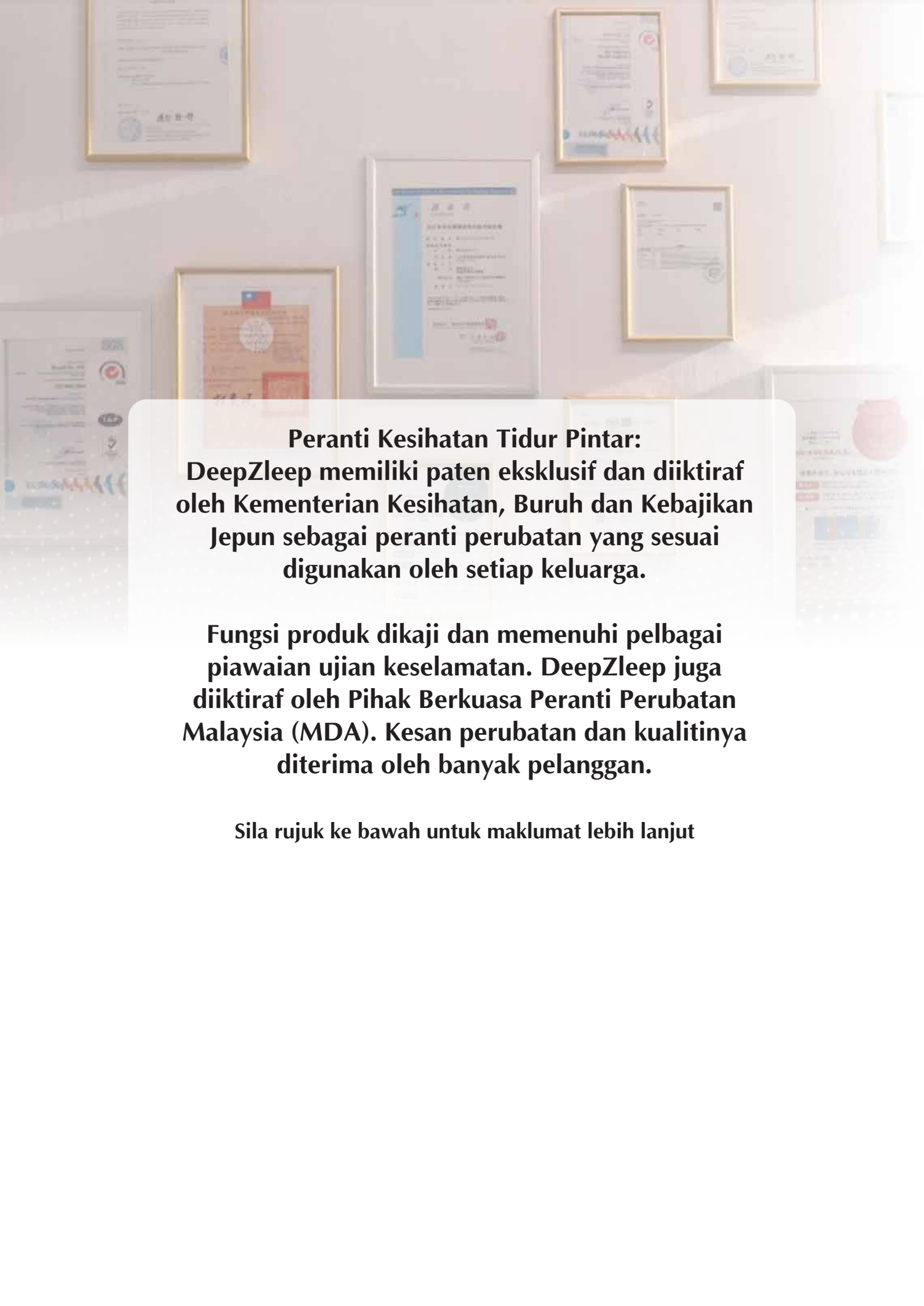




Peranti Kesihatan Tidur Pintar:
DeepZleep memiliki paten eksklusif dan diiktiraf oleh Kementerian Kesihatan, Buruh dan Kebajikan Jepun sebagai peranti perubatan yang sesuai digunakan oleh setiap keluarga.

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

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

10



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 electric massager.
(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 2025

Reissued: 25 September 2025

Valid Until: 16 September 2028



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:
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**
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
Medical Device Name

DEEPZLEEP AMSONIC ELECTRIC POTENTIAL AND HYPERTHERMIA THERAPEUTIC DEVICE

Kelas
Class

CLASS B

Jenama
Brand

AMLIFE

Kelompok
Group

FAMILY

Nama dan alamat pembuat:
Name and address of manufacturer

AMPOWER CO., LTD
[Redacted Address]

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

Date of Issue: 2024-06-06