



EC CERTIFICATE

Electromedical Products International, Inc.

2201 Garrett Morris Parkway
Mineral Wells, TX 76067
USA

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 Classification:
Ila

Device Descriptions:
Cranial electrotherapy stimulation devices

Transcutaneous electrical nerve stimulation devices

Model Type:
See Attachment 1

We hereby declare that an examination of the full quality assurance system has been carried out per report 11507938, 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 attachments listing model numbers.

File Number A28461
Certificate No. 807.161114

Cycle Start Date 13 November 2016
Effective Date 14 November 2016
Expiry Date 12 September 2018

Authorised by

Deborah Stubbs
Certification Manager

For and on Behalf of UL International (UK) Ltd

Notified Body
0843



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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 Microcurrent and Cranial Electrotherapy Stimulator and Transcutaneous Electrical Nerve Stimulator	Ila	
	CES	ALPHA-STIM AID Cranial Electrotherapy Stimulator	Ila	
Probes and Electrodes	CES	Ear Clip Electrodes	Ila	
	TENS	Electrodes	Ila	
		Lead Wires	Ila	
		Treatment Probes with Felt Electrodes	Ila	

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