VENTANA®

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Declaration of Conformity to 98/79/EC

Manufacturer:	Ventana Medical Systems, Inc. 1910 E. Innovation Park Drive Tucson, AZ USA 85755
European Authorized Representative:	ROCHE DIAGNOSTICS GmbH Sandhofer Strasse 116 D-68305 Mannheim Germany
Manufacturing Site:	Ventana Medical Systems, Inc., Tucson, AZ USA Roche Diagnostics GmbH, D-68305 Mannheim, Germany

		Ventana REF	Roche
Product name/ Catalogue No.	10X SSC	950-110	05353947001
Technical Data File:	TDF-0072		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

Ventana Medical Systems, Inc. declares that the product(s) listed is/are in conformity with the essential requirements of Annex I of Council Directive 98/79/EC. All supporting documentation is retained under the premise of the Manufacturer.

Ventana Medical Systems, Inc. maintains a quality system based on EN ISO 13485:2012 / EN ISO 13485:2012 + AC:2012 as certified by TÜV Rheinland LGA Products GmbH (Notified Body No. 0197).

Place of Issue: Tucson, AZ USA 85755

Name of Authorized Signatory: Troy Quander
Vice President, Regulatory Affairs

Signature: _____ Date: 26-Jan-2015

Roxane Bonner for Troy Quander