DECLARATION OF CONFORMITY

Fast Track Diagnostics hereby ensures and declares that the product listed below comply with the requirements of the European Union in Vitro Diagnostic Medical Device Directive 98/79/EC

Fast Track Diagnostics assure et déclare par la présente que les produits listés ci-dessous sont conformes aux exigences de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Fast Track Diagnostics dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Fast Track Diagnostics versichert und erklärt hiermit, dass die im Folgenden aufgeführten Produkte den Auflagen der IVD-Richtlinie für In-vitro Diagnostika der Europäische Union (98/79/EC) entsprechen.

Fast Track Diagnostics asegura y declara que los productos listados a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnostico in vitro.

Products/Produits/Prodotti/Produkte/Producti :

Catalogue no.	Name	Registration No
FTD-2P.3	FTD Respiratory pathogens 33	LU/CA01/IVD/145

Applied standards:	ISO 13485:2012, EN ISO 14971:2012, ISO 18113-1:2009, ISO 18113-2:2009, ISO 23640:2011
Device classification:	Devices covered by Annex II List B
Conformity assessment procedure:	Annex IV without section 4 and 6
Notified Body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 D-80339 München
	CE 0123
Start of CE-marking	25 June 2015

Esch-sur-Alzette, 11 July 2016
Signature:

Name: Graglia Claudine
Position: Quality manager

TRUE POSITIVES. TRUE NEGATIVES.