Certificate of Designation

Eudamed Mandate Summary

Client Ref.	**KOR/2015/07/01**	**Date of Issue:** 14 April 2025
Issued To:	**SPL Life Sciences Co., Ltd** 48, Geumgang-ro 2047 beon-gil, Naechon-Myeon, Pocheon-si, Gyeonggi-do, Korea (11192)	**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-000000234]**
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	**MMA [SRN: MT-CA-019]**

In accordance with the Mandate executed by both the Legal Manufacturer and Advena Limited, this Certificate of Designation is issued and confirms the period of representation. Furthermore, this certificate confirms the medical devices Advena Limited acts as EU Authorised Representative for the Legal Manufacturer.

This certificate alone does not provide confirmation that the devices listed in Appendix A can be legitimately placed on the market. The Legal Manufacturer must be able to provide satisfactory regulatory evidence that the devices mentioned in Appendix A meet with the requirements of the applicable legislation and have the applicable valid certifications.

The devices listed in Appendix A must indicate Advena Ltd as the EU Authorised Representative, and in the following format, as applicable to EU legislation:

EC REP **Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta**

Anthony Kirby – Managing Director

Digitally signed by Plămădeală Inga
Date: 2025.06.28 14:58:49 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

AR Cover Begins: 01 November 2024 **AR Cover Ends:** 31 October 2025

[IVDD + Extension] **Mandate Start:** 30 January 2025 **Mandate End:** N/A **Mandated for Vigilance:** No

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

Table 1: List of devices (generic device group(s)) covered within the executed Mandate (authorised representative list).

Product Details, Names or Trade Names	EU Legislation	Classification	Basic UDI-DI	Date of Declaration
Cell Culture Flask	IVDD	General IVD	N/A	15 April 2022 **Last Signed Addendum:** 18 February 2025
Cell Culture Plate	IVDD	General IVD	N/A	15 April 2022 **Last Signed Addendum:** 18 February 2025
Cell Culture Slide	IVDD	General IVD	N/A	15 April 2022 **Last Signed Addendum:** 18 February 2025
Cell Culture Strainer	IVDD	General IVD	N/A	15 April 2022 **Last Signed Addendum:** 18 February 2025
Cryovial	IVDD	General IVD	N/A	15 April 2022 **Last Signed Addendum:** 18 February 2025
Cell Culture Dish	IVDD	General IVD	N/A	14 April 2022 **Last Signed Addendum:** 18 February 2025

Notes concerning the extended transitional provisions concerning IVD medical devices following Regulation 2024/1860 amending Regulation (EU) 2017/746:

Please note, manufacturers with IVD medical devices benefitting from Regulation 2024/1860 amending Regulation (EU) 2017/746 must provide Advena with a copy of the manufacturer's declaration, and evidence that they have received an IVDR proposal from their notified body. If you have not done so, please email us at info@advena.mt.

Regulation 2024/1860 amending Regulation 2017/746 exists to allow the continued placement on the EU market from May 26th, 2022, onwards provided certain conditions are met. However, to benefit from the full transitional period as outlined in the regulation you must meet the following criteria before May 26th 2025:

- Have a quality management system that meets the requirements of Article 10(8) of the IVDR.

In addition to the above the manufacturer must also lodge a formal application with a notified body no later than:

- 26th May 2025: for devices having a risk classification of Class D.
- 26th May 2026: for devices having a risk classification of Class C.
- 26th May 2027: for devices having a risk classification of Class B.
- 26th May 2027: for devices having a risk classification of Class A in a sterile condition.

If the above is not completed by the date indicated, you must cease to place the devices on the EU market from the respective dates shown for each device classification. And wait until full IVDR compliance is achieved.

Once the above has been achieved, a written agreement must be signed between the manufacturer and a notified body no later than:

- 26th September 2025: for devices having a risk classification of Class D.
- 26th September 2026: for devices having a risk classification of Class C.
- 26th September 2027: for devices having a risk classification of Class B.
- 26th September 2027: for devices having a risk classification of Class A in a sterile condition.

If the above is not completed by the date indicated, you must cease to place the devices on the EU market from the respective dates shown for each device classification. And wait until full IVDR compliance is achieved.

For your information, IVD medical devices placed on the EU market prior to the dates indicated above are permitted to remain on the EU market until their end of life, provided they were placed on the market compliantly at the time.