

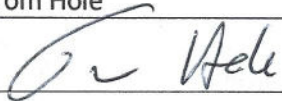
Declaration of Conformity

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:	5060544100258QZ
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 Hole Position Managing Director/ PRRC
Signed  Date 14-4-2023 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/Bulk / 50605441001804	GFX Saliva Collector supplied in multiples of a capped tube filled with 1ml stabilisation buffer and funnel.	WO5019002
GFX-02/Bulk / 50605441001972	GFX Saliva Collector supplied in multiples of a capped tube filled with 2ml stabilisation buffer and funnel.	WO5019002
GFXH-01/Bulk / 50605441004010	GFX Saliva Collector supplied in multiples of an automation tube filled with 1ml stabilisation buffer, automation cap and funnel.	WO5019002
GFXH-02/Bulk / 50605441004188	GFX Saliva Collector supplied in multiples of an automation tube filled with 2ml stabilisation buffer, automation cap and funnel.	WO5019002
GFX-01/02 / 50605441000050	2 x GFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, cap, & instruction manual).	WO5019002
GFX-01/12 / 50605441000128	12 x GFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, cap, & instruction manual).	WO5019002
GFX-01/50 / 50605441000296	50 x GFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, cap, & instruction manual).	WO5019002
GFX-02/02 / 50605441000364	2 x GFX Saliva Collectors (Includes funnel, tube filled with 2ml stabilisation buffer, cap, & instruction manual)	WO5019002
GFX-02/12 / 50605441000432	12 x GFX Saliva Collectors (Includes funnel, tube filled with 2ml stabilisation buffer, cap, & instruction manual)	WO5019002
GFX-02/50 / 50605441000500	50 x GFX Saliva Collectors (Includes funnel, tube filled with 2ml stabilisation buffer, cap, & instruction manual)	WO5019002
GFXA-01/02 / 50605441000678	2 x GFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, 2 swabs, cap, & instruction manual).	WO5019002
GFXA-01/12 / 50605441000746	12 x GFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, 2 swabs, cap, & instruction manual).	WO5019002
GFXA-01/50 / 50605441000814	50 x GFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, 2 swabs, cap, & instruction manual).	WO5019002
GFXH-01/02 / 50605441005314	2 x GFX Saliva Collectors (Includes funnel, automation tube filled with 1ml stabilisation buffer, automation cap, & instruction manual).	WO5019002

Catalogue Number / UDI-DI	Device Description	EMDN Code
GFXH-01/12 / 50605441005482	12 x GFX Saliva Collectors (Includes funnel, automation tube filled with 1ml stabilisation buffer, automation cap, & instruction manual).	WO5019002
GFXH-01/50 / 50605441005550	50 x GFX Saliva Collectors (Includes funnel, automation tube filled with 1ml stabilisation buffer, automation cap, & instruction manual).	WO5019002
GFXHA-01/02 / 50605441005932	2 x GFXH Saliva Collectors (Includes funnel, automation tube filled with 1ml stabilization buffer, 2 swabs, automation cap, & instruction manual).	WO5019002
GFXHA-01/12 / 50605441006090	12 x GFXH Saliva Collectors (Includes funnel, automation tube filled with 1ml stabilization buffer, 2 swabs, automation cap, & instruction manual).	WO5019002
GFXHA-01/50 / 50605441006168	50 x GFXH Saliva Collectors (Includes funnel, automation tube filled with 1ml stabilization buffer, 2 swabs, automation cap, & instruction manual).	WO5019002
GFXH-02/02 / 50605441005628	2 x GFX Saliva Collectors (Includes funnel, automation tube filled with 2ml stabilisation buffer, automation cap, & instruction manual).	WO5019002
GFXH-02/12 / 50605441005796	12 x GFX Saliva Collectors (Includes funnel, automation tube filled with 2ml stabilisation buffer, automation cap, & instruction manual).	WO5019002
GFXH-02/50 / 50605441005864	50 x GFX Saliva Collectors (Includes funnel, automation tube filled with 2ml stabilisation buffer, automation cap, & instruction manual).	WO5019002
BFX/S1/05/50 / 50605441009138	50 x BuccalFix tubes using 2ml screw cap tubes pre filled with 0.5ml BuccalFix stabilisation buffer.	WO5019002
RFX-01/02 / 50605441004560	2 x RFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, cap, & instruction manual).	WO5019002
RFX-01/12 / 50605441004638	12 x RFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, cap, & instruction manual).	WO5019002
RFX-01/50 / 50605441004706	50 x RFX Saliva Collectors (Includes funnel, tube filled with 1ml stabilisation buffer, cap, & instruction manual).	WO5019002
RFXA-01/02 / 50605441004942	2 x RFX Assisted Saliva Collectors, (Includes funnel, tube filled with 1ml stabilisation buffer, 2 swabs, cap, & instruction manual)	WO5019002
RFXA-01/12 / 50605441005000	12 x RFX Assisted Saliva Collectors, (Includes funnel, tube filled with 1ml stabilisation buffer, 2 swabs, cap, & instruction manual)	WO5019002
RFXA-01/50 / 50605441005178	50 x RFX Assisted Saliva Collectors, (Includes funnel, tube filled with 1ml stabilisation buffer, 2 swabs, cap, & instruction manual)	WO5019002
BFX-25 / 50605441008520	BuccalFix stabilisation buffer supplied as 25ml in HDPE bottle	WO5019002
BFX-50 / 50605441003884	BuccalFix stabilisation buffer supplied as 50ml in HDPE bottle	WO5019002
BFX-500 / 50605441002658	BuccalFix stabilisation buffer supplied as 500ml in HDPE bottle	WO5019002
GFX-25 / 50605441003648	GeneFix stabilisation buffer supplied as 25ml in HDPE bottle	WO5019002
GFX-50 / 50605441003716	GeneFix stabilisation buffer supplied as 50ml in HDPE bottle	WO5019002
GFX-500 / 50605441004492	GeneFix stabilisation buffer supplied as 500ml in HDPE bottle	WO5019002

Version History

Version	Compiled by	Date	Description
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.