MANUFACTURER'S DECLARATION OF CONFORMITY

Medical Devices Regulation

Translite, LLC declares that this EU Declaration of Conformity is issued under the sole responsibility of the manufacturer and the devices listed on the product schedule conform to the relevant sections of New MDR 2017/745 Regulations (Medical Devices), as detailed below:

Manufacturer's Name:	Translite LLC
Business Address:	345 Commerce Green Blvd., Sugar Land, TX 77478, USA
***SRN** (Single Registration Number) :*	US-MF-000029360
Basic UDI-DI:	See Attached Product Schedule
Medical Device(s):	See Attached Product Schedule
Classification:	Class I
Conformity Assessment Route:	Annex IV
GMDN Code and Term:	32696 – Skin transilluminator, battery-powered
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.

Notified Body:	***N/A***
CE Mark Certificate number:	***N/A***
Expiry date of CE Mark Certificate:	*N/A*
Standards Applied:	*EN13485; EN14971; EN 1041; EN 980, EN 60601-1 & EN 60601-1-2*
Registrations:	HPRA
Authorised Representative:	E C Rep Ltd 5 Fitzwilliam Square East, Dublin 2, D02 R744, Ireland

Authorised Signatory:

Kelsea Last

Name: Kelsea Last
Title: Vice President
Location: Sugar Land, TX

9-16-25
Date

Veinlite®
TransLite, LLC
Veinlite® Transilluminators

Technical File - Section 1 (Declaration of Conformity)

Product Code	Device Name	Class	Family	Use Single /Reusable	Custom made or Procedure Pack/Kit	Basic UDI-DI	GMDN	GMDN Term
VLEDX	Veinlite LEDX	I	Veinlite®	Reusable	No	195893754281KZ	32696	Transilluminator
VLED+	Veinlite LED+	I	Veinlite®	Reusable	No	195893452019HV	32696	Transilluminator
VEMS-PRO	Veinlite EMS Pro	I	Veinlite®	Reusable	No	195893880973MP	32696	Transilluminator
VNEO	Veinlite NEO	I	Veinlite®	Reusable	No	195893005314FC	32696	Transilluminator
VPEDI2	Veinlite PEDI2	I	Veinlite®	Reusable	No	195893253494JC	32696	Transilluminator
VLEDX-DPC	Accessory to LEDX, Disposable Cover	I	Veinlite®	Single Use	No	195893277230JS	32696	Transilluminator (Accessory)
VLED+-DPC	Accessory to Veinlite LED+, Disposable Cover	I	Veinlite®	Single Use	No	195893232635H9	32696	Transilluminator (Accessory)
VEMS-DPC	Accessory to Veinlite EMS Pro, Disposable Cover	I	Veinlite®	Single Use	No	195893307609HP	32696	Transilluminator (Accessory)
VLN-DPC	Accessory to Veinlite NEO, Disposable Cover	I	Veinlite®	Single Use	No	195893602339HM	32696	Transilluminator (Accessory)
VP2-DPC	Accessory to Veinlite PEDI2, Disposable Cover	I	Veinlite®	Single Use	No	195893435975KK	32696	Transilluminator (Accessory)