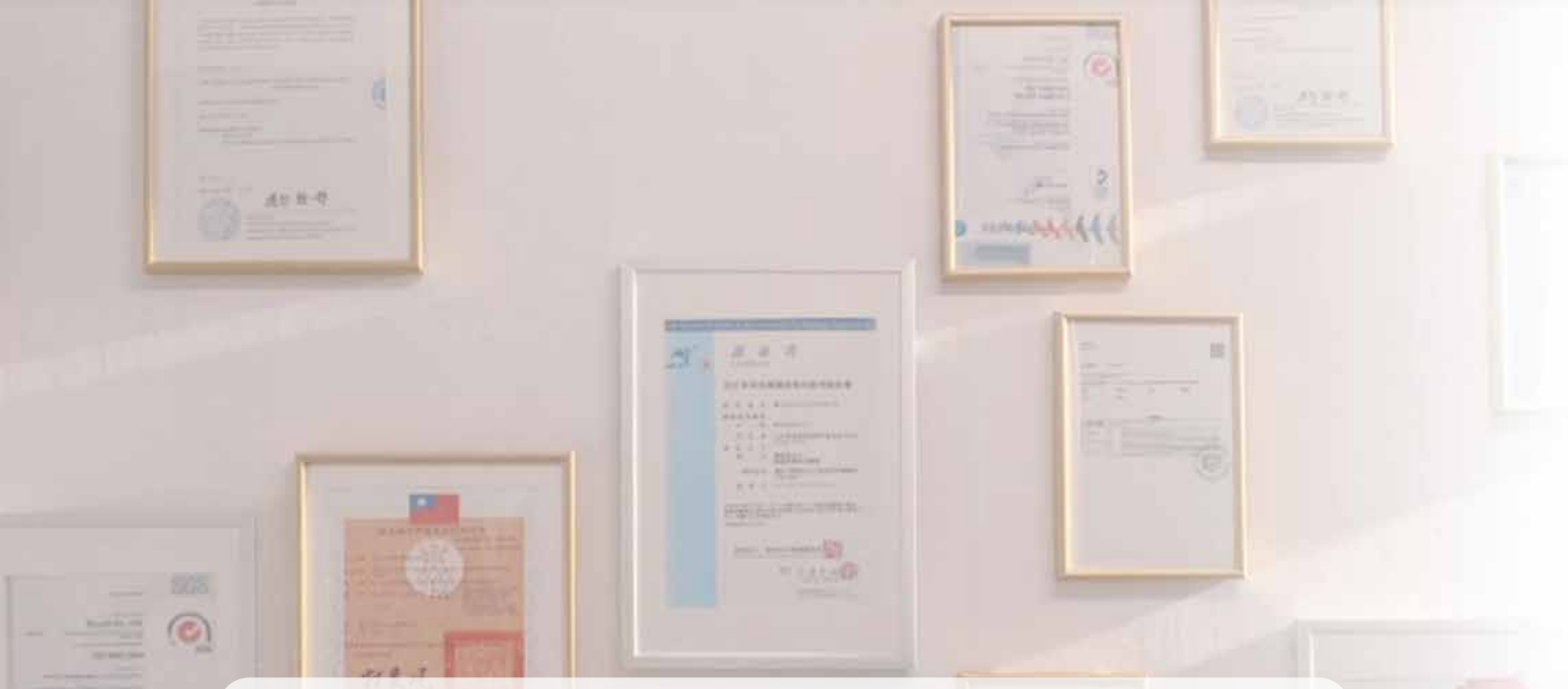

Smart Sleep Wellness Device: DeepZleep owns an exclusive patent and is recognized by the Japanese Ministry of Health, Labour and Welfare as a family-used medical device. Its product functions have been designed and researched and meet various safety testing standards.

DeepZleep has also been recognized by the Malaysian Medical Device Authority (MDA). Its medical effect and quality are highly recognized, and customers can use it with peace of mind.

