



a member of the Roche Group

Ventana Medical Systems, Inc.  
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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	Roche
		REF	
Product name/ Catalogue No.	FITC anti-IgM Primary Antibody	760-2682	05267935001
Technical Data File:	TDF-0113		
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: Fatima Pereira  
Director, Regulatory Affairs

Signature: 

Date: 06-May-2015