

Certificate of Registration



Client Ref. USA/2015/07/61

Issued To: **Enova Illumination, Inc.**
6305 Sandburg Road,
STE 100,
Minneapolis, MN
55427
USA

Legal Manufacturer [SRN: Not yet available]

Issued By: **Advena Limited**
Tower Business Centre, 2nd Flr, Tower
Street, Swatar, BKR 4013. Malta.

EC-REP [SRN: MT-AR-00000234]

EU Competent Authority: **Malta Medicines Authority (MMA)**
Sir Temi Zammit Buildings, Malta Life
Sciences Park, San Gwann SGN 3000
Malta.
Tel: +356 2343 9000
Email: info.medicinesauthority@gov.mt

Eudamed Actor ID: MT-CA-019

We hereby declare that:

- Device registrations for the medical devices mentioned within this certificate have duly been completed with the Malta Medicines Authority (MMA) the Competent Authority of Malta.
- Due to the 26th May 2021 Date of Application of Regulation (EU) 2017/745 (MDR) the validity of this certificate is subject to the Legal Manufacturer providing satisfactory evidence that any device claiming compliance to Directive 93/42/EEC (MDD) through Article 120 (3) of Regulation (EU) 2017/745 as amended, is legitimately permitted.
- Due to the 26th May 2022 Date of Application of Regulation (EU) 2017/746 (IVDR) the validity of this certificate is subject to the Legal Manufacturer providing satisfactory evidence that any device claiming compliance to Directive 98/79/EC (IVDD) through Article 110(3) of Regulation (EU) 2017/746 as amended, is legitimately permitted.

Anthony Kirby – Managing Director

Date of Issue: 16 August 2023

AR Cover Begins: 01 August 2023

AR Cover Ends: 31 July 2024

This certificate is subject to the organisation maintaining their documentation in compliance with the EU legislation as indicated in this certificate.

This certificate is for the exclusive use of Advena Ltd's clients and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

Appendix A



Product Details, Names or Trade Names	EU Legislation	Classification	Device Registration Reference(s)
LED Surgical Headlight with Battery Accessories	MDR	Class I	MT-MDF03-AA623A
Clip-On LED Light System with Battery Accessories	MDR	Class I	MT-MDF03-AA623B
Surgical Loupes	MDR	Class I	MT-MDF03-AA623C

— ADVENA LIMITED —



CERTIFICATE OF REGISTRATION