Please scroll down to continue

MINISTRY OF HEALTH, LABOUR AND WELFARE
GOVERNMENT OF JAPAN
2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916

CERTIFICATE

It is hereby certified that AMPOWER Co., Ltd., Japan is a medical device marketing authorization holder licensed in accordance with the provision of Paragraph 1, Article 23-2 of the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

Name of the Marketing Authorization Holder (or Name of the Office for General Marketing Manager): AMPOWER Co., Ltd.

License Number: 44B2X10008

No. 2515

Tokyo, date SEP. 3. 2019

関野秀人

Hidehito Sekino
Director, Pharmaceutical Safety Division
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare

MINISTRY OF HEALTH, LABOUR AND WELFARE
GOVERNMENT OF JAPAN
2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916

CERTIFICATE

It is hereby certified that the following medical device marketed by AMPOWER Co., Ltd., is manufactured under our supervision as stipulated in the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan, and is certified by Certification Body to be marketed in Japan.

Medical device: ディープズリープAMSONIC (DEEPZLEEP AMSONIC DZ01)
(DEEPZLEEP AMSONIC DZ03)
(DEEPZLEEP AMSONIC DZ04)
(DEEPZLEEP AMSONIC DZ045)
(DEEPZLEEP AMSONIC DZ05)

Name of Registered Certification Body:
Japan Electrical & Environment technology Laboratories
Certification Number: 301AKBZX00030000
Date of Issue: 29.7.2019

No. 2652

Tokyo, date SEP. 12. 2019

Kiyohito Nakai
Director, Medical Device Evaluation Division
Pharmaceutical Safety and Environmental Health Bureau
Ministry of Health, Labour and Welfare

指定管理医療機器製造販売認証書

認証番号　第301AKBZX00030000号

製造販売業者

名　　称　エムパワー株式会社

事務所の名称　エムパワー株式会社

認証品目

類　　別　機械器具78
家庭用電気治療器

一般的名称　電位・温熱組合せ家庭用医療機器
71001000

販売名　ディープズリープAMSONIC

令和　元年（2019年）6月　14日 付けで申請のあった上記医療機器の製造販売を医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律(昭和35年法律第145号)第23条の2の23第1項の規定により、申請のとおり認証する。

令和　元年(2019年) 7月　29日

一般財団法人　電気安全環境研究所
Japan Electrical Safety & Environment Technology Laboratories

理事長
President　薦田 康久

薦田 康久　Yasuhisa Komoda

東京都渋谷区代々木5-14-12
5-14-12 Yoyogi Shibuya-ku, Tokyo

Certificate of Registration

This is to certify that the Quality Management System of

AMPOWER Co., Ltd.

applicable to

Design, manufacture and sale of electric hot-pack apparatus, electric potential therapy apparatus, low frequency electric therapy apparatus and electro massage. (Design and manufacturing process: outsourced)

has been assessed and registered by NQA against the provisions of

BS EN ISO 13485 : 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Managing Director

Certificate No:	118869
Issue Date:	16 September 2019
Valid Until:	16 September 2022
EAC Code:	19

UKAS MANAGEMENT SYSTEMS
015

Certificate of Registration

本登録証は、

エムパワー株式会社

の品質マネジメントシステムが、

温熱治療器、電位治療器、低周波治療器及び電気マッサージ器の設計・製造・販売（設計及び製造工程：アウトソース管理）

という適用範囲において

BS EN ISO 13485：2016

に対してNQAによる審査および登録が完了したことを証するものです。

本登録証は、上記規格のマネジメントシステムを維持し、NQAによる監視を受ける組織に対し付与されます。（本和文登録証は英文登録証とあわせてご使用ください。英文登録証が正式な登録証となります。）

Managing Director

認証番号:	118869
登録日:	2019 年 09 月 16 日
有効期限:	2022 年 09 月 16 日
EAC Code:	19

UKAS MANAGEMENT SYSTEMS
015

Test Report issued under the responsibility of:
Electronics Testing Center, Taiwan
Product Safety Testing Laboratory

