



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>	
Product name(s)/ Number(s):	Protease 1	760-2018	05266688001
Technical Data File:	TDF 0053		
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.

Place of Issue: Tucson, AZ USA 85755

Name of Authorized Signatory: Sam M. Rua  
Senior Director, Regulatory Affairs

Signature: \_\_\_\_\_

Date: 25 AUG 2011