EC CERTIFICATE

Electromedical Products International, Inc.

2201 Garrett Morris Parkway
Mineral Wells, Texas 76067 UNITED STATES

Full Quality Assurance System Approval Certificate

Annex II (excluding section 4) of Council Directive 93/42/EEC concerning medical devices

Scope of Certificate:
Design and manufacture of cranial electrotherapy stimulation devices for the treatment of anxiety, insomnia, pain and depression.
Design and manufacture of transcutaneous electric nerve stimulation devices for management of acute, chronic and post-traumatic pain.

Device Classifications:
Class IIa

Device Descriptions and Model Type:
Please refer to Attachment: 1

We hereby declare that an examination of the full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex II (with the exemption of section 4) of Council Directive 93/42/EEC on Medical Devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive and is subject to periodic surveillance as required by 93/42/EEC. Annex II, Section 5. For Class III devices where they are covered by this certificate, an EC Design Examination certificate according to 93/42/EEC, Annex II, Section 4 is required. This certificate is issued with 1 attachment listing product references covered by this certificate.

File Number	A28461	Cycle Start Date	September 13, 2018
Certificate Number	807.181003	Effective Date	October 3, 2018
Initial Issue Date	September 13, 2018	Expiry Date	September 12, 2023

Authorised by

Paul Daysh
Medical Notified Body Operations Manager
For and on Behalf of UL International (UK) Ltd

Notified Body
0843

Check Certificate Status: here

UL International (UK) Limited
Wonersh House, The Guildway, Old Portsmouth Road,
Guildford, Surrey, GU3 1LR, United Kingdom

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Attachment 1 of 1

The products detailed below are covered under the scope of this certificate:

Product Family	Product Sub-Group	Model/Type	Classification	G/UMDN Code
Cranial electrotherapy stimulation devices and Transcutaneous electrical nerve stimulation devices	TENS and CES	Alpha-Stim M	Class IIa	
	CES	Alpha-Stim AID	Class IIa	-

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