



**Peranti Kesihatan Tidur Pintar:  
DeepZleep memiliki paten eksklusif dan diiktiraf  
oleh Kementerian Kesihatan, Buruh dan Kebajikan  
Jepun sebagai peranti perubatan yang sesuai  
digunakan oleh setiap keluarga.**

**Fungsi produk dikaji dan memenuhi pelbagai  
piawaian ujian keselamatan. DeepZleep juga  
diiktiraf oleh Pihak Berkuasa Peranti Perubatan  
Malaysia (MDA). Kesan perubatan dan kualitinya  
diterima oleh banyak pelanggan.**

**Sila rujuk ke bawah untuk maklumat lebih lanjut**



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

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

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中井清人



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.

A handwritten signature in black ink, appearing to read 'N. Wray', is written over a faint blue circular background.

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



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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



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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:  
Registration Validity Date:

**11/06/2024 - 10/06/2029**

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

yang beralamat di:  
*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*



No. Pendaftaran: **GB3444124-174204** Tarikh Sah Pendaftaran: **11/06/2024 -**  
Registration No.: Registration Validity Date: **10/06/2029**

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

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

Kelas **CLASS B** Jenama **AMLIFE**  
Class Brand

Kelompok **FAMILY**  
Group

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

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).



**Test Laboratory**



LONG Yun Jian, Along  
Authorized Signatory

[www.gdstc.group](http://www.gdstc.group)

**Date of Issue:** 2024-06-06