Isohelix
A Division of Cell Projects Ltd

UK CA

ISOHELIX Swab Pack UK Declaration of Conformity to the Medical Devices Regulations 2002, (SI 2002, No 618), Part II.

Issued under the sole responsibility of Cell Projects Ltd

Manufacturer:	**Cell Projects Ltd**
Manufacturer Address:	**Roebuck Business Park, Ashford Road, Harrietsham, Kent, ME17 1AB, UK**
Device:	**Isohelix Swab Pack, Non-Sterile**
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 stabilising 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	MS-01
SK-2S	MS-02
SK-3S	MS-03
SK-4S	MS-04
SK-5S	RD-01

EC MD Classification: **Class I (Medical Devices Directive Rule 5 – Transient Use)**

This is to certify that the above products conform to the applicable Essential Requirements, as defined in the Directive 93/42/EEC of the European Parliament and of the Council on medical devices, issued 14 June 1993. As adopted in law by the UK government under the Medical Device Regulations 2002. (SI 2002, No 618, as amended) Part II

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: Tom Hole Date: 18.03.2022 Maidstone, UK

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ISO 9001:2015	ISO 13485:2016
GB2005291	MD1348536