

**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:

<b>GFX-01</b>	<b>GFXH-01</b>	<b>FDX-01</b>	<b>RFX-01</b>
<b>GFX-02</b>	<b>GFXH-02</b>	<b>FDX-02</b>	<b>RFXA-01</b>
<b>GFXA-01</b>	<b>GFXHA-01</b>	<b>FDXA-01</b>	<b>BFX/S1/05</b>
<b>GFX-25</b>	<b>GFX-50</b>	<b>BFX-25</b>	<b>BFX-50</b>

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: 18.03.2022

Maidstone, UK

