

# Certificate of Registration



**Client Ref.** USA/2018/01/02

**Issued To:** LumaClean LLC  
9724 Colts Neck Ln,  
Concord,  
NC 28027  
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 26<sup>th</sup> 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 26<sup>th</sup> 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:** 29 January 2024

**AR Cover Begins:** 01 February 2024

**AR Cover Ends:** 31 January 2025

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)
EnClean <sup>®</sup> Cleaning Brush	MDR	Class I	MT-MDF03-AA626A

— ADVENA LIMITED —



CERTIFICATE OF REGISTRATION