Caltag Medsystems Limited
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EC DECLARATION OF CONFORMITY

for TransFix and TransFix Sample Storage Tubes

European Communities Council Directive 98/79/EC concerning In-Vitro Diagnostic Medical Devices as amended by Regulation (EC) 596/2009.

The undersigned declares that the products named in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Names:	TransFix TransFix Sample Storage Tubes
Manufacturer:	Caltag Medsystems Limited Whiteleaf Business Centre 11 Little Balmer Buckingham MK18 1TF United Kingdom
Variants:	As per Appendix II – Product Listing/Schedule
Intended Use:	*"TransFix® and TransFix Sample Storage Tubes are intended for stabilization and storage (in the case of Sample Storage Tubes) of whole blood specimens for immunophenotyping of white blood cells by flow cytometry. Recovery of lymphocyte subset markers can be accomplished over a 14-day period following collection.".*
Intended User:	Professional use
IVD Directive Category:	General
Notified Body:	N/A
IVD Directive Assessment route:	Self-Declaration Annex III
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR 4013 Malta

Name Tim Almond **Position** Chief Executive

Signed  **Date** 26 Nov 2020

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 his own name, regardless of whether these operations are carried out by the Manufacturer, or on their behalf by a third party.

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Appendix I – Applicable Standards

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

Standard/Document Name	Description
98/79/EC	In Vitro Diagnostic Medical Devices EU Council Directive as amended by Regulation (EC) 596/2009
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices

Appendix II – Product Listing/Schedule

Part / Catalogue Number	Description/Name	GMDN Code
TFB-01-1	TransFix 1ml	52735
TFB-01-10	10x TransFix 1ml	52735
TFB-01-50	50x TransFix 1ml	52735
TFB-20-1	20ml TransFix	52735
TF-01-2	TransFix Sample Storage Tubes (2 x 1.2ml tubes)	63232
TF-01-10	TransFix Sample Storage Tubes (10 x 1.2ml tubes)	63232
TF-01-25	TransFix Sample Storage Tubes (25 x 1.2ml tubes)	63232
TF-01-50	TransFix Sample Storage Tubes (50 x 1.2ml tubes)	63232

Version History

Version	Compiled by	Date	Description
1.0	Nicki Kaenzig	26/02/2019	First issue of new format
2.0	Nicki Kaenzig	04/04/2019	Correction of Intended Use statement
3.0	Nicki Kaenzig	16 Nov 2020	Addition of GMDN codes and update to standards