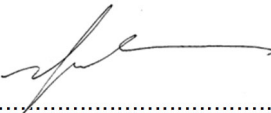


EC Declaration of Conformity



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, 471987233WPCS3, 471987233VELRF, 471987233SAEQ6, 471987233STRSR, 471987233OTHRH
Name of the Device (s):	Electrotherapy Accessories – [Electrodes, Sponges and Leadwires]
Product Model:	Please see list attached.
Intended Purpose	Electrodes, sponges, lead wires, and fixation straps are designed to be used in conjunction with electrical stimulators (such as Transcutaneous Electrical Nerve Stimulation, Electrical Muscular Stimulation, Interferential, or Pulsed Galvanic Stimulation). They serve as a reusable conductive interface between the patient's skin and the stimulators, 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.


.....
Tula Lee
President

22.05.2023
Taiwan(R.O.C)
.....
Place and date


.....
Lawrence Liu
PRRC

22.05.2023
Taiwan(R.O.C)
.....
Place and date