Isohelix

A Division of Cell Projects Ltd

ISOHELIX Swab Pack EC Declaration of Conformity to the European Medical Devices Regulation (EU) 2017/745

Issued under the sole responsibility of Cell Projects Ltd

Manufacturer: Address:	**Cell Projects Ltd** **Roebuck Business Park, Ashford Road, Harrietsham, Kent, ME17 1AB, UK**
Authorised Representative: Address:	**Advena Ltd** **Tower Business Centre, 2nd flr. Tower Street, Swatar, BKR 4013, Malta**
Device:	**Isohelix Swab Pack, Non-Sterile**
Basic UDI:	**5060544100241QG**
GMDN Code:	**33722**
Intended Use:	**Collection of buccal cells for research or clinical diagnosis**
Device description:	**Each Swab consists of a Viscose/Modified Cellulose swab head attached to a Polypropylene shaft that has an inbuilt snap point. Some configurations also include a Polypropylene tube. RapiDri swabs include a stabilizing pouch of paper/plastic construction. All swabs (and tubes where appropriate) are fully sealed in a paper/plastic wrapper and Ethylene Oxide treated.**

Product codes:

SK-1S	SK-4S	MS-02	RD-01
SK-2S	SK-5S	MS-03	
SK-3S	MS-01	MS-04	

EC MDR Classification: **Class I (Annex VIII Rule 5 – Invasive device for Transient Use)**

Conformity has been assessed and technical documentation has been drawn up according to Annex II & III as per Article 52 (7). This is to certify that the above products conform to the applicable General Safety and Procedural Requirements, as defined in the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, issued 05 April 2017.

ISOHELIX SWAB PACK has been developed, and will be manufactured and monitored in accordance with the Quality Management System of **CELL PROJECTS LTD,** based on **ISO 9001:2015 and ISO 13485:2016**

Signed for and on behalf of **CELL PROJECTS LTD** by

TOM HOLE (Managing Director)

Signature: _____ Date: 26/2/2021 Maidstone, UK

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ISO 9001:2015	ISO 13485:2016
GB2005291	MD1348536