

## Technical File - Section 1 (Declaration of Conformity)

# 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)** IE-CA-001

**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:** 14130 – Transilluminator

**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:** NA

**CE Mark Certificate number:** MDG-AR-40

**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:**



Name: Nizar Mullani  
Title: RA /QA Representative/Management Representative/  
Location: Sugar Land, TX

2/15/22  
Date



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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	14130	Transilluminator
VLED+	Veinlite LED+	I	Veinlite®	Reusable	No	195893452019HV	14130	Transilluminator
VEMSPRO	Veinlite EMS Pro	I	Veinlite®	Reusable	No	195893880973MP	14130	Transilluminator
VNEO	Veinlite NEO	I	Veinlite®	Reusable	No	195893005314FC	14130	Transilluminator
VPEDI2	Veinlite PEDI2	I	Veinlite®	Reusable	No	195893253494JC	14130	Transilluminator
VLEDX-DPC	Accessory to LEDX, Disposable Cover	I	Veinlite®	Single Use	No	195893277230JS	14130	Transilluminator (Accessory)
VLEDP-DPC	Accessory to Veinlite LED+, Disposable Cover	I	Veinlite®	Single Use	No	195893232635H9	14130	Transilluminator (Accessory)
VEMS-DPC	Accessory to Veinlite EMS Pro, Disposable Cover	I	Veinlite®	Single Use	No	195893307609HP	14130	Transilluminator (Accessory)
VLN-DPC	Accessory to Veinlite NEO, Disposable Cover	I	Veinlite®	Single Use	No	195893602339HM	14130	Transilluminator (Accessory)
VP2-DPC	Accessory to Veinlite PEDI2, Disposable Cover	I	Veinlite®	Single Use	No	195893435975KK	14130	Transilluminator (Accessory)
VL-DPC	Accessory to (discontinued models) Veinlite II & Veinlite, LED, EMS, PEDI, Disposable Cover	I	Veinlite®	Single Use	No	--	14130	Transilluminator (Accessory)