

ISOHELIX STOOLFIX MICROBIOME DNA 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 StoolFiX Microbiome DNA Collector, Non-Sterile.**
Trade name "StoolFiX"

Device description: **StoolFiX Microbiome DNA Collector consists of 1.5ml of STF stabilizing and lysis solution supplied into:**

- **A Polypropylene 10 ml tube with Polyethylene cap; with a barcode.**

Basic UDI **506054410StoolFiXDR**

Product codes:	Cat No.	UDI	Cat No.	UDI
	STF/K/15	05060544100869		
	STF/K/15/3	05060544100807	STF/K/15/50	05060544100876

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 StoolFiX Microbiome DNA 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 / PRRC))

Signature: _____ 

Date: 22 Oct 2025
Maidstone, UK

