

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) : 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

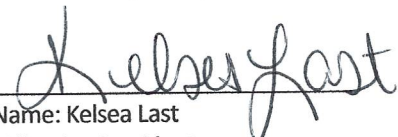
Expiry date of CE Mark Certificate: N/A

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:



Name: Kelsea Last

Title: Vice President

Location: Sugar Land, TX



Date

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) |