CERTIFICATE

EC Certificate No. 1434-MDD-269/2019

Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Electromedical Products International, Inc.

2201 Garrett Morris Parkway,

Mineral Wells, Texas 76067, UNITED STATES

for the design, manufacture and final inspection of

medical devices, class IIa

Cranial electrotherapy stimulation devices for the treatment of anxiety, insomnia, pain anddepression.
Transcutaneous electric nerve stimulation devices for management of acute, chronic and post-traumatic pain.

List of devices covered by this certificate is given in the Annex no. 1

complies with requirements
of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 29.04.2019 to 12.09.2023

The date of issue of the Certificate: 29.04.2019

CE 1434

Application No: 605/2019
Module H

mgr Anna Wyroba
Vice-President

Polish Centre for Testing and Certification 23A Kłobucka Street, 02-699 Warsaw Poland, phone +48 22 46 45 200, e-mail: pcbc@pcbc.gov.pl

Certificate No. **1434-MDD-269/2019**
Issued under the Contract No. **MD-118/2019**
Bears the PCBC hologram
Warszawa, 29/04/2019

ANNEX NO. 1 TO CERTIFICATE

VALID ONLY WITH CERTIFICATE

No 1434-MDD-269/2019

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

Product Family	Product Sub-Group	Model/Type
Cranial electrotherapy stimulation devices and Transcutaneous electrical nerve stimulation devices	TENS and CES	Alpha-Stim M
	CES	Alpha-Stim AID

CE 1434

mgr Anna Wyroba
Vice-President

Annex no. 1 to certificate No. **1434-MDD-269/2019**
Issued under the Contract No. MD-118/2019
Bears the PCBC hologram.
Warsaw, 29/04/2019