

ISOHELIX GENEFIX DNA/RNA Collector, UK Declaration of Conformity to the Medical Devices Regulations 2002. (SI 2002, No. 618, as amended), Part IV.

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 GeneFiX DNA/RNA Collector, Non-Sterile.
Trade name "GeneFiX Saliva DNA/RNA Collector,"
"GeneFiX buffer", "BuccalFiX buffer"**

Device description: **GeneFiX DNA/RNA Collector consists of a Polypropylene collection funnel, an instruction sheet, 2 foam swabs (GFXA, GFXHA and RFXA only) and 1ml or 2ml of stabilizing and lysis solution supplied into either:**

- A Polypropylene 10 ml tube with Polyethylene cap;
- Automation friendly Polypropylene 10 ml tube with Polypropylene cap, both with or without a barcode.

All the components are supplied in bulk or fully sealed into a plastic blister pack.

GFX-25, 50 or 500 And BFX-25, 50 or 500 buffers supplied as bulk solutions in HDPE bottles.

BFX/S1/05 supplied as 0.5ml BLS buffer in 2ml screw capped tube.

Product codes:

GFX-01	GFXH-01	GFX-25	BFX-25
GFX-02	GFXH-02	GFX-50	BFX-50
GFXA-01	GFXHA-01	GFX-500	BFX-500
RFX-01	RFXA-01		BFX/S1/05

IVD Classification

Annex III General IVD

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 IV.

ISOHELIX GeneFiX DNA/RNA Collector 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: 14 4 2023 Maidstone, UK



ISO 9001:2015	ISO 13485:2016
GB2005291	MD1348536