



# CERTIFICATE OF REGISTRATION

## Electromedical Products International, Inc.

2201 Garrett Morris Parkway  
Mineral Wells, Texas 76067 UNITED STATES

D-U-N-S ID No. 610954729

UL Medical Regulatory Services of UL LLC®(UL) issues this certificate to the Firm named above, after auditing the Firm's quality management system and finding it in conformance per the defined scope with respect to:

### ISO 13485:2016

with additional regulatory requirements listed on final page of this certificate.

Design and manufacture of TENS/CES equipment.

For Australia: Design and manufacture of TENS/CES equipment for the indication of pain.

For Canada: Design and manufacture of TENS/CES equipment for the indication of pain and insomnia in the areas of personal use.

For Japan: Design and manufacture of TENS/CES equipment for the indication of pain.

For the United States: Design and manufacture of TENS/CES equipment for the indications of acute, chronic and post traumatic pain control and anxiety, insomnia and depression.



Authorized by



Check Certificate  
Status: [here](#)

**Michael J. Windler, P.E.**  
Manager of Global Regulatory Service  
Distinguished Member of the Technical Staff  
UL Life and Health Sciences  
UL LLC

File Number	A28461	Cycle Start Date	September 13, 2018
Certificate Number	1785.190311	Effective Date	March 11, 2019
Initial Issue Date	September 13, 2018	Expiry Date	September 12, 2021

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL Medical and Regulatory Services of UL LLC. Certificates may be verified by visiting the Online Certifications Directory on UL.com.



**UL Medical and Regulatory  
Services UL, LLC is an MDSAP  
Recognized Auditing  
Organization**

UL LLC  
333 Pfingsten Road  
Northbrook, IL 60062-2096 USA



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### Additional Regulatory Requirements

#### Australia:

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

#### Canada:

- Medical Devices Regulations – Part 1- SOR 98/282

#### Japan:

- MHLW Ministerial Ordinance 169, Article 4 to Article 68  
- PMD Act (,as applicable)

#### United States:

- 21 CFR 820  
- 21 CFR 803  
- 21 CFR 806  
- 21 CFR 807 – Subparts A to D  
- 21 CFR 821 (where applicable)

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