

CERTIFICATE OF EUROPEAN UNION AUTHORISED REPRESENTATIVE



This is to certify that TransLite LLC



345 Commerce Green Blvd, Sugar Land, TX 77478, USA

has duly registered as a manufacturer as a result of Brexit, with the Irish Competent Authority through its Appointed Authorised Representative in accordance with *Article 14* of the Council Directive 93/42/EEC concerning medical devices (The “Medical Devices Directive”) (93/42/EEC), and with *Article 11* REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 (Medical Devices Regulation 2017/745)

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

Annex VII E C Declaration of Conformity,

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

SRN US-MF-000029360

BSI QMS ISO 13485:2016 Exp Date: 2024-09-01 No. FM 633388

Product Class I non-sterile. Product Family: Veinlite

Registered reference with the HPRA: E C Rep Limited / Translite LLC - MDD - IE/CA01/R/GM/1404

***** Appointment *****

We certify that E C Rep Ltd was appointed as the Authorised Representative on the 6th May 2019

Signature
Authorised Representative 

Date: 11 Apr 2023



E C Rep Ltd, 5 Fitzwilliam
Square East, Dublin, D02
R744, Ireland

Certificate No. MDG—AR-40 Valid to 5 May 2024