VENTANA®

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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 REF	Roche
Product name/ Catalogue No.	ultraView Universal Alkaline Phosphatase Red Detection Kit	760-501	05269814001
Technical Data File:	D018734		
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:	Deepshikha Bhandari Vice President, Regulatory Affairs

Signature: _____ Date: 11-May-2016

Roxane Bonner for
Deepshikha Bhandari

Digitally signed by Lazari Cristina
Date: 2023.12.20 14:56:17 EET
Reason: MoldSign Signature
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