



a member of the Roche Group

Ventana Medical Systems, Inc.
1910 E. Innovation Park Drive
Tucson, Arizona 85755

Phone: (520) 887-2155
Toll Free: (800)-227-2155
www.ventanamed.com

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

| | | Ventana | Roche |
|------------------------|-----------------------|------------------------------|-------------|
| | | <input type="checkbox"/> REF | |
| Product name/ | CINtec® p16 Histology | 805-4713 | 06695248001 |
| Catalogue No. | | 825-4713 | 06695256001 |
| Technical Data File: | TDF-0461 | | |
| Classification: | General IVD | | |
| Conformity Assessment: | 98/79/EC Annex III | | |

Ventana Medical Systems, Inc. declares that the product(s) listed 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: Troy Quander Date: 14-May-2012