



a member of the Roche Group

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Declaration of Conformity to 98/79/EC

Manufacturer: Ventana Medical Systems, Inc.
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European Authorized Representative: ROCHE DIAGNOSTICS GmbH
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Manufacturing Site: Ventana Medical Systems, Inc., 1910 E. Innovation Park Dr.,
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CliniChem Kft., H1117 Budapest, Budafoki ut, 111-113
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		Ventana	Roche
Product name/ Catalogue No.	Antibody Diluent	REF 251-018	05261899001
Technical Data File:	TDF 0055		
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 13485:2003 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: Troy Quander

Date: 13-Nov-2012