

## 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

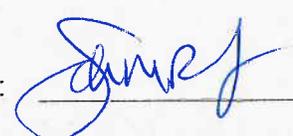
Manufacturing Site: Tucson, AZ USA

		Ventana	Roche
Product name/ Catalogue No.	Anti-MUC1 (H23) Mouse Monoclonal Antibody	<input type="checkbox"/> REF 790-4574	06316514001
Technical Data File:	TDF- 0442		
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: 12 MAY 2011