

Cytomark Regulatory Statement 2018

Customers in Europe

TransFix[®], TransFix[®] Sample Storage Tubes, TransFix[®]/EDTA Vacuum Blood Collection Tubes, and TransFix[®] Phlebotomy Packs are CE marked as IVDs in the following countries:

Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey & United Kingdom

Customers in the United States of America

For customers in the USA, 3ml TransFix[®]/EDTA Vacuum Blood Collection Tubes (product code: TVT-03-50-US) are available as Class II IVDs. For this product, the 510(k) number is [K162723](#). TransFix[®] and TransFix[®] Sample Storage Tubes are also available as General Purpose Reagents, Class I.

Customers in Other Territories

For customers in Canada, TransFix[®] and TransFix[®] Sample Storage Tubes are available as Class I IVDs. TransFix[®]/EDTA Vacuum Blood Collection Tubes are available as RUO products.

For customers in Peru or Kenya: TransFix[®], TransFix[®] Sample Storage Tubes, TransFix[®]/EDTA Vacuum Blood Collection Tubes, and TransFix[®] Phlebotomy Packs are available as CE marked IVD products.

If your country is not listed above, RUO labelled products are available. Please contact Cytomark@caltagmedsystems.co.uk if you require further information on our IVD products.

TransFix[®]/EDTA CSF Sample Storage Tubes and Circulating Tumour Cell TransFix[®]/EDTA Vacuum Blood Collection Tubes are universally RUO products.

