Declaration of Conformity

for the **STOOLFIX MICROBIOME DNA COLLECTOR, Non-Sterile**

Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices

The undersigned, under their sole responsibility, declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	**STOOLFIX MICROBIOME DNA COLLECTOR, Non-Sterile**
Legal Manufacturer: (Name on Label)	**Cell Projects Ltd** **Roebuck Business Park,** **Ashford Road, Harrietsham,** **Kent, ME17 1AB, UK**
SRN:	**GB-MF-000002266**
Basic UDI-DI:	**506054410StoolFiXDR**
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	The product is used for collecting and stabilising Microbiome DNA from human faecal samples delivered into a sealable tube pre-filled with a storage solution in view of downstream microbiome DNA applications
IVDR Classification:	Class A (Rule 5)
Notified Body:	Not Applicable
CE Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
IVDR Assessment Route:	*For Class A: Issuing of the Declaration of Conformity in accordance with Article 17 after drawing up the technical documentation in Annexes II and III of the EU IVDR 2017/746.*

Name Tom Hole **Position** Managing Director/ PRRC

Signed  **Date** 18 Nov 2025 **Place** Maidstone, Kent, UK

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/746	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 concerning In Vitro Diagnostic Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer
EN ISO 18113-1:2022	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements

Appendix II – Product Listing/Schedule

Catalogue Number / UDI-DI	Device Description	EMDN Code
STF/K/15 / 05060544100869	StoolFix microbiome DNA collector, 1 x 1.5ml of STF stabilization buffer in a 10ml screw capped tube, with barcode.	W05019001
STF/K/15/3/ 05060544100807	3 x StoolFix microbiome DNA collector, 1 x 1.5ml of STF stabilization buffer in a 10ml screw capped tube, with barcode.	W05019001
STF/K/15/50 / 05060544100876	50 x StoolFix microbiome DNA collector, 1 x 1.5ml of STF stabilization buffer in a 10ml screw capped tube, with barcode.	W05019001

Version History

Version	Compiled by	Date	Description
1	AH	22/Oct/2025	New Declaration for StoolFix Microbiome DNA collector
2	AH	18/Nov/2025	Addition of Annex VIII Rule 5 to classification.