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:	Tucson, AZ USA

		Ventana REF	Roche
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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: Fatima Pereira
Director, Regulatory Affairs

Signature: _____ Date: 13-May-2015