



TransLite, LLC
Veinlite® Transilluminators

MANUFACTURER'S DECLARATION OF CONFORMITY (U.K) MEDICAL DEVICES

Translite LLC declares that the devices listed on the attached product schedule conform to the relevant sections of Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002) and the EU Withdrawal Agreement Act.

Reference: Attached Product Schedule

Manufacturer's Name: Translite LLC

Business Address: 345 Commerce Green Blvd., Sugar Land, TX 77478, USA

SRN (Single Registration Number): US-MF-000029360

Medical Device(s): See Attached Product Schedule

Classification: Class I

GMDN Code and Term: 32696 – Skin transilluminator, battery-powered

MHRA Device Code Class I: Z999 – Class I, Transilluminator, Optical

Scope of Application: All devices to which the Declaration of Conformity Procedure has been applied

The medical devices in the attached product schedule comply with the applicable provisions of the essential principles and the classification rules before being supplied.

These devices and their manufacturing processes do not incorporate any animal substances, nor do the devices incorporate medicinal substances.

Standards Applied: EN13485; EN14971; EN 1041; EN 980, EN 60601-1 & EN 60601-1-2

Registrations: MHRA

Responsible Person: Responsible Person Ltd. Summit House, 4-5 Mitchell Street, Edinburgh, EH6 7BD, Scotland.

Authorised Signatory:

Name: Nizar Mullani
Title: President, Translite, LLC.

5/3/2023
Date

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Product Schedule

Product Code (SKU)	Device Name	Generic Name	Class	Family	Single Use /Reusable
VLEDX	Veinlite LEDX	Transilluminator, Vein Finder	I	Veinlite®	Reusable
VLED+	Veinlite LED+	Transilluminator, Vein Finder	I	Veinlite®	Reusable
VEMS	Veinlite EMS Pro	Transilluminator, Vein Finder	I	Veinlite®	Reusable
VNEO	Veinlite NEO	Transilluminator, Vein Finder	I	Veinlite®	Reusable
VP2	Veinlite PEDI2	Transilluminator, Vein Finder	I	Veinlite®	Reusable
VLEDX-DPC	Accessory to LEDX, Cover	Transilluminator, Vein Finder accessory	I	Veinlite®	Single Use
VPED-DPC	Accessory to (discontinued models) Veinlite II & Veinlite PEDI, Cover	Transilluminator, Vein Finder accessory	I	Veinlite®	Single Use
VLED+DPC	Accessory to Veinlite LED+, Cover	Transilluminator, Vein Finder accessory	I	Veinlite®	Single Use
VEMS-DPC	Accessory to Veinlite EMS Pro, Cover	Transilluminator, Vein Finder accessory	I	Veinlite®	Single Use
VNEO-DPC	Accessory to Veinlite NEO, Cover	Transilluminator, Vein Finder accessory	I	Veinlite®	Single Use
VP2-DPC	Accessory to Veinlite PEDI2, Cover	Transilluminator, Vein Finder accessory	I	Veinlite®	Single Use