



Certificate No. 5450-2-2024-1

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:

Name of Product(s)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

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 product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the 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 February 23, 2024 to February 22, 2026.



To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.



Certificate No. 5450-2-2024-1

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

Name of Owner Operator

TransLite, LLC
345 Commerce Green Blvd
Sugar Land, TX
USA 77478

Name of Manufacturer

TRANSLITE
345 Commerce Green Blvd
SUGAR LAND, TX
USA 77478

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





Certificate No. 5450-2-2024-2

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Owner Operator

TransLite, LLC
345 Commerce Green Blvd
Sugar Land, TX
USA 77478

Name of Manufacturer

TRANSLITE
345 Commerce Green Blvd
SUGAR LAND, TX
USA 77478

Name of Product(s)

Veinlite LED+ (with disposable plastic covers VLED+-DPC)
Veinlite EMS Pro (with disposable plastic covers VEMS-DPC)
Veinlite LEDX (with disposable plastic covers VLEDX-DPC)
Veinlite PEDI (with disposable plastic covers VPED-DPC)
Veinlite NEO (with disposable plastic covers VLN-DPC)
Veinlite R (with disposable plastic covers VLN-DPC)
Veinlite PEDI2 (with disposable plastic covers VP2-DPC)

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

