



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: Ventana Medical Systems, Inc.  
Tucson, AZ USA  
Roche Diagnostics GmbH  
D-68305 Mannheim - Germany

		Ventana	Roche
		REF	
Product name/ Catalogue No.	Reaction Buffer Concentrate (10X)	950-300	05353955001
Technical Data File:	TDF 0057		
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: Troy Quander  
Vice President, Regulatory Affairs

Signature: Troy Quander Date: 9-Feb-2015