Caltag Medsystems Limited
Whiteleaf Business Centre
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EC DECLARATION OF CONFORMITY

for TransFix/EDTA Vacuum Blood Collection Tubes (TVTs)

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/EDTA Vacuum Blood Collection Tubes (TVTs*)*
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/EDTA Vacuum Blood Collection Tubes (TVTs) are intended for collection and storage of human 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** 24 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
ISO 6710:2017	Single-use containers for human venous blood specimen collection
EN 566-1:2001	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices
ISO 11137-1:2015	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-2:2015	Sterilization of health care products -- Radiation -- Part 2: Establishing the sterilization dose
ISO-11737-1: 2018	Sterilization of health care products -- Microbiological methods -- Part 1: Determination of a population of microorganisms on products
ISO 11737-2:2010	Sterilization of medical devices -- Microbiological methods -- Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process

Appendix II – Product Listing/Schedule

Part / Catalogue Number	Description/Name	GMDN Code
TVT-03-1	TransFix/EDTA Vacuum Blood Collection Tube (1 x 3ml tube)	64508
TVT-03-2	TransFix/EDTA Vacuum Blood Collection Tubes (2 x 3ml tubes)	64508
TVT-03-50	TransFix/EDTA Vacuum Blood Collection Tubes (50 x 3ml tubes)	64508
TVT-09-1	TransFix/EDTA Vacuum Blood Collection Tube (1 x 9ml tube)	64508
TVT-09-2	TransFix/EDTA Vacuum Blood Collection Tubes (2 x 9ml tubes)	64508
TVT-09-50	TransFix/EDTA Vacuum Blood Collection Tubes (50 x 9ml tubes)	64508

Version History

Version	Compiled by	Date	Description
1.0	Nicki Kaenzig	04/04/2019	First issue of new format
2.0	Nicki Kaenzig	16 Nov 2020	Addition of GMDN code and update of standards