



Certificate No. 9606-5-2023

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

<u>Name of Product(s)</u>	<u>Name of Manufacturer/Distributor, Address</u>
See Attached List (One Page)	See Attached List (One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above device product(s) may be marketed in, and legally exported from, the United States of America at this time. While the manufacturing plant(s) in which the device product(s) is produced is subject to inspection, FDA does not routinely inspect manufacturing firms that only make Class 1 medical devices. However, the firm has certified that it is currently operating in substantial compliance with current good manufacturing practice requirements for the device product(s) listed above.

Sincerely,

CDR Cesar A. Perez, PhD, Director
DRP2: Division of Establishment Support
Office of Regulatory Programs
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from May 30, 2023 to May 29, 2025.





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Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

DermLite LLC
21 Argonaut
Unit A
Aliso Viejo, CA
USA 92656

Name of Manufacturer

Manufacturer
DermLite LLC
21 Argonaut
Unit A
Aliso Viejo, CA
USA 92656

----END OF MANUFACTURER/DISTRIBUTOR LIST----





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USA 92656

Name of Manufacturer

Manufacturer

DermLite LLC
21 Argonaut
Unit A
Aliso Viejo, CA
USA 92656

Name of Product(s)

DermLite 1 (DL1)
DermLite DL1 Basic (DL1B)
DermLite 3 (DL3N)
DermLite Carbon (DermLite DLC)
DermLite DL100
DermLite DL200 HR
DermLite DL200 Hybrid
DermLite DL200 HYG
DermLite DL4 (DL4)
DermLite DL4W
DermLite DL5 (DL5)
DermLite Foto II Pro (Foto II Pro)
DermLite Foto X
DermLite GL
DermLite Handyscope
DermLite Lumio (LUM)
DermLite Lumio 2 (DLU2)
DermLite Lumio S (DLUS)
DermLite Lumio UV (LUM UV)
DermLite Nailio
DermLite HUD2 (HUD2)
Syris v900L
SkinLite
SkinLite II

-----END OF PRODUCT LIST-----

