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Declaration of Conformity to 98/79/EC

Manufacturer: Ventana Medical Systems, Inc.
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Tucson, AZ USA 85755

European Authorized Representative: ROCHE DIAGNOSTICS GmbH
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Manufacturing Site: Ventana Medical Systems, 1910 E. Innovation Park Dr. Tucson, AZ 85755 USA

CliniChem Kft., H1117 Budapest, Budafoki ut, 111-113 Hungary

Roche Diagnostics GmbH, Sandhofer Str. 116, 68305 Mannheim, Germany

| | | Ventana | Roche |
|--------------------------------|--------------------|----------------|-------------|
| | | <div>REF</div> | |
| 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(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:

Julio A. Montoya
for Troy Quander

Date:

5 Nov 2012