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No. ..... :	19-05-VAE-002
Date of issue ..... :	2020-07-14
Total number of pages ..... :	51
CB Testing Laboratory ..... :	Electronics Testing Center, Taiwan Product Safety Testing Laboratory
Address..... :	No.8, Lane 29, Wenming Rd., Guishan Dist , Taoyuan City 33383 , Taiwan ,R.O.C.
Applicant's name ..... :	Am Life International Sdn. Bhd.
Address..... :	No. F-7-21, IOI Boulevard, Jalan Kenari 5, Bandar Puchong Jaya, 47170 Puchong, Selangor, Malaysia.
Test specification:	
Standard ..... :	IEC 60601-1:1988 + A1:1991 + A2:1995
Test procedure..... :	Testing
Non-standard test method……..:	N/A
Test Report Form No. ..... :	IEC60601_1C_II
Test Report Form Originator ..... :	Underwriters Laboratories Inc.
Master TRF ..... :	Dated 2011-11

Test item description..... :	DEEPZLEEP AMSONIC
Trade Mark..... :	AmLife
Manufacturer ..... :	AMPOWER. Co., Ltd.
Model/Type reference..... :	DEEP ZLEEP 05, DEEP ZLEEP 03 and DEEP ZLEEP 01
Ratings..... :	DEEP ZLEEP 05: 220 V~, 50 Hz, 420 VA (Hyperthermia) / 28 VA (Electric Potential) DEEP ZLEEP 03: 220 V~, 50 Hz, 320 VA (Hyperthermia) / 28 VA (Electric Potential) DEEP ZLEEP 01: 220 V~, 50 Hz, 270 VA (Hyperthermia) / 28 VA (Electric Potential)

No. Siri:
Serial No.: 034081

ASAL
ORIGINAL

PIHAK BERKUASA PERANTI PERUBATAN

MEDICAL DEVICE AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
SIJIL PENDAFTARAN PERANTI PERUBATAN
MEDICAL DEVICE REGISTRATION CERTIFICATE
Seksyen 5(1) Akta 737
Section 5(1) of Act 737

No. Pendaftaran: **GB11209520-41032**
Registration No.:

Tarikh Sah Pendaftaran: **18/03/2020 - 17/03/2025**
Registration Validity Date:

Sijil ini adalah dengan ini diberi kepada:
This certificate is hereby issued to:

[redacted]

yang beralamat di:
which is located at:

[redacted]

bagi mengesahkan peranti perubatan seperti yang dinyatakan dalam Lampiran 1 adalah berdaftar di bawah Seksyen 5(1) Akta 737.
to confirm that the medical device as detailed out in Attachment 1 is registered under Section 5(1) of Act 737.

Pendaftaran ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan yang dibuat dibawahnya serta syarat-syarat seperti di Lampiran 2.
This registration is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 2.

AHMAD SHARIFF BIN HAMBALI
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **GB11209520-41032**
Registration No.:

Butir-butir peranti perubatan yang didaftarkan
Particulars of the registered medical device

Nama Peranti Perubatan **ELECTRIC POTENTIAL AND THERMAL THERAPY DEVICE**
Medical Device Name

Kelas **CLASS B** Jenama **DEEP ZLEEP AMSONIC**
Class *Brand*

Kelompok **FAMILY**
Group

Nama dan alamat pembuat: **AMPOWER CO., LTD**
Name and address of manufacturer

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Electric Potential and Thermal Therapy Device	760mm×1830mm ,215W	Electric Potential and Thermal Therapy Device with mat size 760mm×1830mm
2	Electric Potential and Thermal Therapy Device	920mm×1830mm 270W	Electric Potential and Thermal Therapy Device with mat size 920mm×1830mm
3	Electric Potential and Thermal Therapy Device	1220mm×1830mm ,350W	Electric Potential and Thermal Therapy Device with mat size 1220mm×1830mm
4	Electric Potential and Thermal Therapy Device	1370mm×1830mm ,350W	Electric Potential and Thermal Therapy Device with mat size 1370mm×1830mm
5	Electric Potential and Thermal Therapy Device	1520mm×1830mm ,410W	Electric Potential and Thermal Therapy Device with mat size 1520mm×1830mm
"End Of Product List"			