TransLite, LLC
Veinlite® Transilluminators

Declaration of Conformity

To Annex VII of the EC Medical Device Directive

Date of Issuance: March 14, 2019

Manufacturer:
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This Declaration is applicable to all products listed and manufactured after the Date of Issuance of this Declaration of Conformity.
We hereby declare under our sole responsibility, that the following products, comply fully with the requirements of the Medical Device Directive (93/42/EEC, as revised by council directives 20/47/EC), ISO 13485:2016, IEC 60601-1, IEC/ EN 60601-1-2, IEC 62133:2012.
The UMDNS code for Veinlite products is 14-346 ('Vein Finder'). The UNSPSC Code is 42181502 ('Diagnostic assessment and exam products for general use, medical exam transilluminators').

Product:

Model Number	Device Class
Veinlite LED+	1
Veinlite PEDI	1
Veinlite LEDX	1
Veinlite EMS Pro	1
Veinlite NEO/ R	1
VLED+DPC (covers for the Veinlite LED+)	1
VEMS-DPC (cover for Veinlite EMS/Pro)	1
VPED-DPC (cover for Veinlite PEDI)	1
VLEDX-DPC (cover for Veinlite LEDX)	1
VNEO-DPC (cover for the Veinlite NEO/R)	

Original Copy Signed: _____

Signature Date: _____

Kristin Mullani, Vice President, TransLite LLC

Document #: DC 2019