

Declaration of Conformity

as per Annex III of Directive 98/79/EC of the European Parliaments and Council of 27 October 1998

Manufacturer: Roche Diagnostics GmbH
Address: Roche Professional Diagnostics
Sandhofer Straße 116
D-68305 Mannheim
Manufacturing Site: Ventana Medical Systems, Inc.
1910 E. Innovation Park Drive
Tucson, AZ USA 85755

Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)

Product name: **VENTANA anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody**
Roche. Id. No.: **05999570001**
Ventana. Id. No.: **790-4493**

to which this declaration relates fulfils the requirements of EC Directive 98/79/EC of the Council of 27 October 1998 (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) concerning in-vitro diagnostic devices.

Mannheim, 06 August 2014

Roche Diagnostics GmbH
ppa./on behalf of the company



Dr. Michael Thein
Head of Quality

i. V./on behalf of the company



Dr. Adelheid Schneider
Head of EU Notification and ROW Support

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