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Cytomark Regulatory Statement May 2019

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 and TVT-03-2-US) are available as Class II IVDs. For these products, the 510(k) number is K162723. TransFix® and TransFix® Sample Storage Tubes are available as General Purpose Reagents, Class I.

Customers in Other Territories

For customers in Canada, TransFix®, TransFix® Sample Storage Tubes, and TransFix®/EDTA Vacuum Blood Collection Tubes are available as Class I IVDs. Medical Device Establishment Licence of Cedarlane Corporation ID: 102158.

For customers in Peru, Kenya, Israel, Brazil, and Costa Rica: TransFix®, TransFix® Sample Storage Tubes, and TransFix®/EDTA Vacuum Blood Collection Tubes are available as CE marked IVD products.

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

RUO products

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