



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
		REF	
Product name/ Catalogue No.	OptiView DAB IHC Detection Kit	760-700	06396500001
	OptiView Amplification Kit	760-099	06396518001
	OptiView Amplification Kit (250 tests)	860-099	06718663001
Technical Data File:	TDF 0446		
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 EN ISO 13485:2012 / EN ISO 13485:2012 + AC:2012 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: 24-March-2015