

**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

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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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Japan Electrical &amp; Environment technology

**Citation:** N

Date of Issue: 30.7.2019

1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 2052, 2053, 2054, 2055, 2056, 2057, 2058, 2059, 2060, 2061, 2062, 2063, 2064, 2065, 2066, 2067, 2068, 2069, 2070, 2071, 2072, 2073, 2074, 2075, 2076, 2077, 2078, 2079, 2080, 2081, 2082, 2083, 2084, 2085, 2086, 2087, 2088, 2089, 2090, 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2098, 2099, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 2108, 2109, 2110, 2111, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2125, 2126, 2127, 2128, 2129, 2130, 2131, 2132, 2133, 2134, 2135, 2136, 2137, 2138, 2139, 2140, 2141, 2142, 2143, 2144, 2145, 2146, 2147, 2148, 2149, 2150, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2159, 2160, 2161, 2162, 2163, 2164, 2165, 2166, 2167, 2168, 2169, 2170, 2171, 2172, 2173, 2174, 2175, 2176, 2177, 2178, 2179, 2180, 2181, 2182, 2183, 2184, 2185, 2186, 2187, 2188, 2189, 2190, 2191, 2192, 2193, 2194, 2195, 2196, 2197, 2198, 2199, 2200, 2201, 2202, 2203, 2204, 2205, 2206, 2207, 2208, 2209, 2210, 2211, 2212, 2213, 2214, 2215, 2216, 2217, 2218, 2219, 2220, 2221, 2222, 2223, 2224, 2225, 2226, 2227, 2228, 2229, 2230, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2238, 2239, 2240, 2241, 2242, 2243, 2244, 2245, 2246, 2247, 2248, 2249, 2250, 2251, 2252, 2253, 2254, 2255, 2256, 2257, 2258, 2259, 2260, 2261, 2262, 2263, 2264, 2265, 2266, 2267, 2268, 2269, 2270, 2271, 2272, 2273, 2274, 2275, 2276, 2277, 2278, 2279, 2280, 2281, 2282, 2283, 2284, 2285, 2286, 2287, 2288, 2289, 2290, 2291, 2292, 2293, 2294, 2295, 2296, 2297, 2298, 2299, 2300, 2301, 2302, 2303, 2304, 2305, 2306, 2307, 2308, 2309, 2310, 2311, 2312, 2313, 2314, 2315, 2316, 2317, 2318, 2319, 2320, 2321, 2322, 2323, 2324, 2325, 2326, 2327, 2328, 2329, 2330, 2331, 2332, 2333, 2334, 2335, 2336, 2337, 2338, 2339, 2340, 2341, 2342, 2343, 2344, 2345, 2346, 2347, 2348, 2349, 2350, 2351, 2352, 2353, 2354, 2355, 2356, 2357, 2358, 2359, 2360, 2361, 2362, 2363, 2364, 2365, 2366, 2367, 2368, 2369, 2370, 2371, 2372, 2373, 2374, 2375, 2376, 2377, 2378, 2379, 2380, 2381, 2382, 2383, 2384, 2385, 2386, 2387, 2388, 2389, 2390, 2391, 2392, 2393, 2394, 2395, 2396, 2397, 2398, 2399, 2400, 2401, 2402, 2403, 2404, 2405, 2406, 2407, 2408, 2409, 2410, 2411, 2412, 2413, 2414, 2415, 2416, 2417, 2418, 2419, 2420, 2421, 2422, 2423, 2424, 2425, 2426, 2427, 2428, 2429, 2430, 2431, 2432, 2433, 2434, 2435, 2436, 2437, 2438, 2439, 2440, 2441, 2442, 2443, 2444, 2445, 2446, 2447, 2448, 2449, 2450, 2451, 2452, 2453, 2454, 2455, 2456, 2457, 2458, 2459, 2460, 2461, 2462, 2463, 2464, 2465, 2466, 2467, 2468, 2469, 2470, 2471, 2472, 2473, 2474, 2475, 2476, 2477, 2478, 2479, 2480, 2481, 2482, 2483, 2484, 2485, 2486, 2487, 2488, 2489, 2490, 2491, 2492, 2493, 2494, 2495, 2496, 2497, 2498, 2499, 2500, 2501, 2502, 2503, 2504, 2505, 2506, 2507, 2508, 2509, 2510, 2511, 2512, 2513, 2514, 2515, 2516, 2517, 2518, 2519, 2520, 2521, 2522, 2523, 2524, 2525, 2526, 2527, 2528, 2529, 2530, 2531, 2532, 2533, 2534, 2535, 2536, 2537, 2538, 2539, 2540, 2541, 2542, 2543, 2544, 2545, 2546, 2547, 2548, 2549, 2550, 2551, 2552, 2553, 2554, 2555, 2556, 2557, 2558, 2559, 2560, 2561, 2562, 2563, 2564, 2565, 2566, 2567, 2568, 2569, 2570, 2571, 2572, 2573, 2574, 2575, 2576, 2577, 2578, 2579, 2580, 2581, 2582, 2583, 2584, 2585, 2586, 2587, 2588, 2589, 2590, 2591, 2592, 2593, 2594, 2595, 2596, 2597, 2598, 2599, 2600, 2601, 2602, 2603, 2604, 2605, 2606, 2607, 2608, 2609, 2610, 2611, 2612, 2613, 2614, 2615, 2616, 2617, 2618, 2619, 2620, 2621, 2622, 2623, 2624, 2625, 2626, 2627, 2628, 2629, 2630, 2631, 2632, 2633, 2634, 2635, 2636, 2637, 2638, 2639, 2640, 2641, 2642, 2643, 2644, 2645, 2646, 2647, 2648, 2649, 2650, 2651, 2652, 2653, 2654, 2655, 2656, 2657, 2658, 2659, 2660, 2661, 2662, 2663, 2664, 2665, 2666, 2667, 2668, 2669, 2670, 2671, 2672, 2673, 2674, 2675, 2676, 2677, 2678, 2679, 2680, 26

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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

nqa.

This is to certify that the Quality Management System of

**AMPOWER Co., Ltd.**

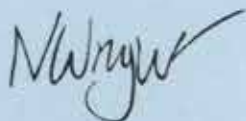
applicable to

**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

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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"			