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, as amended), 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 stabilizing pouch of paper/plastic construction. All swabs (and tubes where appropriate) are fully sealed in a paper/plastic wrapper. All swabs are supplied DNA free.** **Foam Saliva Swabs (FSS) are white reticulated polyurethane foam on a polypropylene plastic handle.**
Product codes:	SK-1S, MS-01 SK-2S, MS-02 SK-3S, MS-03 SK-4S, RD-01 FSS
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 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: _____ Date: 21/8/2024 Maidstone, UK

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