

Declaration of Conformity

for the GENEFIX DNA/RNA 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:	GENEFIX DNA/RNA 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:	506054410Genefix8M
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	The product is used for collecting and stabilising DNA/RNA from human primary saliva samples delivered into a sealable tube pre-filled with a storage solution in view of downstream DNA/RNA applications
IVDR Classification:	Class A
Notified Body:	Not Applicable
CE Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
IVDR Assessment Route:	<i>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.</i>

Name Tom HolePosition Managing Director/ PRRCSigned Date 21 8 2024 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
GFX-01 / 05060544100746	GFX Saliva Collector (Includes funnel, tube filled with 1ml stabilisation buffer, cap, & instruction manual).	WO5019002
GFX-02 05060544100753	GFX Saliva Collector (Includes funnel, tube filled with 2ml stabilisation buffer, cap, & instruction manual)	WO5019002
GFXA-01 05060544100203	GFX Saliva Collector (Includes funnel, tube filled with 1ml stabilisation buffer, 2 swabs, cap, & instruction manual).	WO5019002
GFXH-01 05060544100760	GFX Saliva Collector (Includes funnel, automation tube filled with 1ml stabilisation buffer, automation cap, & instruction manual).	WO5019002
GFXH-02 05060544100777	GFX Saliva Collector (Includes funnel, automation tube filled with 2ml stabilisation buffer, automation cap, & instruction manual).	WO5019002
GFXHA-01 05060544100425	GFXH Saliva Collector (Includes funnel, automation tube filled with 1ml stabilization buffer, 2 swabs, automation cap, & instruction manual).	WO5019002
RFX-01 05060544100487	RFX Saliva Collector (Includes funnel, tube filled with 1ml stabilisation buffer, cap, & instruction manual).	WO5019002
RFXA-01 05060544100524	RFX Assisted Saliva Collector, (Includes funnel, tube filled with 1ml stabilisation buffer, 2 swabs, cap, & instruction manual)	WO5019002
GFX-01/Bulk / 05060544100180	GFX Saliva Collector supplied in multiples of a capped tube filled with 1ml stabilisation buffer and funnel.	WO5019002
GFX-02/Bulk / 05060544100197	GFX Saliva Collector supplied in multiples of a capped tube filled with 2ml stabilisation buffer and funnel.	WO5019002
GFXH-01/Bulk / 05060544100401	GFX Saliva Collector supplied in multiples of an automation tube filled with 1ml stabilisation buffer, automation cap and funnel.	WO5019002
GFXH-02/Bulk / 05060544100418	GFX Saliva Collector supplied in multiples of an automation tube filled with 2ml stabilisation buffer, automation cap and funnel.	WO5019002
GFX-01/02 / 05060544100005	2 x GFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, cap, & instruction manual).	WO5019002
GFX-01/12 / 05060544100012	12 x GFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, cap, & instruction manual).	WO5019002

