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:	**5060544100241QG**
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, 2nd 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** 16 6 22 **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 / 50605441006304	**SK-1S**: 1x Regular Swab, 1x 5ml tube, 1x sealing cap	**A11**
SK-2S / 50605441006472	**SK-2S**: 1x Regular Swab, 1x 2ml tube, 1x sealing cap with stopper	**A11**
SK-3S / 50605441006540	**SK-3S**: 1x Regular Swab	**A11**
SK-4S / 50605441006618	**SK-4S**: 2x Regular Swabs	**A11**
MS-01 / 50605441006854	**MS-01**: 1x Mini Swab, 1x 5ml tube, 1x sealing cap	**A11**
MS-02 / 50605441006922	**MS-02**: 1x Mini Swab	**A11**
MS-03 / 50605441007080	**MS-03**: 2x Mini Swabs	**A11**
RD-01 / 50605441007226	**RD-01**: 1 x Shorter regular swab, RapiDri Pouch and barcode label	**A11**

Version History

Version	Compiled by	Date	Description
4.0	AH	16/06/2022	Change to formatting, listing all UDI-DI's