



a member of the Roche Group

Ventana Medical Systems, Inc.  
1910 E. Innovation Park Drive  
Tucson, Arizona 85755  
Phone: (520) 887-2155  
Toll Free: (800) 227-2155  
www.ventana.com

## **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
		<div>REF</div>	
Product name /	anti-MLH-1 (M1) Mouse	Catalogue #	Catalogue #
Catalogue No.	Monoclonal Primary Antibody	790-4535	06472966001
Technical Data File:	TDF-0438		
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: 27 Jun 2011