



*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
		<div>REF</div>	
<b>Product name/ Catalogue No.</b>	Bluing reagent	760-2037	05266769001
<b>Technical Data File:</b>	TDF-0046		
<b>Classification:</b>	General IVD		
<b>Conformity Assessment:</b>	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:** 22 FEB 2011