

Verification of Registration



Certificate No. CE/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-00000234]

EU Competent Authority: **Malta Medicines Authority (MMA)**
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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: 14 March 2023

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
Isohelix Swab Pack, Non-Sterile	MDR	Class I	5060544100241QG
Isohelix GeneFiX Saliva DNA/RNA Collector, Non-Sterile.	IVDR	Class A	5060544100258QZ

