

## Cytomark Regulatory Statement December 2018

### Customers in Europe

TransFix<sup>®</sup>, TransFix<sup>®</sup> Sample Storage Tubes, TransFix<sup>®</sup>/EDTA Vacuum Blood Collection Tubes, and TransFix<sup>®</sup> 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<sup>®</sup>/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<sup>®</sup> and TransFix<sup>®</sup> Sample Storage Tubes are also available as General Purpose Reagents, Class I.

### Customers in Other Territories

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

For customers in Peru, Kenya or Israel: TransFix<sup>®</sup>, TransFix<sup>®</sup> Sample Storage Tubes, TransFix<sup>®</sup>/EDTA Vacuum Blood Collection Tubes, and TransFix<sup>®</sup> 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](mailto:Cytomark@caltagmedsystems.co.uk) if you require further information on our IVD products.

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

