



a member of the Roche Group

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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

Product name/ Catalogue No. PATHWAY anti-HER-2/neu (4B5) Rabbit Monoclonal Primary Antibody
Ventana Roche
REF 790-2991 05278368001

Technical Data File: TDF-0052

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: [Handwritten Signature] Date: 24 MAY 2011