BIOSISTEM-MLD S.R.L.
Cod Fiscal: 1010600028048; IBAN: MD95ML0000000002251429243;
Banca: BC "Moldindconbank" S.A. fil. Invest; Codul bancii: MOLDMD2X329;
Adresa poştală a băncii: mun. Chişinău, bd. Moscovei, 14/1;

№ 651/19 din 25.06.2019 **Către Președintele Raionului Glodeni**

Prin prezenta, S.R.L. BIOSISTEM MLD, va aduce la cunostinta ca nu dispune de contract cu banca pentru a putea prezenta Garantie Bancara.

Din motiv ca **Președintele Raionului Glodeni**, nu acceptă garantie prin transfer la contul autoritatii contractante, SRL Biosistem mld se obliga in caz că vom încălca unul dintre punctele următoare:

a) Ofertantul şi-a retras oferta în timpul perioadei valabilităţii ofertei sau a modificat oferta după expirarea termenului-limită de depunere a ofertelor; sau

b) Ofertantul fiind anunţat de către autoritatea contractantă, în perioada de valabilitate a ofertei, despre adjudecarea contractului: (i) eşuează sau refuză să semneze formularul contractului;; sau (ii) eşuează sau refuză să prezinte garanţia de bună execuţie, dacă se cere conform condiţiilor licitaţiei, ori nu a executat vreo condiţie specificată în documentele de atribuire, înainte de semnarea contractului de achiziţie.

stipulate in formularul 3.2 din documentatia standart pentru licitatia nr. ocds-b3wdp1-MD-1560423105573 din 05.07.2019, sa achite catre Președintele Raionului Glodeni o penalitate sub forma de transfer în contul beneficiarului pina la 1% din valoarea totala a ofertei fara TVA, ceea ce constitue 85,00 lei MDL.

Cu respect,

Director SRL ”Biosistem MLD” Digitally signed by Poiata Vitalie
Date: 2019.06.25 09:14:40 EEST
Reason: MoldSign Signature
Location: Moldova

Vitalie Poiată_____

L.Ș.

adresa: str. Albișoara 16/1 of.7, MD-2001 Chișinău, Republica Moldova
tel.+373-22-808517, +373-22-808719, fax +373-22-808519.
Web: www.biosistem-mld.com; e-mail: biosistem.mld@gmail.com

CERTIFICATE OF EUROPEAN UNION AUTHORISED REPRESENTATIVE

CE

This is to certify that Translite LLC.

has duly registered the following relevant product types with the UK Competent Authority through its Appointed Representative in accordance with *Article 14* of the Council Directive 93/42/EEC as revised by Council Directive 20/47/EC concerning medical devices (The "Medical Devices Directive") (UK Medical Devices Regulation 1994: Regulation 14).

********** Applicable ANNEX **********

Annex VII

********** Scope of Supply **********

Product Class I non-sterile. Product Family: Veinlite

Competent Authority Registration Reference CA008352

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In accordance by self-declaration with *Article 11* and *Annex VII* for Class I devices may apply the CE Mark

********** Appointment **********

We certify that M Devices Group/EC Rep Ltd was appointed as the Authorised Representative on the 4th August 2004

Signature Authorised Representative	Date: 7 Sept 2018

Certificate No. MDG—AR-40 Valid to 4-August-2019

EC REP Ltd

Health & Education Centre, The Church
Portland Street, Southport PR8 1HU
United Kingdom

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 4578-1-2018

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries , the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

Name of Manufacturer
TRANSLITE
345 Commerce Green Blvd
SUGAR LAND, TX USA 77478

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from January 12, 2018 to January 11, 2020.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Certificate No. 4578-1-2018

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Manufacturer

TRANSLITE
345 Commerce Green Blvd
SUGAR LAND, TX USA 77478

Name of Product(s)

Veinlite LED+ (with disposable plastic covers VLED+DPC)
Veinlite EMS Pro (with disposable plastic covers VEMS-DPC)
Veinlite LEDX (with disposable plastic covers VLEDX-DPC)
Veinlite LED (with disposable plastic covers VLED-DPC)
Veinlite EMS (with disposable plastic covers VEMS-DPC)
Veinlite PEDI (with disposable plastic covers VPED-DPC)
----------END OF PRODUCT LIST----------

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Translite LLC
345 Commerce Green Blvd.
Sugar Land
Texas
77478
USA

Holds Certificate No: **FM 633388**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, manufacture and servicing of vein access devices.

