MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:	Initial certification date:	Expiry Date:
10000513723-PA-MDSAP-TWN	2019-11-11	2028-11-10

This is to certify that the management system of

ZMI Electronics Ltd.

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

F005995

has been found to conform to the Quality Management System standard:

ISO 13485:2016 and the requirements of the following regulatory authorities

Australia:

- Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil:

- RDC ANVISA n. 665/2022
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/200

Canada:

- Medical Devices Regulations (SOR/98-282) Part 1 - General

Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

United States:

- 21 CFR 803
- 21 CFR 806
- 21 CFR 807 Subparts A to D
- 21 CFR 820

This certificate is valid for the following scope:

The design and development, manufacture, servicing of physical therapy devices and related medical accessories, electrical stimulator, electrotherapy device, electrotherapy electrode, electrotherapy lead wire, cable, vacuum stimulator, vacuum electrode, static electric therapy device, infrared therapy device, light therapy devices, traction therapy device, ultrasound therapeutics device, ultrasound therapeutics probe, shortwave diathermy device, shortwave electrode and applicator, bandage, elastic for the area of physical therapy, rehabilitation.

Place
Høvik

Effective Date:
2025-11-11

DNV is an MDSAP Recognized Auditing Organization

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

For the issuing office:

DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Hazem Tinawi
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 1, 1363 Høvik, Norway, Tel +47 67 57 88 00, www.dnv.com

Your certificate is stored in DNV's secure certificate storage, providing traceability and trust to further enhance the value of your certification. Anyone can easily verify the validity of a certificate and details through the QR code on the certificate or or in the link, https://certificatechecker.dnv.com/ with the certificate number/manufacturer name.