

## 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/<br>Catalogue No. | anti-Thyroid Transcription<br>Factor-1 (SP141) Rabbit<br>Monoclonal Primary<br>Antibody | <input type="checkbox"/> REF<br>790-4756 | 06640613001 |
| Technical Data File:           | TDF-0469  |  |             |
| 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:  Date: 14-Jan-2013