Certificate of Designation

Eudamed Mandate Summary

Client Ref.	**USA/2015/08/04**	**Date of Issue:** 29 April 2024
Issued To:	**Avery Biomedical Devices Inc.** 61 Mall Drive Commack NY 11725 USA	**Legal Manufacturer [SRN: US-MF-000001250]**
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	**Eudamed Actor ID: 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

AR Cover Begins: 01 November 2023 **AR Cover Ends:** 31 October 2024

[AIMDD + Extension] **Mandate Start:** 26 April 2024 **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	Date of Declaration
Breathing Pacemaker / Avery Diaphragm Pacemaker System	AIMDD	Class III	25/05/2021

Notes concerning the extended transitional provisions concerning medical devices following Regulation 2023/607:

Please note, manufacturers with medical devices benefitting from Regulation 2023/607 must provide Advena with a copy of the manufacturers declaration and evidence they have received a MDR proposal from their notified body. If you have not done so please email us at info@advena.mt

Regulation 2023/607 exists to allow the continued placement on the EU market from May 26th 2021 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 2024:

- Have a quality management system that meets the requirements of Article 10(9) of the MDR.
- Have applied to an MDR notified body and crucially received a proposal from the notified body

If the above has not been completed, you must cease to place devices on the EU market from May 26th 2024. And wait until full MDR compliance is achieved.

Once the above has been achieved, the following criteria must be met by September 26th 2024:

- Have signed a contract with your MDR notified body.

If the above is not completed, you must cease to place devices on the EU market from September 26th 2024. And wait until full MDR compliance is achieved.

For your information, medical devices placed on the EU market prior to May 26th 2024 or prior to September 26th 2024 are permitted to remain on the EU market until their end of life, provided they were placed on the market compliantly at the time.