Certificate of Designation

Eudamed Mandate Summary

Client Ref.	**GBR/2020/07/14**	**Date of Issue:** 6 August 2026
Issued To:	**Rapid Labs Ltd** Unit 2 & 2a Hall Farm Business Centre, Church Road Little Bentley Colchester, Essex CO7 8SD UK	**Legal Manufacturer [SRN: GB-MF-000026335]**
Issued By:	**Advena Limited** Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013. Malta.	**EU-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:

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

Anthony Kirby – Managing Director

AR Cover Begins:	01 December 2025	**AR Cover Ends:**	30 November 2026			
[MDR/IVDR]	**Mandate Start:**	29 October 2024	**Mandate End:**	N/A	**Mandated for Vigilance:**	No
[IVDD + Ext (mix)]	**Mandate Start:**	06 August 2026	**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
ELISA kits	IVDD	General IVD	N/A	17 November 2020 Will not transition to the IVDR
Febrile antigens reagents & kits	IVDD	General IVD	N/A	17 November 2020 Will not transition to the IVDR
Latex and slide agglutination kits	IVDD	General IVD	N/A	23 May 2022 Last Signed Addendum: 15 July 2026
Lectins	IVDD	General IVD	N/A	17 November 2020 Will not transition to the IVDR
Syphilis reagents & kits	IVDD	General IVD	N/A	20 May 2022 Last Signed Addendum: 17 July 2026
Urinalysis	IVDD	General IVD	N/A	17 November 2020
Anti-Human Globulin	IVDD	List B	N/A	17 November 2020 Will not transition to the IVDR
Blood grouping reagents	IVDD	List A	N/A	23 May 2022 **Last Signed Addendum:** 13 July 2026
Antibiotic discs & rings	IVDD	General IVD	N/A	17 November 2020 Will not transition to the IVDR
Covid-19 rapid tests	IVDD	General IVD	N/A	28 April 2022 Will not transition to the IVDR
Viral Transport Medium(Inactivated Type)	IVDR	Class A	5060599400002XPB	03 August 2022
Viral Transport Medium	IVDR	Class A	5060599400002WP9	03 August 2022
Hemoglobin Meter	IVDR	Class A	5060599400002SNZ	03 August 2022
Automatic Chemiluminescence Immunoassay Analyzer	IVDR	Class A	5060599400002VP7	03 August 2022
Urine Analyzer	IVDR	Class A	5060599400002QNV	03 August 2022 **Last Signed Addendum:**

- ADVENA LIMITED -
advena.mt®
CERTIFICATE OF DESIGNATION

Fluorescence Immunoassay Analyzer	IVDR	Class A	5060599400002PNT	03 August 2022
Cup Reader	IVDR	Class A	5060599400002RNX	03 August 2022
Lateral Flow Reader Plus	IVDR	Class A	5060599400002UP5	03 August 2022
Lateral Flow Reader	IVDR	Class A	5060599400002TP3	03 August 2022
Rapid Strips & devices	IVDD	General IVD	N/A	15 May 2022 **Last Signed Addendum:** 10 April 2024
Cholesterol Meter	IVDR	Class A	5060599401942YP	12 December 2024
Glucose Meter	IVDR	Class A	506059940195978	12 December 2024
Blood Glucose/Ketone/Uric Acid/Total Cholesterol 4 in 1 Meter	IVDR	Class A	506059940196625	12 December 2024

ADVENA LIMITED
advena.mt®
CERTIFICATE OF DESIGNATION

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.