

## **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	Roche
	<b>REF</b>	
Product name/ Catalogue No.	CONFIRM anti-Kappa Rabbit Polyclonal Primary Antibody	760-2514 05267013001
Technical Data File:	TDF-0090	
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 ISO 13485:2003 as certified by TÜV Rheinland LGA Products GmbH (Notified Body No. 0197).

Place of Issue: Tucson, AZ USA 85755

Name of Authorized Signatory: Sam M. Rua  
Senior Director, Regulatory Affairs

Signature:  Date: 14 APR 2011