-05031-DJ	27658-4	Sponge
SPS-R-05031-DJ2	27658-40	Sponge
SPS-R-11032		Cellulose Sponge
SPS-R-11032-MRD		Cellulose Sponge
SPS-R-11032-PH	00322	Viscose Sponge / Cellulose Sponge
SPS-R-11065		Cellulose Sponge
SPS-R-11065-DJ	56806-4	Sponge
SPS-R-11065-DJ2	56806-40	Sponge
SPS-R-11065-PH	00320	Viscose Sponge / Cellulose Sponge
SPS-R-11065P	340648	Cellulose Sponge
SPS-R-11065P-GU	340648	Cellulose Sponge
SPS-R-11065P-ZMR	3444505/262	Viscose sponge for Electrotherapy
SPS-R-11090P-ZMR	3444506/263	Viscose sponge for Electrotherapy
SPS-R-20061		Cellulose Sponge
SPS-R-20065-MRD		Cellulose Sponge
SPS-R-20090		Cellulose Sponge

SPS-R-20090-DJ	56807-4	Sponge
SPS-R-20090-DJ2	56807-40	Sponge
SPS-R-20090GU	114687	Cellulose Sponge
SPS-R-20090-MRD		Cellulose Sponge
SPS-R-20090-PH	00321	Viscose Sponge / Cellulose Sponge
SPS-R-20090P-ZMR	251	Viscose sponge for Electrotherapy
SPS-R-3444516	3444516	Cellulose Sponge
SPS-S-6080-GU	340681	Cellulose Sponge
SPS-S-80120-GU	340692	Cellulose Sponge

Basic UDI-DI: **471987233SAEQ6** Device List

ZMI Part No.	Distributor REF Code	Product Name
SAE-SC040000WP-VT		DuraPad / FLOWTENS Electrodes
SAE-SC050000WP-VT		DuraPad / FLOWTENS Electrodes
SAE-MC050050BP-VI		DuraPad / Self-Adhesive Electrodes
SAE-MC050090BP-VI		DuraPad / Self-Adhesive Electrodes

Basic UDI-DI: **471987233OTHRH** Device List

ZMI Part No.	Distributor REF Code	Product Name
OTH-01-01A	114142	Electrotherapy Electrode
OTH-01-03		Electrotherapy Electrode
OTH-3444180	3444180	Electrode pen

Basic UDI-DI: 471987233WPCS3 Device List		
ZMI Part No.	Distributor REF Code	Product Name
WPC-00261	00261	Connection cable DEEP OSCILLATION / Electrotherapy Leadwire
WPC-015	329967	Electrotherapy Leadwire
WPC-022P	340428	Electrotherapy Leadwire
WPC-226	114110	Electrotherapy Leadwire
WPC-257	329945	Electrotherapy Leadwire
WPC-260	329956	Electrotherapy Leadwire
WPC-261	330792	Electrotherapy Leadwire
WPC-266	340406	Electrotherapy Leadwire
WPC-340659	340659	Electrotherapy Leadwire
WPC-340670	340670	Electrotherapy Leadwire
WPC-3444101	3444101	Adapter cable
WPC-3444112	3444112	Electrode Cable
WPC-3444211	3444211	Electrode Cable
WPC-3444669	3444669	Electrode Cable
WPC-3444673	3444673	Electrode Cable
WPC-3444674	3444674	Electrode Cable

Basic UDI-DI: 471987233VELRF Device List		
ZMI Part No.	Distributor REF Code	Product Name
VEL-522S		Electrotherapy Leadwire
VEL-542S		Electrotherapy Leadwire
VEL-544S		Electrotherapy Leadwire
VEL-562S		Electrotherapy Leadwire
VEL-562S-564S	340615	Electrotherapy Leadwire
VEL-562S-PH	00315	Vacuum hose / Electrotherapy Leadwire
VEL-562S-ZMR	3444508/255	Electrode Hose
VEL-564S		Electrotherapy Leadwire
VEL-564S-ZMR	3444507/254	Electrode Hose
VEL-572S		Electrotherapy Leadwire
VEL-572S-574S	340604	Electrotherapy Leadwire
VEL-574S		Electrotherapy Leadwire