

## EC DECLARATION OF CONFORMITY


for TransFix/EDTA CSF Sample Storage Tubes

### REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on in vitro diagnostic medical devices

The undersigned declares that the products named in this document conform to the Council Regulation provisions that apply to them and the CE Mark may be affixed and that this Declaration is issued under the sole responsibility of the Manufacturer, Caltag Medsystems Ltd.

<b>General Product Names:</b>	TransFix/EDTA CSF 1-4ml Sample Storage Tubes TransFix/EDTA CSF 0.25-1ml Sample Storage Tubes
<b>Manufacturer:</b>	Caltag Medsystems Limited Whiteleaf Business Centre 11 Little Balmer Buckingham MK18 1TF United Kingdom
<b>Variants:</b>	As per Appendix I – Product Listing/Schedule
<b>Intended Use:</b>	<i>“TransFix®/EDTA Cerebrospinal Fluid (CSF) Sample Storage Tubes are intended for stabilisation and storage of human CSF specimens for characterisation of infiltrated white blood cells by flow cytometry. Recovery of infiltrated leucocyte subset can be accomplished over a 3-day period following stabilisation.”</i>
<b>Intended User:</b>	Professional use
<b>IVD Regulation Category:</b>	Class A in accordance with Annex VIII Rule 5 (c)
<b>Notified Body:</b>	N/A
<b>IVDR Assessment route:</b>	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.
<b>Single Registration Number:</b>	GB-MF-000021669
<b>EMDN:</b>	W050301020101
<b>Basic UDI-DI:</b>	506053171CSFCG
<b>EU Authorised Representative:</b>	Advena Limited. Tower Business Centre, 2nd Floor, Tower Street, Swatar BKR 4013 Malta
<b>SRN for EU Authorised Representative:</b>	MT-AR-000000234

Name D.Coupar Position Managing Director

Signed  Place and Date of Signature Buckingham, UK  
14 March 2023

### Applicable Regulations and Standards

All devices listed in Appendix I of this present declaration are in conformity with the following European Regulations and standards

Regulation Standard/	Document Name
Regulation (EU) 2017/746	REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on in vitro diagnostic medical devices
REACH 1907/2006	Registration, Evaluation, Authorisation and Restriction of Chemicals
(EC) No 1272/2008	Classification, Labelling and Packaging (CLP) Regulation
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
ISO 23640:2015	In vitro diagnostic medical devices — Evaluation of stability of in vitro diagnostic reagents
BS EN ISO 18113-1:2011 BS EN ISO 18113-2:2011	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling)
BS EN ISO 15223-1:2016 BS EN ISO 15223-2:2016	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied

### Appendix I – Product Listing/Schedule

Part / Catalogue Number	Description/Name	UDI-DI
TF-CSF-L-2	TransFix/EDTA CSF 1-4ml Sample Storage Tubes(2 tubes)	05060531710040
TF-CSF-L-10	TransFix/EDTA CSF 1-4ml Sample Storage Tubes(10 tubes)	05060531710040
TF-CSF-L-50	TransFix/EDTA CSF 1-4ml Sample Storage Tubes(50 tubes)	05060531710040
TF-CSF-S-2	TransFix / EDTA CSF 0.25-1ml Sample Storage Tube (2 tubes)	05060531710057
TF-CSF-S-10	TransFix / EDTA CSF 0.25-1ml Sample Storage Tube (10 tubes)	05060531710057
TF-CSF-S-50	TransFix / EDTA CSF 0.25-1ml Sample Storage Tube (50 tubes)	05060531710057

### Version History

Version	Compiled by	Date	Description
1.0	Nicki Kaenzig	17/09/2021	First issue
2.0	Nicki Kaenzig	11 May 2022	Update for IVDR
2.1	Nicki Kaenzig	15 June 2022	Removal of LRQA/UKAS logo, to avoid confusion
2.2	Nicki Kaenzig	27 June 2022	Addition of '0' to start of UDI-DI
3.0	Nicki Kaenzig	14 Mar 2023	Removal of 25 pack version (TF-CSF-L-25). Addition of TransFix/EDTA 0.25-1ml Sample Storage Tube product format (TF-CSF-S-2, TF-CSF-S-10, TF-CSF-S-50)