DeepZleep智能睡眠养生器拥有独家专利，
获日本厚生劳动省承认为家庭用医疗器材，
其产品功能经过精心设计和研究，
并符合各种安全检测标准。

DeepZleep智能睡眠养生器也获得
马来西亚医疗器械管理局（MDA）承认，
医疗效果及品质备受肯定，客户可放心使用。

请继续往下查阅

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
Previous Certificate Expiry: 16 September 2022
Reissued: 20 September 2022
Valid Until: 16 September 2025

UKAS MANAGEMENT SYSTEMS
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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
前回認証期限：2022 年 09 月 16 日
再発行日：2022 年 09 月 20 日
有効期限：2025 年 09 月 16 日

UKAS MANAGEMENT SYSTEMS
0015

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: **GB3444124-174204**
Registration No.:

Tarikh Sah Pendaftaran: **11/06/2024 - 10/06/2029**
Registration Validity Date:

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

yang beralamat di: [redacted]
which is located at:

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.

MURALITHARAN PARAMASUA
KETUA EKSEKUTIF
CHIEF EXECUTIVE
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

LAMPIRAN 1
Attachment 1

No. Pendaftaran: **GB3444124-174204**
Registration No.:

Tarikh Sah Pendaftaran: **11/06/2024 - 10/06/2029**
Registration Validity Date:

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

Nama Peranti Perubatan: **DEEPZLEEP AMSONIC ELECTRIC POTENTIAL AND HYPERTHERMIA THERAPEUTIC DEVICE**
Medical Device Name

Kelas: **CLASS B**
Class

Jenama: **AMLIFE**
Brand

Kelompok: **FAMILY**
Group

Nama dan alamat pembuat:
Name and address of manufacturer

AMPOWER CO., LTD
[redacted]

APPENDIX

NO	NAME AS PER DEVICE LABEL	IDENTIFIER	BRIEF DESCRIPTION OF ITEM
1	Electric Potential and Thermal Therapy Device	DeepZleep AmSonic DZ01	Electric Potential and Thermal Therapy Device with mat size 760mm×1830x50mm
2	Electric Potential and Thermal Therapy Device	DeepZleep AmSonic DZ03	Electric Potential and Thermal Therapy Device with mat size 920mm×1830x50mm
3	Electric Potential and Thermal Therapy Device	DeepZleep AmSonic DZ04	Electric Potential and Thermal Therapy Device with mat size 1220mm×1830x50mm
4	Electric Potential and Thermal Therapy Device	DeepZleep AmSonic DZ045	Electric Potential and Thermal Therapy Device with mat size 1370mm×1830x50mm
5	Electric Potential and Thermal Therapy Device	DeepZleep AmSonic DZ05	Electric Potential and Thermal Therapy Device with mat size 1520mm×1830x50mm
6	Electric Potential and Thermal Therapy Device	DeepZleep AmSonic DZM1(DZ Lite)	Electric Potential and Thermal Therapy Device with mat size 280mm×1060x25mm
"End Of Product List"			

STC (Guangdong) Company Limited

EC VERIFICATION OF COMPLIANCE

Reference Number: EMC- D247542VOC

Applicant:		Amlife International (HK) Limited Flat 03-05, 16/F Grand Place, 560 Nathan Road, Kowloon, Hong Kong
Description:		Electric Potential Thermal Therapy Home Use Device
Brand Name:		DEEPZLEEP AMSONIC
Model:	(basic)	DZ05
	(additional)	DZ01, DZ03, DZ04, DZ045, DZM1

We verify that the mentioned product complies with the requirements of the
EC Electromagnetic Compatibility Directive 2014/30/EU

Applicable Standard(s) with amendments:
EN IEC 55014-1:2021
EN IEC 55014-2:2021
EN IEC 61000-3-2:2019+A1:2021
EN 61000-3-3:2013+A2:2021

General Remarks:
This verification confirmation is only valid when used in conjunction with the technical file(s) refers to DM24040163.
This document applies specifically to the sample(s) investigated in the technical report mentioned above, and not to the bulk.

The CE marking as shown below can be affixed on the product after preparation of necessary conformity documentation, as stipulated in articles of above Directive(s).

CE

Test Laboratory

STC (GUANGDONG) COMPANY LIMITED

LONG Yun Jian, Along
Authorized Signatory

www.gdstc.group

Date of Issue: 2024-06-06