



a member of the Roche Group

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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: Tucson, AZ USA

Table with 4 columns: Field, Ventana, REF, Roche. Rows include Product name/Catalogue No., Technical Data File, Classification, and Conformity Assessment.

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: Deepshikha Bhandari
Vice President, Regulatory Affairs

Signature: [Handwritten Signature] Date: 26-MAY-2016