



*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

		Ventana	Roche
		<div>REF</div>	
Product name/	CINtec® p16 Histology	805-4713	06695248001
Catalogue No.		825-4713	06695256001
Technical Data File:	TDF-0461		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

Ventana Medical Systems, Inc. declares that the product(s) listed 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:

Date: 14-May-2012