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Ventana Medical Systems, Inc.
1910 E. Innovation Park Drive
Tucson, Arizona 85755
Phone: (520) 887-2155
Toll Free: (800)-227-2155
www.ventanamed.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(s): Ventana Medical Systems, 1910 E. Innovation Park Dr. Tucson, AZ 85755 USA

CliniChem Kft., H1117 Budapest, Budafoki ut, 111-113 Hungary

Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany

		Ventana	Roche
		<div>REF</div>	
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 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: Troy Quander
Vice President, Regulatory Affairs

Signature:

Jules A. Reategui
for Troy Quander

Date:

5 NOV 2012