For and on behalf of BSI:

Carlos Pitanga, Chief Operating Officer Assurance – Americas

Original Registration Date: 2015-09-02
Effective Date: 2018-09-02
Latest Revision Date: 2018-08-20
Expiry Date: 2021-09-01

...making excellence a habit.™

TransLite, LLC
Veinlite® Transilluminators

Declaration of Conformity

To Annex VII of the EC Medical Device Directive

Date of Issuance: March 14, 2019

Manufacturer:
TransLite, LLC.
345 Commerce Green Blvd
Sugar Land, TX 77478
Tel: 281.240.3111
E-Mail: info@veinlite.com

EC Representative:
M. Devices Group
The Church, Portland Street
Southport, PR81HU, UK
Tel: +44 1704 544 944
E-Mail : info@ecrep.com

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: 3·14·19

Kristin Mullani, Vice President, TransLite LLC

Document #: DC 2019

Veinlite® LEDX, Veinlite LED, Veinlite EMS and Veinlite PEDI

TransLite, LLC, offers four portable transilluminators for assisting vein access. These devices all use TransLite's patented side-transillumination method for imaging veins anywhere on the body. A unique C-shaped ring design gives uniform illumination of a small region of tissue. To achieve the best contrast for vein imaging, bright orange light (for strong illumination) is combined with a darker red light (for deeper penetration and darkly pigmented skins). Veinlites not only help find the vein, they also hold it in place, prevent it from rolling and stretch the skin for easy access without a tourniquet. Custom designed light shields snap on to the units to block bright overhead light which can interfere with the transillumination technique. Pediatric or neonate adapters can be used to cone down the light area for use with infants or neonates. All models come with latex free, single-use plastic covers to prevent cross contamination between patients.

Veinlite LEDX

Veinlite LEDX is our most powerful hand-held device designed for general vein access in adults and children. It has the largest field of view of all portable Veinlites and is the most suitable portable model for use during sclerotherapy. It is rechargeable and has 32 LEDs (24 orange and 8 red). Two switches are used to select either or both colors for optimum vein imaging in all skin types. The Veinlite LEDX kit includes disposable plastic covers, battery charger, a snap-on pediatric adapter and a snap-on light shield attachment. A carrying case with belt clip is available as an optional extra.

Veinlite LED

The model most widely used in hospitals, Veinlite LED is designed for general vein access in adults, children and infants. It is rechargeable and has 24 LEDs (12 orange and 12 red). Two switches are used to select either or both colors for optimum vein imaging in all skin types. The Veinlite LED kit includes disposable plastic covers, battery charger, a snap-on pediatric adapter and a snap-on light shield attachment. A carrying case with belt clip is available as an optional extra.

Veinlite EMS

The most popular model with fire departments and on ambulances, the Veinlite EMS is a simpler version of the Veinlite LED and uses 16 LEDs (12 orange and 4 red). It is a lower cost option for vein access in adults, children and infants. It is well suited to mobile emergency response teams. The Veinlite EMS uses 2 AA alkaline batteries and has a single switch to illuminate both orange and red LEDs. The Veinlite EMS kit includes disposable plastic covers, 2 AA batteries, a snap-on pediatric adapter and a snap-on light shield attachment. A carrying case with belt clip is available as an optional extra.

Veinlite PEDI

Designed for the NICU, the Veinlite PEDI is our smallest vein transilluminator. It is designed for neonates (including preterm) and infants. The Veinlite PEDI has 12 LEDs (8 orange and 4 red) and one CR2 lithium battery. Two switches allow for selection of either or both colors for optimum vein imaging in the smallest patients. A snap-on neonatal adapter is designed to shine six closely packed LEDs through a small opening for safe through-the-body transillumination of hands, feet and limbs in neonates. The Veinlite PEDI kit includes disposable plastic covers, CR2 battery, a snap-on neonatal adapter and a snap-on light shield attachment. A detachable lanyard is available as an optional extra.

Comparison of Veinlite LEDX, Veinlite LED, Veinlite EMS and Veinlite PEDI

Features	LEDX	LED	EMS	PEDI
Application	Vein Access in Adults and older Children, also for Sclerotherapy	Vein Access in Adults, Children and Infants Hospital model	Vein Access in Adults, Children and Infants Ambulance model	Vein Access in Neonates and Infants (max. age 24 months) NICU model
Number of LEDs	32	24	16	12
Color of LEDs	Orange (24) + Red (8)	Orange (12) + Red (12)	Orange (12) + Red (4)	Orange (8) + Red (4)
Color Selection	Yes	Yes	No	Yes
Number of Switches	2	2	1	2
Ring Diameter (mm)	31	21	21	14
Battery Charger	Yes	Yes	No	No
Batteries	Rechargeable Lithium	Rechargeable Lithium	2 AA Alkaline	CR2 3V Lithium
Battery Run Time (min)	130/160 (32/24 LEDs)	250/350 (24/12 LEDs)	360	200
Pediatric Adapter	Included	Included	Included	Neonate Adapter Included
Light Shield	Included	Included	Included	Included
Dimensions (mm)	102 x 65 x 24	95 x 55 x 21	115 x 55 x 21	67 x 42 x 21
Weight Including Battery	83g	71g	108g	41g

TransLite, LLC: www.veinlite.com, info@veinlite.com, Tel: 281.240.3111, Fax: 281.240.3122