

## **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  
Sandhofer Strasse 116  
68305 Mannheim  
Germany

*Roche Diagnostics GmbH declares that the product/the product line*

**Product name:** VENTANA HER2 Dual ISH DNA Probe Cocktail

**Roche Id.-No.:** 08314373001

**Ventana Id.-No.:** 800-6043

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

Mannheim, 16 April 2019

Roche Diagnostics GmbH

*ppa./on behalf of the company*



Ralf Zielenski  
Head of Quality  
Centralised and Point of Care Solutions

*ppa./on behalf of the company*

i.V. Stefan Grigarczik



Dr. Stefan Scheib  
Director Global Regulatory Affairs  
Centralised and Point of Care Solutions

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