



a member of the Roche Group

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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
		REF	
Product name/ Catalogue No.	CONFIRM anti-Prostate Specific Antigen (PSA) Rabbit Polyclonal Primary Antibody	760-2506	05266939001
Technical Data File:	TDF 0005		
Classification:	List IIB		
Conformity Assessment:	98/79/EC Annex IV		

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: 07 July 2011