## **Certificate of Registration**



Client Ref. KOR/2015/07/01

Issued To: SPL Life Sciences Co., Ltd

26 Geumgang-ro 2047 beon-gil Naechon-Myeon, Pocheon-si

Gyeonggi-do Korea

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

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

Legal Manufacturer [SRN: Not yet available]

**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: 24 October 2023 AR Cover Begins: 01 November 2023 AR Cover Ends: 31 October 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)
Cell Culture Dish	IVDD	General IVD	DVC-MT-19-02-000026
Cell Culture Flask	IVDD	General IVD	DVC-MT-19-02-000027
Cell Culture Plate	IVDD	General IVD	DVC-MT-19-02-000028
Cell Culture Slide	IVDD	General IVD	DVC-MT-19-02-000029
Cell Culture Strainer	IVDD	General IVD	DVC-MT-19-02-000030
Cryovial	IVDD	General IVD	DVC-MT-19-02-000031

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