## **Certificate of Registration**



Client Ref. GBR/2018/07/31

Issued To: Outside In (Cambridge) Ltd also trading

as Lumie

3 The Links, Trafalgar Way Bar Hill, Cambridge

CB 23 8UD United Kingdom

Issued By: Advena Limited

Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013. Malta.

**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

FC-REP [SRN: MT-AR-000000234]

Legal Manufacturer [SRN: GB-MF-000009152]

**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.

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Anthony Kirby – Managing Director

Date of Issue: 1 December 2023 AR Cover Begins: 01 December 2023 AR Cover Ends: 30 November 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)
Bodyclock Glow 150	MDR	Class I	MT-MDF03-AA343A
Bodyclock Luxe 700FM	MDR	Class I	MT-MDF03-AA343B
Bodyclock Luxe 750 DAB	MDR	Class I	MT-MDF03-AA343C
Bodyclock Rise 100	MDR	Class I	MT-MDF03-AA343D
Bodyclock Shine 300	MDR	Class I	MT-MDF03-AA343E
Bodyclock Spark 100	MDR	Class I	MT-MDF03-AA343F

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