



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 409974 DNS Lab Pty Ltd - Cosmetic phototherapy system, home-use

ARTG entry for Medical Device Included Class IIa

Sponsor DNS Lab Pty Ltd

Postal Address 6 Regent Street, Paddington, NSW, 2021
Australia

ARTG Start Date 2/06/2023

Product Category Medical Device Class IIa

Status Active

Approval Area Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address
Shenzhen Kaiyan Medical Equipment Co Ltd	Building #3 and Building #5 40th of Fuxin Street Huaide Community Fuyong Town Baoan District Shenzhen, Guangdong, 518103 China

Products

1 . Cosmetic phototherapy system, home-use

Product Type	Single Device Product	Effective Date	2/06/2023
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GMDN 47704 Cosmetic phototherapy system, home-use

Intended Purpose The LED It Glow Mask is an over the counter device that is intended for the use in the treatment of full-face wrinkles.

Specific Conditions

No Specific Conditions included on Record

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