



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 |
|--------------------------------|-----------------------------------|----------|-------------|
| | | REF | |
| Product name/ Catalogue No. | FITC Anti-IgG Primary Antibody | 760-2680 | 05267919001 |
| Technical Data File: | TDF-0112 | | |
| 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 EN ISO 13485:2012 / EN ISO 13485:2012 + AC:2012 as certified by TÜV Rheinland LGA Products GmbH (Notified Body No. 0197).

Place of Issue: Tucson, AZ USA 85755
Name of Authorized Signatory: Fatima Pereira
Director, Regulatory Affairs

Signature: 

Date: 15-May-2015