

# Wakelife Beauty Achieves ISO 13485:2016 Certification, Elevating Standards in LED Light Therapy Production

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Shenzhen Sungrow LED Technology

Co., Ltd., the parent company of

[Wakelife Beauty](#), has recently secured

the prestigious ISO 13485:2016

certification for its medical device

quality management system. This

accreditation, issued by the British

Standards Institution (BSI),

underscores the company's

commitment to excellence in

manufacturing [LED light therapy](#)

[devices](#). The scope of registration for

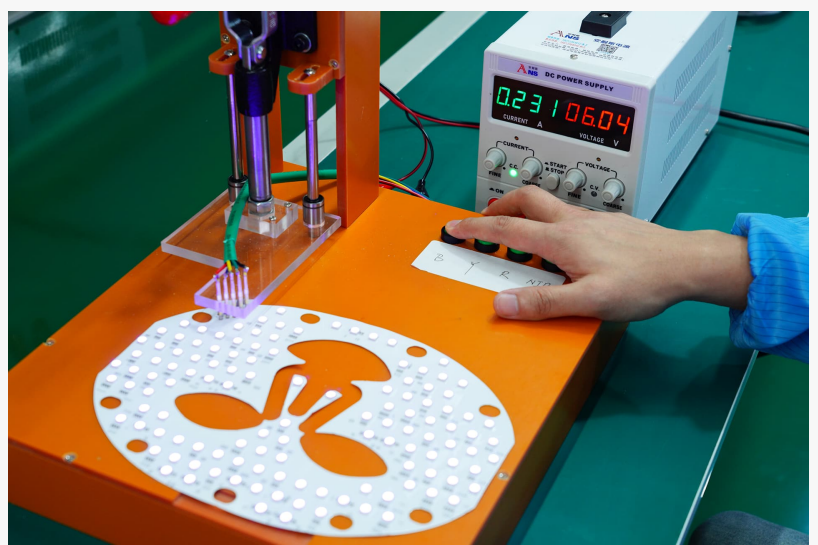
Certificate MD 800872 encompasses

the manufacture and distribution of LED light therapy devices used for professional and home-

use skincare, including anti-aging treatments and acne management. The certification, valid until

May 13, 2027, demonstrates a significant leap in the company's capacity to meet international

quality standards.



LED light therapy devices

ISO 13485 is recognized globally as a benchmark for quality management systems in the medical device sector, emphasizing critical aspects such as design and development, production, quality control, risk management, documentation, traceability, and continuous improvement. Obtaining this certification not only validates the company's operational procedures but also enhances its credibility in the LED therapy device market.

The certification also extends to MDSAP (Medical Device Single Audit Program) standards, ensuring compliance with medical device regulations across Australia, Canada, and the United States, including stringent requirements outlined in U.S. regulations like 21 CFR 820 and 21 CFR 803. This dual certification positions Wakelife Beauty as a formidable player in the global market, capable of providing compliant products that meet diverse regulatory demands.

Wakelife Beauty, as a specialized manufacturer of LED red light therapy devices, including masks

and panels, Wakelife Beauty serves a wide array of clients in the beauty, health, and medical device sectors. The company has established a comprehensive OEM/ODM service system that facilitates all stages from product definition and optical design to structural development, electronic engineering, sample validation, quality inspection, and mass production. This streamlined process ensures clients receive products that are not only stable and traceable but also tailored to meet the specific needs of their target markets.

Looking ahead, Wakelife Beauty is committed to continuously refining its [medical-grade manufacturing systems](#). The company is focused on the development of innovative products, including LED therapy masks, red light therapy panels, photodynamic therapy devices, hair growth light therapy devices, and eye care equipment. Wakelife Beauty welcomes brand clients, distributors, and partners to engage in factory audits, sample evaluations, and collaborations on OEM/ODM projects, with the goal of advancing the standardized development of medical-grade LED light therapy devices in the international market.

In conclusion, Wakelife Beauty's achievement of ISO 13485:2016 certification marks a significant milestone in its journey toward excellence. The company invites brand clients to submit project proposals and connect with its OEM/ODM team to explore sample requests, certification documentation, and tailored solutions. Together, they can drive the future of LED light therapy equipment on a global scale.

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