

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

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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:

Ventana Medical Systems, Tucson, AZ USA

Roche Diagnostics GmbH, Mannheim, Germany

Ventana

Roche

REF

Product name/

Cell Conditioning Solution

950-124

05279801001

Catalogue No.

Technical Data File:

(CC1)

Classification:

TDF-0041 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: Troy Quander

Vice President, Regulatory Affairs

Date: 12- Feb-2015