Catalogue Number / UDI-DI	Device Description	EMDN Code
GFX-01/50 / 05060544100029	50 x GFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, cap, & instruction manual).	WO5019002
GFX-02/02 / 05060544100036	2 x GFX Saliva Collectors (Includes funnel, tube filled with 2ml stabilisation buffer, cap, & instruction manual)	WO5019002
GFX-02/12 / 05060544100043	12 x GFX Saliva Collectors (Includes funnel, tube filled with 2ml stabilisation buffer, cap, & instruction manual)	WO5019002
GFX-02/50 / 05060544100050	50 x GFX Saliva Collectors (Includes funnel, tube filled with 2ml stabilisation buffer, cap, & instruction manual)	WO5019002
GFXA-01/02 / 05060544100067	2 x GFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, 2 swabs, cap, & instruction manual).	WO5019002
GFXA-01/12 / 05060544100074	12 x GFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, 2 swabs, cap, & instruction manual).	WO5019002
GFXA-01/50 / 05060544100081	50 x GFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, 2 swabs, cap, & instruction manual).	WO5019002
GFXH-01/02 / 05060544100531	2 x GFXH Saliva Collectors (Includes funnel, automation tube filled with 1ml stabilisation buffer, automation cap, & instruction manual).	WO5019002
GFXH-01/12 / 05060544100548	12 x GFXH Saliva Collectors (Includes funnel, automation tube filled with 1ml stabilisation buffer, automation cap, & instruction manual).	WO5019002
GFXH-01/50 / 05060544100555	50 x GFXH Saliva Collectors (Includes funnel, automation tube filled with 1ml stabilisation buffer, automation cap, & instruction manual).	WO5019002
GFXHA-01/02 / 05060544100593	2 x GFXHA Saliva Collectors (Includes funnel, automation tube filled with 1ml stabilization buffer, 2 swabs, automation cap, & instruction manual).	WO5019002
GFXHA-01/12 / 05060544100609	12 x GFXHA Saliva Collectors (Includes funnel, automation tube filled with 1ml stabilization buffer, 2 swabs, automation cap, & instruction manual).	WO5019002
GFXHA-01/50 / 05060544100616	50 x GFXHA Saliva Collectors (Includes funnel, automation tube filled with 1ml stabilization buffer, 2 swabs, automation cap, & instruction manual).	WO5019002
GFXH-02/02 / 05060544100562	2 x GFX Saliva Collectors (Includes funnel, automation tube filled with 2ml stabilisation buffer, automation cap, & instruction manual).	WO5019002
GFXH-02/12 / 05060544100579	12 x GFX Saliva Collectors (Includes funnel, automation tube filled with 2ml stabilisation buffer, automation cap, & instruction manual).	WO5019002
GFXH-02/50 / 05060544100586	50 x GFX Saliva Collectors (Includes funnel, automation tube filled with 2ml stabilisation buffer, automation cap, & instruction manual).	WO5019002
BFX/S1/05/50 / 05060544100913	50 x BuccalFix tubes using 2ml screw cap tubes pre filled with 0.5ml BuccalFix stabilisation buffer.	WO5019002
RFX-01/02 / 05060544100456	2 x RFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, cap, & instruction manual).	WO5019002
RFX-01/12 / 05060544100463	12 x RFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, cap, & instruction manual).	WO5019002
RFX-01/50 / 05060544100470	50 x RFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, cap, & instruction manual).	WO5019002
RFXA-01/02 / 05060544100494	2 x RFX Assisted Saliva Collectors, (Includes funnel, tube filled with 1ml stabilisation buffer, 2 swabs, cap, & instruction manual)	WO5019002
RFXA-01/12 / 05060544100500	12 x RFX Assisted Saliva Collectors, (Includes funnel, tube filled with 1ml stabilisation buffer, 2 swabs, cap, & instruction manual)	WO5019002
RFXA-01/50 / 05060544100517	50 x RFX Assisted Saliva Collectors, (Includes funnel, tube filled with 1ml stabilisation buffer, 2 swabs, cap, & instruction manual)	WO5019002
BFX-25 / 05060544100852	BuccalFix stabilisation buffer supplied as 25ml in HDPE bottle	WO5019002

Catalogue Number / UDI-DI	Device Description	EMDN Code
BFX-50 / 05060544100388	BuccalFix stabilisation buffer supplied as 50ml in HDPE bottle	WO5019002
BFX-500 / 05060544100265	BuccalFix stabilisation buffer supplied as 500ml in HDPE bottle	WO5019002
GFX-25 / 05060544100364	GeneFix stabilisation buffer supplied as 25ml in HDPE bottle	WO5019002
GFX-50 / 05060544100371	GeneFix stabilisation buffer supplied as 50ml in HDPE bottle	WO5019002
GFX-500 / 05060544100449	GeneFix stabilisation buffer supplied as 500ml in HDPE bottle	WO5019002
SFX-LS-1-50 / 05060544100623	50 x SaliFix supplied as 1ml of SaliFix buffer in a 5ml swab catcher tube, individually wrapped foam saliva swab and instructions	WO5019002
L-00-50 / 05060544100784	50 x Swab-Catcher 5ml collection tubes and caps (empty)	WO5019002
BFX/L/05/50 / 05060544100791	50 x BuccalFix tubes using 5ml SwabCatcher collection tubes pre filled with 0.5ml BuccalFix stabilisation buffer.	WO5019002

Version History

Version	Compiled by	Date	Description
9.0	AH	21/08/2024	Addition of SaliFix model, Swabcatcher tubes and BuccalFix in SwabCatcher tubes.
8.0	AH	21/03/2024	Amendments to UDI numbers
7.0	AH	14/04/2023	Update descriptions. Addition of GFX & BFX buffers supplied in bulk.
6.0	AH	16/06/2022	Change of format, addition of all UDI-DI variants.