Verification of Registration

Client Ref. **GBR/2021/01/34**

Issued To: **Cell Projects Ltd**
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Legal Manufacturer [SRN: GB-MF-000002266]

Issued By: **Advena Limited**
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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: devices.medicinesauthority@gov.mt

Eudamed Actor ID: MT-CA-019

Please note, this document confirms that Advena Ltd. has verified that the Legal Manufacturer has complied with their registration obligations as laid down in Article 27 and 29 of the Regulation (EU) 2017/745 (MDR) or Article 26 of Regulation (EU) 2017/746 (IVDR) for the devices / Basic UDI-DIs listed in Appendix A below.

The Legal Manufacturer must ensure that Advena Limited are advised of any changes to the information supplied to the Eudamed UDI-DI/Devices registration module after the date of issue of this document. Any changes must be verified, and a new Verification of Registration document issued.

Anthony Kirby – Managing Director

Date of Issue: 17 September 2024

This verification document is subject to the Legal Manufacturer maintaining their documentation in compliance with the EU legislation as indicated in Appendix A.

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Appendix A

Product Details, Names or Trade Names	EU Legislation	Classification	Basic UDI-DI Eudamed Verification	Date of Verification
GeneFiX DNA/RNA Collector, Non-Sterile.	IVDR	Class A	506054410Genefix8M	17/09/2024
Isohelix Swab Pack, Non-Sterile	MDR	Class I	506054410SwabPack3W	13/09/2024

For Legacy devices, Advena performs 10% sample verification of the variants listed on the Declaration of Conformity.

For device registered under applicable regulation Advena performs only a 10% sample check on UDI-DIs that are linked to the Basic UDI-DIs.