



a member of the Roche Group

Ventana Medical Systems, Inc.
1910 E. Innovation Park Drive
Tucson, Arizona 85755
Phone: (520) 887-2155
Toll Free: (800)-227-2155
www.ventana.com

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 Sites: Tucson, AZ USA
Mannheim, Germany

		Ventana	Roche
		REF	
Product name/ Catalogue No.	LCS (Predilute)	650-010	05264839001
Technical Data File:	TDF 0044-1		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

Ventana Medical Systems, Inc. declares that the product listed is 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: 26-Jan-2015
Roxane Bonner for Troy Quander

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
Product name/ Catalogue No.	Hematoxylin	 760-2021	05266726001
Technical Data File:	TDF-0043		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

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Place of Issue: Tucson, AZ USA 85755
Name of Authorized Signatory: Troy Quander
Vice President, Regulatory Affairs

Signature: 

Date: 5- March - 2015



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European Authorized Representative: ROCHE DIAGNOSTICS GmbH
Sandhofer Strasse 116
D-68305 Mannheim
Germany

Manufacturing Site: Tucson, AZ USA

		Ventana	Roche
		<input type="checkbox"/> REF	
Product name/ Catalogue No.	Bluing Reagent	760-2037	05266769001
Technical Data File:	TDF 0046		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

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Place of Issue: Tucson, AZ USA 85755
Name of Authorized Signatory: Troy Quander
Vice President, Regulatory Affairs

Signature: Troy Quander Date: 10- April 2015



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European Authorized Representative: ROCHE DIAGNOSTICS GmbH
Sandhofer Strasse 116
D-68305 Mannheim
Germany

Manufacturing Site: Tucson, AZ USA

		Ventana	Roche
Product name/ Catalogue No.	ultraView Universal DAB Detection Kit	REF 760-500	05269806001
Technical Data File:	TDF-0266		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

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Place of Issue: Tucson, AZ USA 85755

Name of Authorized Signatory: Troy Quander
Vice President, Regulatory Affairs

Signature:

Date: 17 - March - 2015



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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.	ultraView Universal Alkaline Phosphatase Red Detection Kit	760-501	05269814001
Technical Data File:	D018734		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

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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



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European Authorized Representative: ROCHE DIAGNOSTICS GmbH
Sandhofer Strasse 116
D-68305 Mannheim
Germany

Manufacturing Site: Tucson, AZ

		Ventana	Roche
Product name/ Catalogue No.	CONFIRM anti-CD34 (QBEnd/10) Primary Antibody	REF 790-2927	05278210001
Technical Data File:	TDF 0010		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

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Place of Issue: Tucson, AZ USA 85755
Name of Authorized Signatory: Fatima Pereira
Director, International Regulatory Affairs

Signature: _____

Date: _____

04 June 2015



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European Authorized Representative: ROCHE DIAGNOSTICS GmbH
Sandhofer Strasse 116
D-68305 Mannheim
Germany

Manufacturing Site: Ventana Medical Systems, Inc.
Tucson, AZ USA
Roche Diagnostics GmbH
D-68305 Mannheim - Germany

		Ventana	Roche
		<input type="checkbox"/> REF	
Product name/ Catalogue No.	EZ Prep Concentrate (10X)	950-102	05279771001
Technical Data File:	TDF 0037		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

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Place of Issue: Tucson, AZ USA 85755
Name of Authorized Signatory: Troy Quander
Vice President, Regulatory Affairs

Signature: Troy Quander Date: 9-Feb-2015



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European Authorized Representative:	ROCHE DIAGNOSTICS GmbH Sandhofer Strasse 116 D-68305 Mannheim Germany		
Manufacturing Site:	Ventana Medical Systems, Tucson, AZ USA Roche Diagnostics GmbH, Mannheim, Germany		
		Ventana	Roche
		<input type="checkbox"/> REF	
Product name/ Catalogue No.	Cell Conditioning Solution (CC1)	950-124	05279801001
Technical Data File:	TDF-0041		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

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Place of Issue: Tucson, AZ USA 85755
Name of Authorized Signatory: Troy Quander
Vice President, Regulatory Affairs

Signature: Troy Quander Date: 12-Feb-2015



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European Authorized Representative:	ROCHE DIAGNOSTICS GmbH Sandhofer Strasse 116 D-68305 Mannheim Germany		
Manufacturing Site:	Ventana Medical Systems, Inc., Tucson, AZ USA Roche Diagnostics GmbH, D-68305 Mannheim, Germany		
		Ventana	Roche
		<input type="checkbox"/> REF	
Product name/ Catalogue No.	10X SSC	950-110	05353947001
Technical Data File:	TDF-0072		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

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Place of Issue: Tucson, AZ USA 85755
Name of Authorized Signatory: Troy Quander
Vice President, Regulatory Affairs

Signature: Date: 26-Jan-2015
Roxane Bonner for Troy Quander



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Sandhofer Strasse 116
D-68305 Mannheim
Germany

Manufacturing Site: Ventana Medical Systems, Inc.
Tucson, AZ USA
Roche Diagnostics GmbH
D-68305 Mannheim - Germany

		Ventana	Roche
		REF	
Product name/ Catalogue No.	Reaction Buffer Concentrate (10X)	950-300	05353955001
Technical Data File:	TDF 0057		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

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Vice President, Regulatory Affairs

Signature: Troy Quander Date: 9-Feb-2015



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Sandhofer Strasse 116
D-68305 Mannheim
Germany

Manufacturing Site: Tucson, AZ USA

		Ventana	Roche
Product name/ Catalogue No.	anti-Cytokeratin 5/6 (D5/16B4) Mouse Monoclonal Primary Antibody	<u>REF</u> 790-4554	06478441001
Technical Data File:	TDF-0433		
Classification:	General IVD		
Conformity Assessment:	98/79/EC Annex III		

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Place of Issue: Tucson, AZ USA 85755
Name of Authorized Signatory: Troy Quander
Vice President, Regulatory Affairs

Signature: Troy Quander Date: 10-march-2015



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Manufacturing Site:	Ventana Medical Systems, Tucson, AZ USA Roche Diagnostics GmbH, Mannheim, Germany		
		Ventana	Roche
		<input type="checkbox"/> REF	
Product name/ Catalogue No.	Cell Conditioning Solution (CC1)	950-124	05279801001
Technical Data File:	TDF-0041		
Classification:	General IVD		
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Vice President, Regulatory Affairs

Signature: Troy Quander Date: 12-Feb-2015