



VENTANA®

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
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Manufacturing Site(s): Ventana Medical Systems, Inc., 1910 E. Innovation Park Dr.,
Tucson, AZ 85755 USA
CliniChem Kft., H1117 Budapest, Budafoki ut, 111-113 Hungary
(applies to 1637700 / 05250935001 only)

		Ventana	Roche
Product name/ Catalogue No.	ASSY, Prep Kit, BM, BM XT, BM LT	<div>REF</div> 1637700	05250935001
	Customer Filled Dispenser Pack (FLO-LOK)	1637600	05250927001
Technical Data File:	TDF-0049		
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

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