수허 14-440 호

의료기기 수입 허가증

임허가번호 제 560호

구분	수입	품목/품목류	품목
제품명 (상품명, 품목명, 모델명)	Alpha-Stim AID,심리요법용뇌용전기자극장치,Alpha-Stim AID	분류번호(등급)	A16180.02(3)
모양 및 구조	별첨		
원재료	별첨		
제조방법	별첨		
사용 목적	사용목적 : 별첨, 성능 : 별첨		
사용방법	별첨		
사용 시 주의사항	별첨		
포장단위	별첨		
저장방법 및 사용기한	저장방법 : 별첨, 사용(유효)기한 : 별첨		
시험규격	별첨		
제조(수입)업자 정보	제조(수입)업자 : (주)경원메디칼, 충청북도 청원군 오송읍 정중연제로 765 (연제리) 제조원 : 별첨		
허가조건	없음		
비고			

「의료기기법」 제15조 및 같은 법 시행규칙 제18조 제3항에 따라 위와 같이 허가합니다.

2014 년 01 월 14 일

식 품 의 약 품 안 전 처 장 (인)

수허 14-439 호

의료기기 수입 허가증

업허가번호 제 560호

구분	수입	품목/품목류	품목
제품명 (상품명, 품목명, 모델명)	Alpha-Stim M,심리요법용뇌용전기자극장치,Alpha-Stim M	분류번호(등급)	A16180.02(3)
모양 및 구조	별첨		
원재료	별첨		
제조방법	별첨		
사용 목적	사용목적 : 별첨, 성능 : 별첨		
사용방법	별첨		
사용 시 주의사항	별첨		
포장단위	별첨		
저장방법 및 사용기한	저장방법 : 별첨, 사용(유효)기한 : 별첨		
시험규격	별첨		
제조(수입)업자 정보	제조(수입)업자 : (주)경원메디칼, 충청북도 청원군 오송읍 정중연제로 765 (연제리) 제조원 : 별첨		
허가조건	없음		
비고			

「의료기기법」 제15조 및 같은 법 시행규칙 제18조 제3항에 따라 위와 같이 허가합니다.

2014 년 01 월 14 일

식 품 의 약 품 안 전 처 장 (인)

Ref. Certif. No.

US/13579A/UL

IEC SYSTEM FOR CONFORMITY TESTING AND CERTIFICATION OF ELECTRICAL EQUIPMENT (IECEE) CB SCHEME

SYSTEME CEI D'ESSAIS DE CONFORMITE ET DE CERTIFICATION DES EQUIPEMENTS ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE
CERTIFICAT D'ESSAI OC

Product *Produit*	Cranial Electrotherapy Stimulator
Name and address of the applicant *Nom et adresse du demandeur*	ELECTROMEDICAL PRODUCTS INTERNATIONAL INC 2201 GARRETT MORRIS PKY MINERAL WELLS TX 76067, USA
Name and address of the manufacturer *Nom et adresse du fabricant*	ELECTROMEDICAL PRODUCTS INTERNATIONAL INC 2201 GARRETT MORRIS PKY MINERAL WELLS TX 76067, USA
Name and address of the factory *Nom et adresse de l'usine*	HANG YIK ELECTRONICS PLASTICS & MOLD FACTORY FIFTH INDUSTRIAL ZONE SHIYAN SHENZHEN GUANGDONG, CHINA
Rating and principal characteristics *Valeurs nominales et caractéristiques principales*	Alpha-Stim M:3 Vdc (Two AA 1.5 V Batteries) Alpha-Stim AID:3 Vdc (Two AAA 1.5 V Batteries)
Trademark (if any) *Marque de fabrique (si elle existe)*	cpi ELECTROMEDICAL
Model / Type Ref. *Ref. de type*	Alpha-Stim M, Alpha-Stim AID
Additional information (if necessary) *Information complémentaire (si nécessaire)*	The CB Test Report comprises 6 enclosures. The CB Test Certificate and Report were amended on August 26, 2009 to add alternate construction.
A sample of the product was tested and found to be in conformity with *Un échantillon de ce produit a été essayé et a été considéré conforme à la*	**PUBLICATION** **IEC 60601-1 (1988) Second Edition, with Amendment No. 1 (1991) and No. 2 (1995)** with the exception of: Clause 36, Electromagnetic Compatibility, Clause 48, Biocompatibility and Clause 52.1, Programmable Electronic Systems. See Test Report for National Differences.
as shown in the Test Report Ref. No. which forms part of this Certificate *comme indiqué dans le Rapport d'essais numéro de référence qui constitue partie de ce Certificat*	E184631-A1-CB-1

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme National de Certification

Underwriters Laboratories

Underwriters Laboratories Inc. / GMA Certification Department, US
333 Pfingsten Road, Northbrook, IL 60062-2096
United States of America
TEL INT* +1 847 664 3008, FAX INT* +1 847 313 3008
email: jolanta.m.wroblewska@us.ul.com

Date: Issued: 2009 February 25
Amended: 2009 August 26 (Am. 1)

Signature: Jolanta M. Wroblewska

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Certificate No. 6376-10-2012

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)	Name of Manufacturer/Distributor, Address
See Attached List (1 Page)	Electromedical Products International, Inc. 2201 Garrett Morris Pkwy. Mineral Wells, Texas 76067-9484 USA

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

Ann M. Ferriter
Director
Division of Risk Management Operations
Office of Compliance
Center for Devices and Radiological Health

This certificate expires 24 months from the date notarized.

COUNTY OF MONTGOMERY
STATE OF MARYLAND

Subscribed and sworn to before me this 26 day of Nov month 2012 year.

CATHRYN N. MORRIS
NOTARY PUBLIC STATE OF MARYLAND
County of Montgomery
My Commission Expires January 4, 2013

Certificate to Foreign Government-Attachment (Page 1 of 1)

Name of Products	Name of Manufacturer/Distributor, Address
Alpha-Stim M Microcurrent Stimulator/ Cranial Electrotherapy Stimulator	Electromedical Products International, Inc. 2201 Garrett Morris Pkwy. Mineral Wells, Texas 76067-9484 USA
Alpha-Stim AID Cranial Electrotherapy Stimulator	

"End of Product List"