

Declaration of Conformity

for the Isohelix Swab Pack, non-sterile

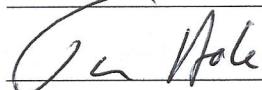
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Isohelix Swab Pack, non-sterile
Legal Manufacturer: (Name on Label)	Cell Projects Ltd Roebuck Business Park, Ashford Road, Harrietsham, Kent, ME17 1AB, UK
Manufacturers SRN:	GB-MF-000002266
Basic UDI-DI:	506054410SwabPack3W
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	Collection of buccal cells for research or clinical diagnosis
MDR Classification:	Class 1
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Issuing of the Declaration of Conformity in accordance with Article 19 after drawing up the technical documentation laid out in Annexes II and III of the EU MDR 2017/745.

Name Tom Hole

Position Managing Director / PRRC

Signed 

Date 21/8/2024 Place Maidstone, Kent, UK

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer

Appendix II – Product Listing/Schedule

Catalogue Number / UDI-DI	Device Name	EMDN Code
SK-1S / 05060544101101	SK-1S: 1x Regular Swab, 1x 5ml tube, 1x sealing cap	A1101
SK-2S / 05060544101118	SK-2S: 1x Regular Swab, 1x 2ml tube, 1x sealing cap with stopper	A1101
SK-3S / 05060544101125	SK-3S: 1x Regular Swab	A1101
SK-4S / 05060544101132	SK-4S: 2x Regular Swabs	A1101
MS-01 / 05060544101149	MS-01: 1x Mini Swab, 1x 5ml tube, 1x sealing cap	A1101
MS-02 / 05060544101156	MS-02: 1x Mini Swab	A1101
MS-03 / 05060544101163	MS-03: 2x Mini Swabs	A1101
RD-01 / 05060544101170	RD-01: 1 x Shorter regular swab, RapiDri Pouch and barcode label	A1101
SK-1S / 05060544100630	SK-1S: 100 x 1 swab with 5ml tube and cap. individually wrapped and ethylene oxide treated.	A1101
SK-2S / 05060544100647	SK-2S: 100 x 1 swab with 2ml tube and special release cap individually wrapped and ethylene oxide treated	A1101
SK-3S / 05060544100654	SK-3S: 250 x 1 swabs individually wrapped and ethylene oxide treated	A1101
SK-4S / 05060544100661	SK-4S: 250 x 2 swabs per wrapper, ethylene oxide treated	A1101
MS-01 / 05060544100685	MS-01: 100 x 1 swab with 5ml tube individually wrapped and ethylene oxide treated.	A1101
MS-02 / 05060544100692	MS-02: 250 x 1 mini swab individually wrapped and ethylene oxide treated	A1101

Catalogue Number / UDI-DI	Device Name	EMDN Code
MS-03 / 05060544100708	MS-03: 250 x 2 mini swabs per wrapper, ethylene oxide treated	A1101
RD-01 / 05060544100722	RD-01: Box of 200, 1 x Shorter regular swab, RapiDri Pouch and barcode label	A1101
FSS / 05060544100739	FSS: Box of 50, Foam Saliva Swabs White reticulated polyurethane foam on a polypropylene handle.	A1101

Version History

Version	Compiled by	Date	Description
6.0	AH	21/08/2024	Addition of Foam Saliva swabs FSS
5.0	AH	21/03/2024	Amendments to UDI numbers
4.0	AH	16/06/2022	Change to formatting, listing all UDI-DI's