

Certificate of Designation

Eudamed Mandate Summary



Client Ref. KOR/2023/04/19

Date of Issue: 7 July 2025

Issued To: **Atria Co.**
A-#701-712, Seoulsup SKV1 Tower, 5,
Seongsuil-ro 8-gil Seongdong-gu, Seoul,
Korea 04793
Republic of Korea

Legal Manufacturer [SRN: KR-MF-000036351]

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
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Anthony Kirby – Managing Director

AR Cover Begins: 01 July 2025

AR Cover Ends: 30 June 2026

[MDR/IVDR]

Mandate Start: 28 April 2023

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
Gingival retraction cord (AtriaPak)	MDR	Class I	88000236cord-06KM	01 May 2023
Mouth mirrors	MDR	Class I	88000236mirror-19TF	01 May 2023
Irrigation metal syringe	MDR	Class I	88000236WS10MJ8	01 May 2023
Amalgam retainer	MDR	Class I	88000236TR-6009W	01 May 2023
Cord packers	MDR	Class I	88000236packer-07AD	01 May 2023
Irrigation tubing sets	MDR	Class I	88000236tube-04RP	01 May 2023
Metal suction tips	MDR	Class I	88000236MS-02CJ	01 May 2023
Tissue punches	MDR	Class I	88000236TP-06EJ	01 May 2023
Crown remover	MDR	Class I	88000236CR-4002P	01 May 2023
A-Seal plugger and remover	MDR	Class I	88000236PR17L6	01 May 2023
Scissor for A-seal	MDR	Class I	88000236SC12J6	01 May 2023
Utility waxes	MDR	Class I	88000236wax-027F	01 May 2023
Mouth props	MDR	Class I	88000236prop-03V6	01 May 2023
Syringes	MDR	Class I	88000236syringe-09GU	01 May 2023
Endo ruler	MDR	Class I	88000236ER35HT	01 May 2023

CERTIFICATE OF DESIGNATION