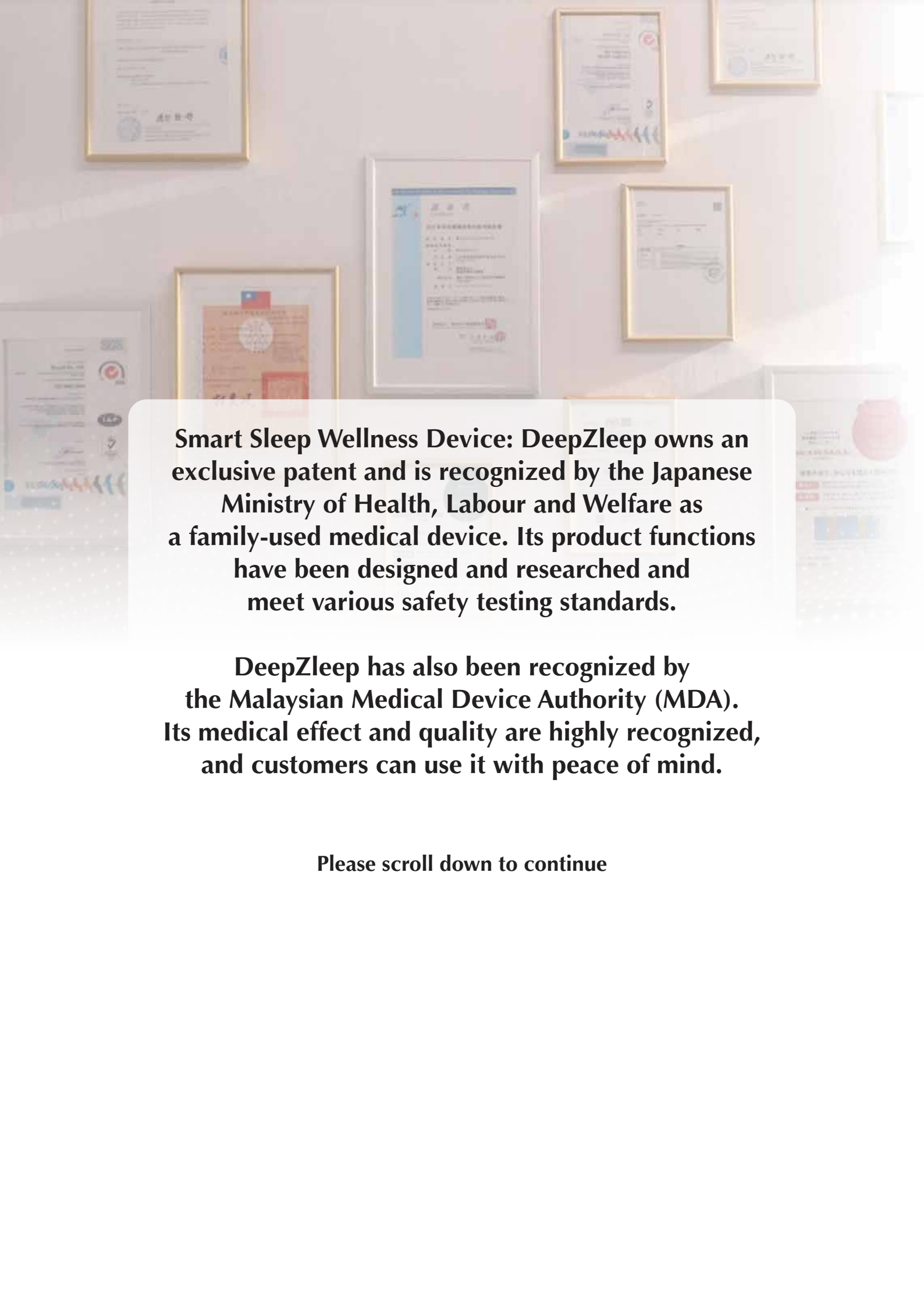




Smart Sleep Wellness Device: DeepZleep owns an exclusive patent and is recognized by the Japanese Ministry of Health, Labour and Welfare as a family-used medical device. Its product functions have been designed and researched and meet various safety testing standards.

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

1997

Journal of Management Inquiry 18(6)

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中井清人



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

nqa.

This is to certify that the Quality Management System of

AMPOWER Co., Ltd.

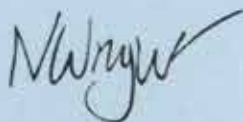
applicable to

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



015



nqa.

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、

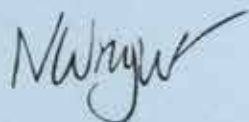
温熱治療器、電位治療器、低周波治療器及び電気マッサージ器の設計・製造・販売（設計及び製造工程：アウトソース管理）

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



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
Copyright © 2011 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved. This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context. If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo shall be removed This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.	
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:



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.

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"			