



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  
D-68305 Mannheim  
Germany

Manufacturing Site: Tucson, AZ USA

|                        |  | Ventana        | Roche       |
|------------------------|--|----------------|-------------|
|                        |  | <div>REF</div> |             |
| Product name/          | CONFIRM anti-Progesterone                                    | 790-2223       | 05277990001 |
| Catalogue No.          | Receptor (PR) (1E2) Rabbit<br>Monoclonal Primary<br>Antibody | 790-4296       | 05278392001 |
| Technical Data File:   | TDF-0254   |                |             |
| 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: Sam M. Rua  
Senior Director, Regulatory Affairs

Signature: \_\_\_\_\_

Date: 17 May 2011