

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, FDXA and RFXA only) and 1ml (RFX only) 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 or 50 And BFX-25 or 50 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	FDX-01	RFX-01
GFX-02	GFXH-02	FDX-02	RFXA-01
GFXA-01	GFXHA-01	FDXA-01	BFX/S1/05
GFX-25	GFX-50	BFX-25	BFX-50

IVD Classification

Annex III General IVD

This is to certify that the above product conforms to the applicable Essential Requirements, as defined in Regulation 98/79, as adopted in law by the UK government under Medical Device Regulations 2002. (SI 2002, No 618, as amended), UK MDR 2002, 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:

5/10/2021

Maidstone, UK



ISO 9001:2015	ISO 13485:2016
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